ORIGINAL ARTICLE

# Application of high viscosity bone cement in vertebroplasty for treatment of painful vertebral body fracture

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## ABSTRACT

**Aim** To evaluate the effectiveness and complication of vertebroplasty with high viscosity cement (HVC).

**Methods** The patients with intensive pain caused by a fractured vertebrae were treated by application of HVC into the vertebral body, through unilateral transpedicular approach. The application was performed in 422 patients (221 were treated for osteoporosis and 201 for malignancy) on 846 vertebrae.

**Results** Preoperative Visual Analogue Scale (VAS) score was 8.35 and 2.21 ($p<0.00001$) 24 hours after surgery and 3 months later, respectively. There was no serious intra- and post-surgery complication. By diascopy during the surgery in 121 (14.3%) vertebrae cement leakage from the fractured vertebral body was evidenced, which did not cause any aggravation of patients' clinical status.

**Conclusion** Vertebroplasty with HVC is a method that successfully combines all advantages of this method but it also minimizes the risk of extra-ossal cement leakage which makes it significantly safer for the surgeon and for the patient as well.

**Key words**: bone cement, vertebral augmentation, Visual Analogue Scale

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## INTRODUCTION

Compressive vertebral fracture is a frequent complication caused by osteoporosis and expansion of malignant tumors into the skeleton (1). Frequency of these fractures increases with the population age, and they include compression, collapse and wedging of the body causing kyphosis (1). Such fractures lead to the significant rate of morbidity and mortality, nourishment disorders, lungs function troubles, lack of self-reliance, increased pain and psychic disorder caused by pain and drugs (1).

Traditional method of treating vertebrae fractures include the use of narcotics, analgesics, non-steroidal anti-inflammatory drugs (NSAID), resting, and the use of orthosis, and in case of malignancies – hormonal, radiotherapy and chemotherapy (2). In most patients, pain is reduced within 2 – 3 months, while pain persists in a smaller number of cases, so that they make a group where surgery is indicated as well (2).

Vertebroplasty is a stabilization surgery that achieves its effect by applying the cement through a needle into the broken vertebral body by means of diascopy in situ, without correction of kyphosis, and with the aim to relieve pain (3-13).

A number of papers and studies describe vertebroplasty as a safe and efficient method in the treatment of pathological fractured vertebrae (1-11). This method is accompanied by some complications, both local and general ones (14). Frequency rate of complications is much higher in the treatment of malignancy than in osteoporosis (15).

The most frequent complication includes the cement leakage extra-ossal from the vertebra body to the surrounding tissue caused by too high quantity of cement applied, inadequate selection of patients, poor surgery technique or inadequate cement viscosity (14-17).

## PATIENTS AND METHODS

### Patients and study design

In the period from October 2008 to July 2015, 422 patients were treated in 846 surgeries applying the method of vertebroplasty in the Orthopedic Department of the Clinical Hospital Centre Osijek. Ethics Committee of Clinical Hospital Osijek approved of this research.

The research covered patients with pain in the back caused by osteoporotic vertebral fractures, who did not react positively to the conservative method of treatment, or caused by a malignant process (hemangioma, multiple myeloma metastasis) with or without previously performed hormonal, radio or chemotherapy.

For the purpose of the method efficiency evaluation, all patients filled in the visual analogue scale (VAS) questionnaire with a scale from 1 to 10 before surgery, 24 hours and 3 months after surgery (18).

### Methods

All surgeries were performed by the same surgeon under local or general anesthesia (in cases of non-tolerance of the local one). Surgery was carried out in a prone position, the fractured vertebra was located by means of diascopy, the operation area was washed and covered, and the skin and subcutaneous tissue to the periosteum was anesthetized with 2% lidocaine when applying local anesthesia. In five patients surgery was performed on the cervical spine due to the metastatic process and fracture, and the procedure was carried out openly, with standard left-anterior approach to the cervical spine.

High viscosity cement (HVC) confidence was used for vertebral body augmentation in all procedures. (19).

After the application of anesthetic, a needle was placed in anterior posterior (AP) or latero lateral (LL) projection next to the joint of the pedicle and the back vertebral body and then, the biopsy needle was introduced along the cannula and a bone piece was taken for histopathological analysis. After performed bone biopsy, we proceeded by preparing cement (mixing) of appropriate viscosity, which was applied in the vertebral body. Diascopy was performed during the whole process of the cement application in order to detect its leakage and stop applying the cement on time to prevent more serious complications.

The cement application was completed when it was situated in the appropriate position in the last quarter of the body in LL direction (Figure 1) or if

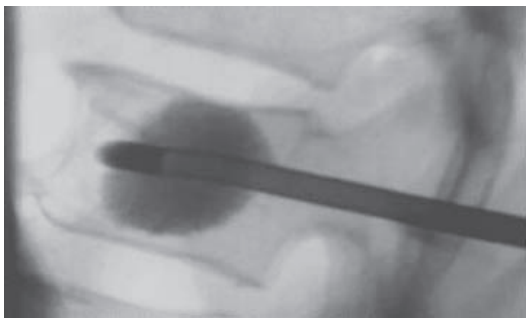

**Figure 1. Post-surgery x-ray image after high viscosity cement (HVC) application. Fractured vertebral body filled with high viscosity cement** (Rapan, S., 2009)

extra-ossal extravasation of cement occurred (Figure 2). The needles were removed immediately after cement application was completed, which significantly shortens the procedure. The patient remained in bed for minimum one hour, and 24 hours after surgery the patient was discharged from hospital, after having filled-in the VAS questionnaire.

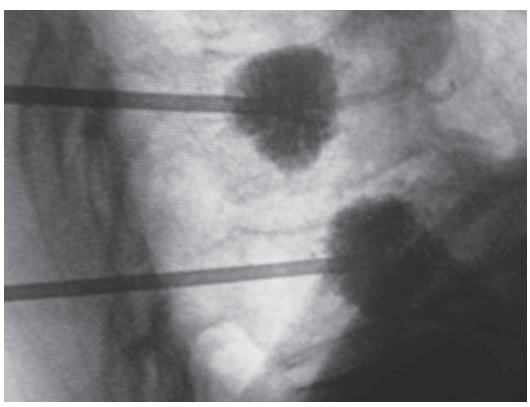

**Figure 2. Extra-ossal cement leakage: high viscosity cement leaking in frontal part of vertebral body** (Rapan, S., 2009)

### Statistical analysis

Wilcoxon signed-rank test was used for the analysis of preoperative VAS score, 24 hours after surgery and 3 months after surgery. For statistically significant difference $p \leq 0.05$ was used.

## RESULTS

The total of 422 patients (271 women, 151 men, aged from 29 to 82 years) underwent visual analogue scale evaluation directly before surgery, immediately within 24 hours and 3 months after surgery.

The total of 422 surgeries (201 patients were treated for malignancy and in 221 for osteoporosis) were carried out on 846 vertebrae. The HVC volume applied amounted to 3 mL on average (1.5 – 5 mL) in lumbar segment and HVC 2.5 mL (2 – 4) applied in thoracic segment. Local anesthesia was applied in 356 and general anesthesia in 64 surgeries. The surgery using HVC was performed on 401 thoracic and 445 lumbar vertebrae (Figure 3).

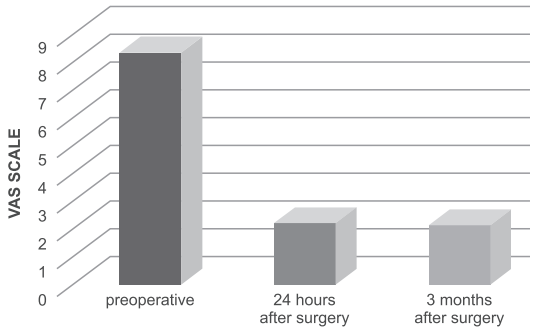


**Figure 3. Pain intensity before and after vertebroplasty**
VAS, Visual Analogue Scale

The surgery time was 17.5 (15-25) minutes, and average stay in hospital was about 2 (1-4) days.

The average time of pain suffering prior to surgery was 18 (2-124) days.

According to VAS score pain reduction was significant ranging from 8.35 ± 0.82 before surgery to 2.21±0.77 (- 72.63%) 24 hours later and 2.13±0.72 three months after surgery, respectively. For patients in whom HVC was applied, a significant difference between preoperative VAS score and the value measured 24 hours after surgery ($p<0.00001$) and 3 months after surgery ($p=0.00001$) was demonstrated. A compliance between two VAS measurements after surgery was noticed indicating that the rapid achieved pain reduction remained stable during the 3-month follow-up (Figure 3).

There were no serious intra- and post-surgery complications. By diascopy during the surgery in 121 vertebrae (14.3%) cement leakage from the fractured vertebral body was evidenced, which did not cause any aggravation of patients' clinical status.

## DISCUSSION

In pathologically changed bone a vertebral fracture may result in constant pain despite analgesic and anti-rheumatic treatment, resting or immobilization (1). As osteoporotic fractures are connected with older age, and metastatic with poor general condition, beside the pain, the condition is worsened due to reduced mobility, urinary disorders, depression or neurological disorder (2). Similarly, because of bad quality of bones, con-

ventional surgery methods of stabilization, osteosynthesis and lumbar fusion have no success (2).

Vertebroplasty is a surgical method for achieving stabilization of fracture in a pathologically changed vertebral body, when due to osteoporosis, tumor or malignancy, the conventional methods of treatment fail (3-13). By this method, stabilization is achieved about 10 minutes after the application of cement into the vertebral body, and analgesic effect is either the result of preventing micro-movements or only slightly less destruction of nerve ends by thermal reaction during the polymerization of cement (20).

The success of vertebroplasty with high viscosity cement method of treatment in pain reduction by 75-90% is described by many authors (3-13), and our result of pain reduction by 72.63% is in the line with this statement. There is no direct relation between the quantity of cement applied and the level of reduction in pain (21,22). This method also causes numerous complications, general and local ones. Frequency of complications is much higher in treatment of malignancy (up to 10 %) than in osteoporosis (1 to 3%) (8).

The force enabling the cement flow through trabecular bone is of crucial importance for uniform distribution of cement among trabeculae (18). Extra-ossal leakage is the most frequent complication of vertebroplasty, and it occurs on the trabecular bone with the lowest resistance (18). The risk of bone cement leakage into the spinal canal correlates with bone destruction, so that the surgery is contra-indicated in more serious destructions of vertebral body (23). Confidence system is based on the law of physics that enables direct impact on the change in speed and pressure at the needle end by changing the intra-system tube diameter and friction. In such a way, high pressure at start of the system, which is required to push HVC into the needle, becomes low at end of the system and inside the vertebral body, which provides additional preservation of trabecular bone structure (19). There is a direct dependence between cement leakage into the spinal canal and the quantity of cement applied during the surgery on the fractured vertebral body (24, 25). Cement leakage into the inter-vertebral discus increases the risk of new fracture of adjacent vertebral body (27).

Ali Ali et al. (13) did not notice dependence either between the fracture of adjacent vertebral body with the amount of cement applied or its leakage. In spite of high percentage of cement leakage (0.5-65.6%) (14, 27-31), only about 7.5% of the cases are symptomatic (20) and they respond to conservative treatment with anti-rheumatics and the use of corticosteroids. Neurological disturbance which requires decompression of spinal canal and cement removal accounts for only 1% of complications (32-36). Cotton et al. (37) and Barragan-Campus et al. (38) stated that cement is frequently leaking into the spinal canal (52%), the neuroforamen (27.6%), and into the intervertebral discus (about 27.6%). In our case, cement leakage occurred in 14.3% vertebrae treated when HVC was used, which corresponds to the results of Anselmetti et al. (27), wherein cement leakage into the veins plexus occurred in 8.2 % and into the discus it occurred in 6.1% cases. Georgy et al. (28) described high percentage of leakage when HVC was used: extra-ossal leakage occurred in 50% of cases, into epidural vein plexus in 25% of cases, and intradiscal leakage in about 20%, and paravertebral leakage occurred in less than 5%.

Confirmation of cement leakage in our study was based on diascopy during surgery and X-ray taken after surgery. We did not take routine CT scans or MRIs, because all the patients with no occurrence of cement leakage had no subjective disturbances, but it can be assumed that the percentage of cement leakage into surrounding tissue would be higher if these diagnostic methods were also used by routine.

Hydraulic pump, higher cement viscosity, the exact position of the punctuation needle and diascopy throughout the procedure, particularly during the cement application are essential and significantly reduce the possibility of such serious complications (19).

In conclusion, vertebroplasty with HVC retains all the advantages of vertebroplasty with low viscosity cement, but it also minimizes the risk of extra-ossal cement leakage, which makes it significantly safer for the surgeon and for the patient as well.

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## TRANSPARENCY DECLARATION

Competing interests: None to declare

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# Aplikacija visokoviskoznog koštanog cementa u vertebroplastici u liječenju bolnog prijeloma trupa kralješka

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## SAŽETAK

**Cilj** Ocijeniti uspješnost i komplikacije vertebroplastike s visokoviskoznim cementom (HVC).

**Metode** Pacijenti s jakom boli zbog prijeloma trupa kralješka liječeni su aplikacijom visokoviskoznog cementa (HVC) u trup kralješka unilateralnim transpedikularnim pristupom. Cement je apliciran kod 422 pacijenta, u 846 kralježaka.

**Rezultati** Prijeoperacijski VAS (*Visual Analogue Scale*) iznosio je 8,35 i 2,21 ($p<0,00001$) 24 sata, odnosno 3 mjeseca nakon operacije. Nije bilo ozbiljnijih intraoperacijskih i poslijeoperacijskih komplikacija. Dijaskopijom je, za vrijeme operacijskog zahvata, u 121 kralješku (14,3%) uočeno istjecanje cementa koje nije utjecalo na promjenu kliničkog statusa pacijenta.

**Zaključak** Vertebroplastika s HVC-om je procedura koja u sebi uspješno ujedinjuje sve prednosti ove metode do sada, ali i minimalizira mogućnost istjecanja cementa ekstraosalno, što ju čini znatno sigurnijom kako za operatera, tako i za pacijenta.

**Ključne riječi:** koštani cement, vertebralno ojačanje, *Visual Analogue Scale*