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ORIGINAL ARTICLE

Vertebroplasty and kyphoplasty: complementary techniques for the treatment of painful osteoporotic vertebral compression fractures. A prospective non-randomised study on 154 patients

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Abstract In a prospective study, we aimed to evaluate the potential use of kyphoplasty (KP) and vertebroplasty (VP) as complementary techniques in the treatment of painful osteoporotic vertebral compression fractures (VCFs). After 1 month of conservative treatment for VCFs, patients with intractable pain were offered treatment with KP or VP according to a treatment algorithm that considers time from fracture (Δt) and amount of vertebral body collapse. Bone biopsy was obtained intra-operatively to exclude patients affected by malignancy or osteomalacia. 164 patients were included according to the above criteria. Mean age was 67.6 years. Mean follow-up was 33 months. 10 patients (6.1%) were lost to follow-up and 154 reached the minimum 2-year follow-up. 118 (69.5%) underwent VP and 36 (30.5%) underwent KP. Complications affected five patients treated with VP, whose one suffered a transient intercostal neuropathy and four a subsequent VCF (two at adjacent level). Results in terms of visual analogue scale and Oswestry scores were not different among treatment groups. In conclusion, at an average follow-up of almost 3 years from surgical treatment of osteoporotic VCFs, VP and KP show similar good clinical outcomes and appear to be complementary techniques with specific different indications.

Keywords Osteoporotic vertebral compression fracture · Vertebroplasty (VP) · Kyphoplasty (KP)

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Introduction

Osteoporotic vertebral compression fractures (VCFs) are a major healthcare problem. Symptomatic VCFs (about 30% of all VCFs esteemed to occur in the western world) can be associated with decreased quality of life and increased mortality in the elderly [9, 16]. Irrespective of fracture pain, disability associated with VCFs is apparently caused by changes in the alignment of the spine and related to the severity of spinal deformity [18]. Different approaches for the treatment of painful osteoporotic VCFs are currently available. Standard management includes bed rest, analgesia, bracing or a combination of these. Prolonged bed rest leads to a further loss of bone mass, while bracing cannot restore spinal alignment and often is poorly tolerated by older patients [7, 25]. Open surgical treatment is reserved to the rare cases of progressive deformity and neurological deterioration or to the more frequent cases of persistent intractable pain. Vertebroplasty (VP) and kyphoplasty (KP) are well-known percutaneous vertebral body augmentation procedures that provide good pain relief when used to treat osteoporotic VCFs [5, 9, 25]. VP involves percutaneous injection of bone cement into the fractured vertebra/e in order to stabilise the fracture. KP involves an initial step of expansion of a balloon into the vertebral body, which creates a cavity to be filled with bone cement and allows for reduction of the fracture. VP and KP have so far been proposed as alternative [9, 25] techniques because of the supposed possibility of KP to reduce vertebral body deformity. In fact, VP has also been reported to be able to provide some fracture reduction [13]. To date, a few prospective studies have reported comparative results of KP and VP in patients affected by osteoporotic VCFs [8]. Aim of this study is to prospectively evaluate the use of KP and VP as complementary

techniques, with different indications, in the treatment of painful osteoporotic VCFs.

Materials and methods

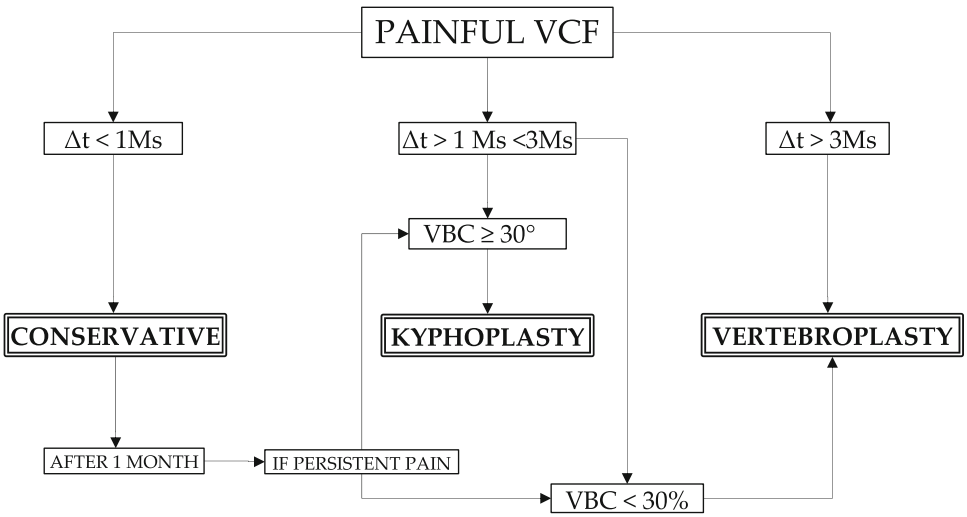
The authors of the study practise at a tertiary referral Centre for spinal disorders, where patients are seen as acute admissions to the Emergency Department, or as outpatients referred by other medical professionals.

For inclusion in the present study, the authors have considered patients seen from January 2003 to January 2005 with a diagnosis of painful VCF associated with primary (senile and postmenopausal) or secondary (long-term steroid use) osteoporosis [18]. Osteoporosis was defined as a 2.5 or more standard deviations decrease in bone mineral density at observation [20], and confirmed on bone biopsy in patients who were later operated on. Patients whose bone histology showed features of Osteomalacia or neoplasma were excluded from the study. VCFs were defined as those fractures that showed a vertebral body collapse (VBC) of at least 20% [26], comparing the absolute values of three vertical body heights (anterior, mid-vertebral and posterior) of the fractured vertebra with the vertebra above ("referent" vertebra) on plain lateral radiographs [22]. Two-plane radiographs of the affected spinal region and magnetic resonance imaging (MRI) of the whole spine were obtained in all patients at observation [6, 7, 25]. Symptomatic levels were identified by correlating the clinical findings (i.e. pain on pressure and tapping over the spinous processes), with MRI findings of marrow signal changes on short tau inversion recovery (STIR) sequences consistent with the presence of compression fractures at the symptomatic levels [7, 23, 26]. Minimum follow-up for evaluation of data was set at 2 years.

Treatment algorithm

Once the diagnosis of symptomatic osteoporotic VCF was established, patients were managed according to a specific treatment algorithm (Table 1), designed to take into account the presence of pain, the time elapsed from fracture to observation (Δt) and the amount of vertebral body collapse at observation. The algorithm helped to decide whether conservative or surgical treatment (VP or KP with injection of PMMA) should be considered in a given case. This algorithm was first proposed at the IMAST meeting of the year 2003 [2]. *Conservative treatment* was proposed to all patients with painful VCFs in the first month from fracture. As far as timing was concerned, minimum Δt to consider surgical treatment (either with VP or KP) was 1 month from fracture, while maximum Δt to consider surgical treatment with KP was 3 months due to the reported difficulties in reducing VCFs after this time interval [7, 18, 19]. As far as deformity was concerned, VP was considered in case of fracture deformity less than 30%, while KP was considered in case of VBCs equal or higher than 30%. As a result, surgical treatment with VP was offered to patients with persistent pain due to VCFs with vertebral collapse less than 30% and a Δt longer than 1 month, or a Δt longer than 3 months with any amount of fracture deformity. KP was offered to patients with

Table 1 Algorithm for the treatment of osteoporotic VCFs



VCF = Vertebral Compression Fracture, Δt = time from fracture. M/Ms = month/s, VBC=Vertebral Body Collapse. See text for details.

persistent pain due to VCFs with vertebral collapse equal or higher than 30% and a Δt between 1 and 3 months.

Patients included into the study were entered into a prospective cohort database and managed according to the above-described criteria. Conservative treatment consisted of a period of relative bed rest and analgesia, with the application of a thoraco-lumbar extension orthosis while standing [26]. Length of bed rest was restricted to that necessary to achieve a reasonable control of pain at mobilisation. Those patients who were improved after 1 month were followed by family physicians. Patients who were still reporting severe pain were then referred to surgical treatment. This was performed as an inpatient procedure in case of both for VP and for KP. VP was performed under local anaesthesia and intravenous sedation in patients affected by one fracture, and under general anaesthesia in patients affected by more than one fracture to be treated in the same session [25]. KP was always performed under general anaesthesia. The surgical techniques did not differ from those already described for VP and KP with PMMA [5, 10, 11, 15, 21], except for the use of the inflatable bone tamp in KP, with identical cannulae and PMMA density. Patients were mobilised as soon as tolerated on the same day of surgery and discharged on the following day.

Follow-up was performed at 1, 3 and 6 months and at a minimum of 2 years from treatment. The clinical results in all patients were evaluated by comparing preoperative and follow-up data from a visual analogue scale (VAS) and an Oswestry disability index (ODI) 2.0 questionnaire. On plain lateral radiographs, the anterior, mid-vertebral and posterior VBCs were calculated in percentage comparing the absolute value of the anterior, mid-vertebral and posterior vertical heights of the treated vertebra with the vertebra above ("referent vertebra") in all patients.

For statistical analysis, preoperative and follow-up VAS, ODI scores and radiographic vertebral height values were compared using Student's paired t test by means of a SPSS program (SPPS Inc, Chicago IL, USA). Differences between groups were evaluated by the Fisher's exact test. Correlations were investigated via Pearson's analysis. For all comparisons, a P value of less than 0.05 (two-tailed) was considered significant. Two observers made radiographic measurements independently. Intra-observer and inter-observer reliability were assessed using the kappa statistic.

Results

Out of 314 patients suffering symptomatic, osteoporotic VCFs seen consecutively in the study period, 164 patients were included in the study cohort according to the above-described criteria and 150 were treated conservatively. 10 patients (6.1%) were excluded because they were lost to follow-up. Patients included had records of follow-up consultations and radiograms made at the above described intervals until a minimum of 2 years from fracture. Out of the 154 enrolled patients, who were treated surgically, 49 (31.8%) had initially been treated conservatively. Furthermore, in 16 (32.6%) of those patients with an initial VBC of less than 30%, VBC deteriorated to more than 30% after 1 month. The latter patients were included in the statistics according to an intention to treat analysis.

Out of 154 surgical patients, 118 (69.5%) underwent VP (VP group) and 36 (30.5%) underwent KP (KP group). In this cohort composed of 98 women and 56 men, mean age was 67.6 years (range 53–95 years) and mean follow-up was 33 months (range 28–40 months). Gender distribution, age and follow-up time did not differ significantly among the two surgical groups.

In total, 199 fractured levels were operated. The number of levels treated per surgery was 1.86 on average (range 1–4). In 104 out of 154 patients (67.5%) surgical treatment was performed at multiple levels. Two of these patients had staged procedures that were analysed independently. The levels treated ranged from T7 to L5, with 84 (42.2%) thoracic and 115 (57.8%, $P < 0.05$) lumbar treated levels. The mean Δt was 4 months (122 days; range 44–240 days) in VP group and 1.5 months (46 days; range 34–91 days; $P = 0.01$) in KP group. Both VP and KP were performed via a trans-pedicular approach for levels caudal to T10 and via an extra-pedicular approach for levels cranial to T10. On average, 2.5 ml of PMMA were injected per vertebra in VP procedures, compared to 3.2 ml per vertebra in KP ($P > 0.05$). The average procedure time per level was 15 min (range 10–30 min) for VP and 25 min (range 15–40 min; $P = 0.01$) for KP. Mean hospital stay was 2.0 days (range 1–2 days) for VP and 2.2 days (range 1–3 days) for KP ($P > 0.05$).

Table 2 summarises the *clinical results* in the treatment groups. In VP group, mean VAS scores decreased significantly ($P < 0.05$) between preoperative and 1-month follow-up. Pain relief was complete (VAS = 0) in 22 out of 118 cases (18.6%) at the first month follow-up and continued to decrease non-significantly until the last follow-up. In KP group, VAS scores decreased significantly ($P < 0.05$) between preoperative and 1-month follow-up and behaved similarly to VP group for the rest of the follow-up period. Pain relief was complete (VAS = 0) in 6 out of 36 cases (16.6%; $P > 0.05$ compared to VP group) at the first month follow-up. ODI scores had a similar trend to that of VAS scores in all groups, with significant decreases between preoperative and 1-month follow-up. ODI scores improved significantly in all groups at the 3-month follow-up and later showed a slow, non-significant improvement distributed throughout the follow-up period. ODI scores

Table 2 Main clinical data

	Baseline	1 month	3 months	6 months	24 months
VAS (mean)					
VP group	8.4	3.6*	3.2	3	2
KP group	8	3.4*	3	2.6	1.9
ODI (mean)					
VP group	52.3	23*·**	12.7*	8.5	6.7
KP group	49.1	22.1*·**	13.1*	7.2	4.8

* $P < 0.05$ compared to value on left column (Student's t test)

** $P < 0.05$ compared to group 1 on same column (Fisher's test)

were also significantly higher in both surgical groups compared to the conservative group at the first month follow-up. Clinical results were not significantly different after stratification of the number of levels treated per patient, either with VP or KP.

Radiographic measurements Table 3 showed that at 1-month follow-up, no significant height restoration was observed in 110 out of 156 (70.5%) vertebral levels treated with VP, while in 46 vertebrae (29.5%) the measurements of vertebral body height showed mild but significant differences for anterior height restoration (5%, $P < 0.05$) and mid-vertebral height restoration (5%, $P < 0.05$) (Fig. 1a–c). In KP group, mean anterior VBC was higher than the mean mid-vertebral and posterior VBC at observation. After 1 month, the measurements of vertebral body height showed mild but significant differences for anterior height restoration (7%, $P < 0.05$) and mid-vertebral height restoration (7%, $P < 0.05$) (Fig. 2a–c). On the other hand, in 10 out of 43 (23.2%) vertebral levels treated with KP, there was no measurable height restoration. Analysis of height restoration in VP and KP groups did not show statistical differences between thoracic and lumbar levels. For

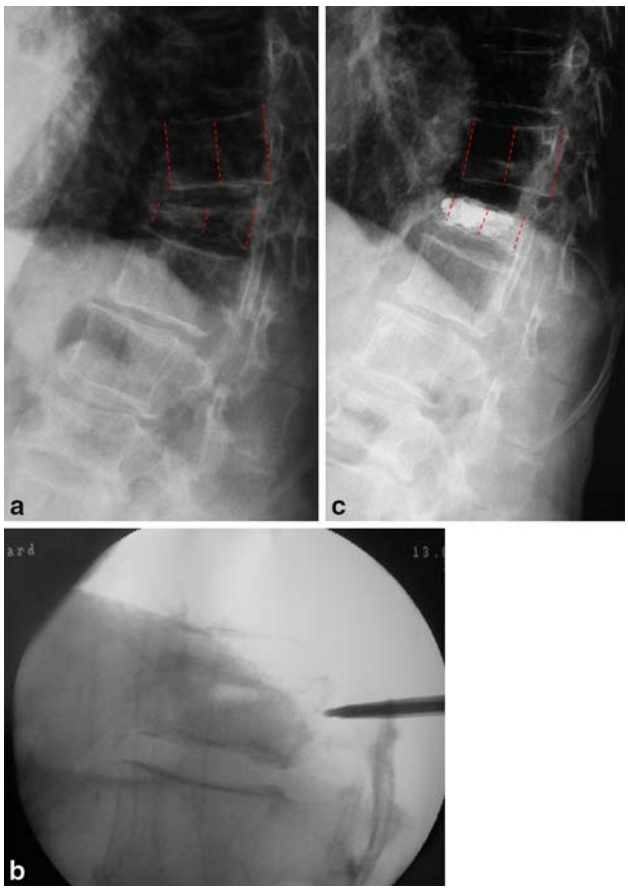


Fig. 1 a–c A 82-year-old woman with a severe collapse of T12 treated with vertebroplasty 3 months after fracture. **a** Preoperative lateral radiograph. **b** Intraoperative sequence of vertebroplasty, before injection of PMMA, shows partial restoration of vertebral body height. This is the consequence of the height restoration effect of prone position of patient when intravertebral cleft is present. **c** Six-month follow-up plain lateral radiographs shows a mean restoration percentage for the vertebral body height of 5% compared to T11 "referent" vertebra

Table 3 Main radiographic data

	Preoperative (%)	Postoperative (%)	3 months (%)	6 months (%)	24 months (%)
Anterior VBC (mean ± SD)					
VP group	21 ± 2	21 ± 1	20 ± 3	20 ± 3	21 ± 3
KP group	39 ± 3	32 ± 2	33 ± 3	33 ± 2	34 ± 3
Midline VBC (mean ± SD)					
VP group	19 ± 1	20 ± 2	20 ± 2	19 ± 1	19 ± 2
KP group	37 ± 4	30 ± 3	30 ± 3	31 ± 2	31 ± 3
Posterior VBC (mean ± SD)					
VP group	9 ± 2	10 ± 2	10 ± 2	9 ± 1	9 ± 1
KP group	12 ± 2	10 ± 2	10 ± 2	11 ± 2	11 ± 1

VBC vertebral body collapse

* $P < 0.05$ compared to value on left column (Student's t test)

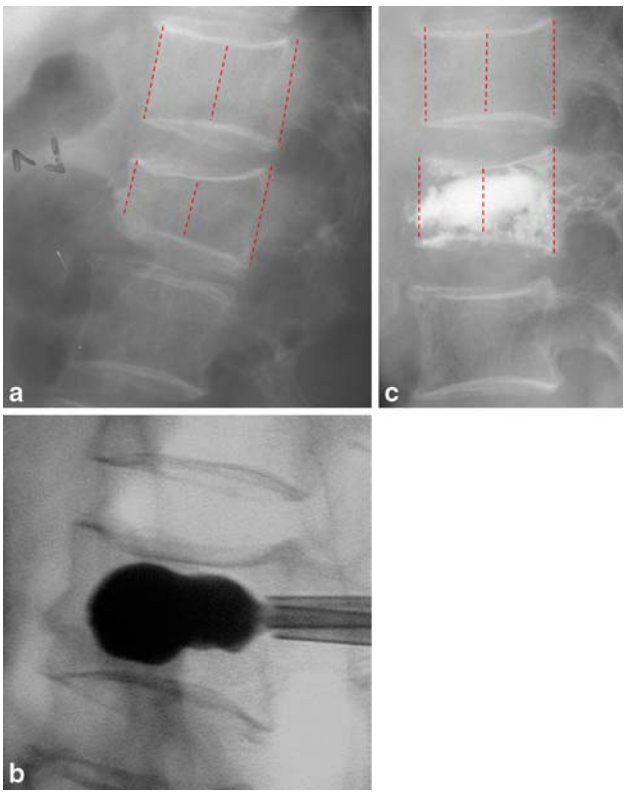


Fig. 2 **a–c** A 74-year-old woman with an osteoporotic vertebral compression fracture of L1 treated with kyphoplasty 2 months after fracture. **a** Preoperative lateral radiograph. **b** Intraoperative sequence of kyphoplasty (balloon inflation). **c** Two-year follow-up lateral radiograph. The restoration percentage for the anterior vertebral body height is 12% compared to T12 "referent" vertebra

radiographic measurements, K values for intra-observer agreement were excellent (0.79) and for inter-observer agreement were good (0.70). No significant correlation was found in any group between VAS or ODI scores and radiographic measurements.

Complications

Cement leakage outside the vertebral body was observed in 29 out of 199 vertebrae (14.6%). The site of leakage was the adjacent disc in 14 levels (10 treated by VP and 4 by KP, $P < 0.05$), the peri-vertebral veins in 9 levels (7 treated by VP and 2 by KP, $P < 0.05$) and the epidural space in a single case of VP. The last occurred in a woman, who underwent a VP at T8. After the procedure the patient developed intercostal neuralgia. A postoperative computed tomography scan showed extravasations of cement into the epidural space and right neuroforamen. I.v. and oral analgesia helped to control the neuropathic pain, which eventually resolved in 3 months. Four patients in VP group suffered subsequent VCF (two at adjacent level) for a mean time of 9 months after the index procedure. These fractures were initially treated conservatively for the first month, but two patient required VP because of persisting pain. One patient died 7 months after VP, because of a preexisting chronic obstructive pulmonary disease.

Discussion

The necessity of an algorithm for the treatment of such a frequent disease as a painful osteoporotic VCF is based on the lack of consensus regarding the proper surgical indications, i.e. timing, application and effectiveness of the percutaneous vertebral body augmentation techniques [7, 19, 26]. Although VP and KP are currently well diffused into clinical practice and generally considered as alternative techniques, their role compared to conservative treatment is still controversial [19, 26]. This is because many patients report only mild and transient symptoms, with significant improvement in the first month of conservative care. The analysis of the current literature is confusing as far as the most appropriate timing of application of VP and KP is concerned. On the one hand, it is suggested that VP should be considered after a course of 3 months of conservative treatment [16]. On the other, supporters of KP suggest that the procedure should be done within 3 months from fracture to increase the likelihood of a favourable outcome [10], or even within a few days from fracture to achieve a good restoration of vertebral height [11]. However, in a recent prospective series [14] patients treated with KP had chronic pain of more than 12 months duration, and still there were improvements in vertebral body height, pain and mobility compared to the preoperative status. The authors of the present study, in accordance with others, believe that 1 month is the minimum waiting period before considering surgery, because of the natural history of osteoporotic VCFs and the higher risk of cement leakage within the first month from fracture [19, 26]. We then suggest that after 1 month of failed conservative treatment, VP should be considered for persistent painful fractures with a VBC less than 30%, whereas KP is considered for fractures that have progressed to a vertebral body collapse equal or higher than 30% within the third month (Table 1). KP must be performed earlier than 3 months in order to maximise the possibility of improvement in spinal sagittal alignment [7, 23]. This matter leads to the controversy that has arisen around the most appropriate fracture to be treated with VP versus KP. In fact, both techniques are able to provide dramatic pain relief in appropriately selected patients. It is also shown by the recent literature that both VP and KP are able to produce partial restoration of vertebral body heights. This effect might be due to patient positioning in both techniques, and to the direct mechanical effect of the balloon inflation in KP [23, 26]. In our series,

a significant increase in mid-vertebral body heights was observed in both groups, but these data were not correlated with a different outcome in terms of VAS and ODI scores. It has recently been suggested that reduction of vertebral body compression fracture has no real influence on the overall sagittal alignment [25]. Although the higher costs of KP compared to VP [19] must be considered, our 5 years experience shows that in a case-mix analysis also the cost of these procedures, according to the VP/KP ratio reported in the present study (118/36), is more than reasonable in all reimbursement systems. In our cohort of surgically treated patients, VAS and ODI values improved in all groups with minimal differences (Tables 2, 3), while the number of levels treated per patient was not a predictor of outcomes of either VP or KP.

The main reported risk of VP and KP is extra-vertebral cement leakage. This is due to cement leaking through cortical defects or to injection of cement into the draining vertebral venous plexus. Cement leakage with clinical consequences has been reported with both VP and KP. Complications due to cement leakage have included pulmonary embolism, mediastinitis, neuropathic pain and paraplegia among others. VP has a higher reported incidence of cement leakage than KP [7, 19, 24, 26], as confirmed by the present study. In order to decrease the risk of cement leakage, we decided to perform VP with cannulae (using stiffer cement) and only after 4 weeks from fracture, as reported by several other authors [23, 24, 26]. This has possibly helped to maintain a low rate of neurological complications in the present series (one out of 154 patients or 0.6%) with lower rate of cement leaks than reported in the previous literature [1, 3, 4, 12].

The fracture rate at adjacent level was low (four out of 154 patients or 2.5%) in this series at 2-year follow-up, well comparing with other authors' series [18, 19, 23]. It is not clear whether injection of acrylic cement might favour fractures at adjacent levels at a higher rate than that caused by the underlying osteoporosis itself, especially at a longer follow-up. Also, it is unclear whether different amounts of injected cement might influence the stiffness of the treated vertebra and the clinical outcome [26].

Conclusion

From the experience made with this algorithm the following conclusions could be drawn. First, the reduction by KP of severely collapsed and painful VCFs provides similar pain relief and function scores to that occurring with VP applied to less severe VCFs. Secondly, KP shows a significantly lower risk of cement extravasation and then eventual major neurological complications. Finally, the higher costs of KP compared to VP could have negative impact in promoting KP as the sole treatment of painful osteoporotic VCFs, while in our experience with the algorithm, the case-mix analysis of the VP/KP ratio shows affordable costs in all reimbursement systems. The improvement seen in the clinical outcome scores (Table 2) is due to a strict selection criteria for both VP and KP and to a consistent surgical technique applied by trained surgeons (cannulae and dense cement). Finally, the rational application of the above described algorithm could effectively help to address the best treatment option for any single patient affected by painful osteoporotic VCFs.

Conflict of interest statement None of the authors has any potential conflict of interest.

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