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Percutaneous transpedicular vertebroplasty with PMMA: operative technique and early results

A prospective study for the treatment of osteoporotic compression fractures

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Abstract Vertebroplasty-percutaneous cement augmentation of osteoporotic vertebrae is an efficient procedure for the treatment of painful vertebral fractures. From a prospectively monitored series of 70 patients with 193 augmented vertebrae for osteoporotic and metastatic lesions, we analysed a group of 17 patients suffering from back pain due to osteoporotic fractures. The reinforcement of 45 vertebral bodies in these patients led to a significant and lasting pain reduction ($P < 0.01$). The presented technique is useful, as, in one session, at least four injections can be performed when required, allowing the prophylactic reinforcement of adjacent vertebrae as well. The use of a low-viscosity polymethyl methacrylate (PMMA) in combination with a non-ionic liquid contrast dye provides a reliable and safe procedure. Extraosseous cement leakage was seen in 20% of the interventions; however, none of them had clinical sequelae.

Key words Vertebroplasty · PMMA · Osteoporosis · Augmentation

Introduction

The technique of percutaneous vertebroplasty with polymethylmethacrylate (PMMA) was first introduced as an augmentation procedure for the treatment of vertebral angiomas by Galibert et al. in 1987 [9]. Following encouraging early clinical results, particularly with respect to pain relief, indications for PMMA augmentation were extended and comprise at present the treatment of metastatic osteolytic bone disease, myeloma, and, more recently, osteoporotic compression fractures of the spine as well [6, 8, 11, 18]. Biomechanical studies have shown significant increases in stability parameters following augmentation with PMMA and also calcium phosphate cements [1, 3, 15, 16, 17]. Clinical experiences, however, are still sparse.

This study reports our technique and experience with percutaneous transpedicular vertebroplasty in the treatment of patients suffering from severe disabling focal back pain due to osteoporotic insufficiencies and vertebral compression fractures.

Materials and methods

Operative technique

The presented technique allows four injections to be carried out in one session under local anaesthesia, i.e. either four vertebrae unipedicularly or two vertebrae bipedicularly.

Patients are placed in a prone position on a radiolucent operating table. An i.v. line is established with an anaesthetist on standby, continuously monitoring the vital signs. Following fluoroscopic localisation of the levels to be augmented, the skin and soft tissues over the pedicles are anaesthetised with 1% mepivacaine hydrochloride, with deep injections down to the periosteum (Fig. 1 a). Under fluoroscopic anteroposterior control, a skin stab incision is established and a 2.0-mm K-wire is guided into the pedicle of each vertebra to be reinforced. In severe osteoporosis, the wire can be advanced by hand, otherwise some gentle hammer blows may be necessary (Fig. 1 b). Under lateral projection control, the wires are adjusted to the appropriate depth, i.e. the centre of the vertebral body. Bone marrow biopsy needles (7 or 8 G, Somatex, Berlin, Germany) are guided over the K-wires, which are then removed (Fig. 1 c). The free passage in front of the needle is checked by a blunt probe.

The augmentation material consists of a low-viscosity bone cement (Palacos E-flow, Essex Chemie, Lucerne, Switzerland). In

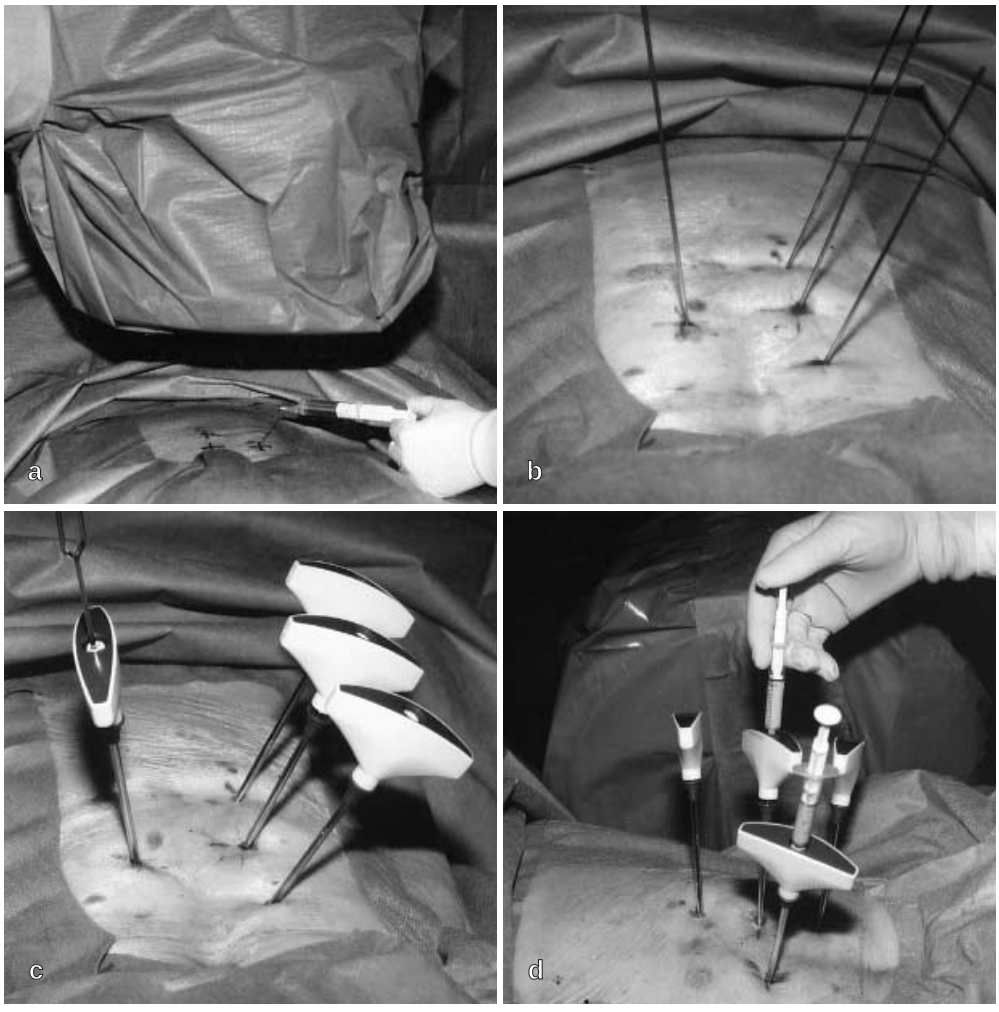

Fig. 1 Intraoperative setting: **a** localisation of the pedicles and local anaesthesia of the skin and soft tissue; **b** placement of K-wires under image control; **c** bone marrow biopsy needles in place; **d** injection of bone cement by 2 cc syringes

order to enhance the radiographic visibility, a non-ionic liquid contrast dye is added to the cement during the mixing procedure (Iopamiro 300, Bracco, Milan, Italy) in the ratio of 10 cc of contrast dye per one portion of PMMA. The material is filled into 2-cc standard syringes.

Two minutes into the cement curing, filling of the vertebral bodies is commenced under continuous fluoroscopic control in the lateral view (Fig. 1 d). The cement remains injectable for the following 2 or 3 min. The simultaneous filling of two vertebral bodies is possible. The flow of the cement must be monitored very carefully, and should behave like a "growing cloud" (Fig. 2). Cement leaks posteriorly into the spinal canal and anteriorly through the nutritional vessels must particularly be avoided. The maximum amount of cement to be injected is determined during the procedure, as with any cement extrusion the filling is stopped. However, in these cases the needle position can be slightly altered, which may allow further filling with less liquid cement. In cases of normal filling ("growing cloud") the augmentation is stopped with visible filling of the entire vertebral frame. Prior to withdrawal of the needles, the material should be allowed to fully cure to avoid dragging of cement into the soft tissues.

Additional analgesia may be needed either during placement of the K-wires and needles or, particularly, during the injection of cement, which sometimes is felt as regional low back pain. In these cases i.v. administration of morphine (Rapifen = alfentanilhydrochloride) also helps the patients to maintain the prone position for the required 45–60 min of the entire procedure.

Patients

At present, our prospectively monitored series contains 70 patients with 193 augmented vertebrae treated for osteoporosis and metastatic lesions of the lumbar and thoracic spine. The paper presented here analyses the first 45 percutaneous vertebroplasties for osteoporotic fractures, with a minimum follow-up of 1 year (Table 1, Table 2). This includes 17 consecutive patients, 15 women and 2 men, aged 50–86 years (mean 74 years). All patients were suffering from disabling back pain refractory to conservative treatment for at least 4 weeks, including analgesics, physiotherapy, and braces in three cases. Most of the patients had initially been treated at other institutions, and were referred because of persistent pain. All patients had radiographic evidence of progressive or new vertebral compression fractures. This was related to the exacerbation of pain after a minor trauma (simple fall, sitting down suddenly). Further, during physical examination, in our patients the region of pain seemed equivalent to the radiological changes. However, the exact clinical determination of a painful level is difficult. Twelve patients showed fractures due to age-related osteopoenia, three patients had received long-term oral steroids for chronic conditions,

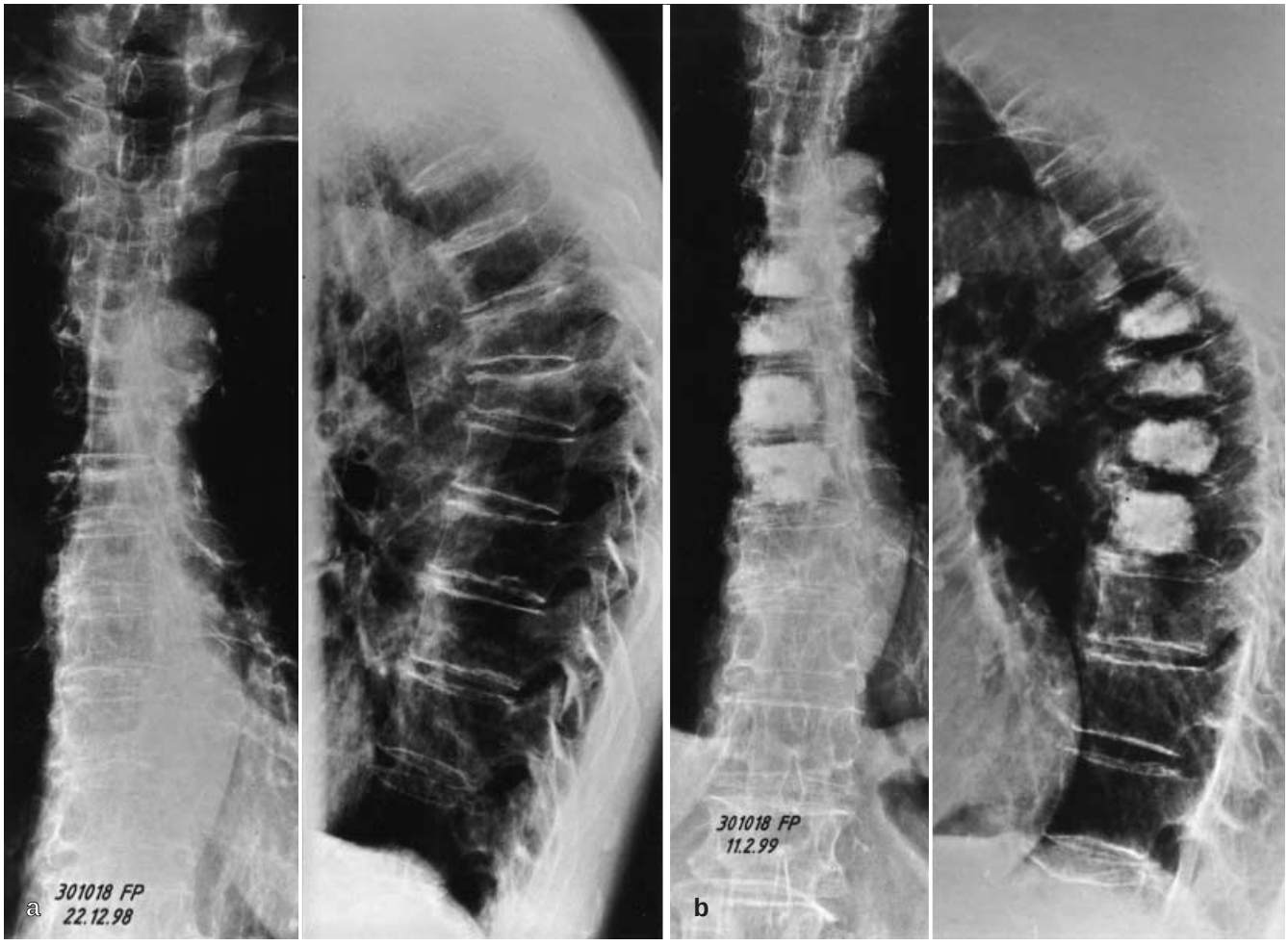

Fig. 2 a, b Clinical example. An 80-year-old female, smoker, otherwise healthy, with disabling back pain due to fractures of the midthoracic vertebrae (**a**). After augmentation of the fractured and adjacent vertebrae, the patient presents painfree (**b**)

Table 1 Data on the patients treated in this series (*VAS* visual analogue scale, *FU* follow-up)

Initials	Age/sex	Levels fractured	Levels augmented	VAS score preop	VAS score postop	VAS score at 3 mo./ 1 year FU
S. W.	86/M	L3	L3 Bi	10	0	0/1
B. B.	86/F	L1	T11–L2 Mono	8	1	0/2
Z. E.	84/F	L1–L3	L1–L3 Bi	6	5	2/2
B. I.	81/F	T11–L1	T11–L2 Mono	10	6	3/3
F. M.	80/F	L1–L3	L1–L4 Mono	7	3	0/3
H. M.	78/F	L4	L4 Bi	8	2	6/4
B. E.	77/F	L3, L4	L3, L4 Bi	6	0	4/4
S. H.	75/M	L2–L5	L2–L5 Mono	6	5	2/3
S. R.	75/F	L1–L3	L1–L4 Mono	8	4	2/4
S. I.	72/F	L4	L3–L5 Mono	8	6	2/3
C. A.	71/F	L1	L1 Mono	6	1	1/2
K. A.	61/F	T11, L1	T11–L1 Mono	9	8	6/6
F. R.	59/F	T12–L2, L4	T12–L2, L4 Mono	8	5	3/2
S. B.	50/F	T11	T11 Mono	7	2	6/6
G. A.	81/F	L2, L4	L2, L4 Mono	5	1	1/1
E. H.	72/F	L3, L4	L3, L4 Mono	7	5	7/7
F. P.	80/F	T6–T7	T6–T9 Mono	9	1	2/2

Table 2 Distribution of levels augmented

Level	No. of segments augmented
T6, T7, T8, T9	4 (1 each)
T11	4
T12	3
L1	7
L2	8
L3	8
L4	9
L5	2
Total	45

and one patient had severe osteopenia due to secondary hyperthyroidism. Plain radiographs were obtained prior to intervention in all patients. Three patients were further evaluated with computed tomography (CT) to assess the spinal canal and the posterior vertebral wall. Clinical and radiological follow-up controls were performed at 1 day, 12 weeks and 1 year post intervention. Pain intensity was assessed using a numerical scale (0–10), 0 points corresponding to "no back pain at all" and 10 points corresponding to "the most severe pain ever experienced".

In four patients only one level was reinforced, in three patients two levels, and in a further three patients three levels were treated, with the remaining seven patients being augmented at four levels (Table 1). The extent of augmentation was decided according to the radiological appearance of the spine, i.e. in cases with a single-level fracture and normal vertebral shape of the adjacent levels, one vertebra was augmented only. Patients were mobilised a few hours after the procedure. For local pain control, all patients received mild pain medication (paracetamol) for 24–48 h.

Results

All 17 procedures were successfully performed under local anaesthesia in combination with slight sedation monitored by the anaesthetist. None of the procedures lasted more than 1 h. Four patients reported discomfort with local low back pain upon PMMA injection.

Thirty-eight of the 45 vertebral bodies were augmented through one pedicle; six bodies were injected through both pedicles. The mean volume of filling per vertebra was 5.9 ml PMMA (4–8 ml). Extraosseous cement leakage was noted in eight vertebral bodies (20%), five times (12.5%) into the paravertebral soft tissues, twice (5%) into the spinal canal and once (2.5%) into a segmental vein. All of these cement extrusions remained without clinical sequelae.

All patients reported a considerable pain benefit following the procedure. The median scores of pain intensity were reduced significantly ($P < 0.01$, Wilcoxon signed rank test) (Fig. 3). With the exception of one patient, all patients were able to get out of bed 3–4 h after intervention, and the mean hospital stay was 2.6 days (1–5 days).

At 3 months follow-up, radiographs revealed further compression of an augmented vertebral body in one case. The clinical rating stayed unchanged. At 1 year follow-up,

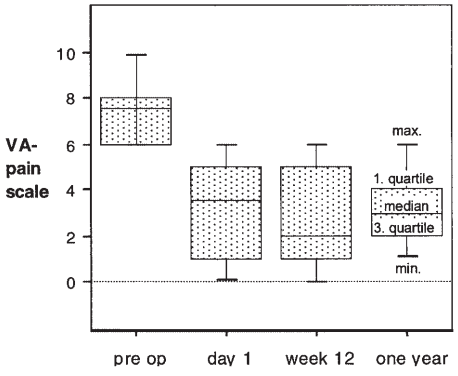

Fig. 3 Box plot representing the visual analogue (VA) scale of pain assessment prior to treatment, 1 day after, 3 months later and 1 year postoperatively. There is significant pain relief immediately after the procedure (Wilcoxon signed rank test $P < 0.01$)

all injected vertebrae seemed radiologically stable; however, at this stage, additional new compressions of non-reinforced vertebral bodies were noted in two patients with secondary osteoporosis at T9 and T10 respectively. Again, at this time the pain scale remained unchanged.

Discussion

The spine is the most common site of fracture in patients with osteoporosis. In the United States, 25% of women over the age of 70 and 50% of women over the age of 80 years show evidence of vertebral fractures, the majority of which occur in the midthoracic region and the thoracolumbar junction [12,13]. The morbidity associated with osteoporosis and vertebral fractures has an enormous socio-economic impact [2].

Percutaneous vertebroplasty (PVP) with PMMA offers an efficient tool in augmenting vertebral bodies, which has been clearly demonstrated in biomechanical studies [12,13]. Clinical experience of more than 10 years in the treatment of haemangiomas, metastatic lesions and, more recently, osteoporotic deficiencies are also encouraging [5, 8, 9, 10, 11, 14,18]. Our series confirms these results, as all patients reported pain relief following augmentation. The intervention can be performed under local anaesthesia and slight sedation as an outpatient procedure, despite the fact that mainly elderly patients are treated. The average stay of 2.6 days for our patients is only due to the fact that prior to our intervention most patients had been treated as in-patients in the internal department. The presented technique allows for the reinforcement of four vertebrae in less than 1 h. In contrast to other reports, no CT-guided puncture of the vertebral pedicles, nor a venography prior to cement injection, was used [4, 5, 7,9]. Care has to be taken concerning the distribution of cement, and continuous monitoring of cement flow at any time during the injection procedure is mandatory. Never-

theless, extravasation of cement did occur in 20% of our cases. However, no serious clinical sequelae were observed, as the vast majority extravasations seem clinically irrelevant [11]. With advanced destruction of the vertebral body, the risk of cement leakage increases [19]. Cotten et al. observed extrusions in 29 out of 40 injected vertebral bodies with metastatic diseases, and two patients out of 37 required decompressive back surgery for severe neurological complications [5].

The minimum amount of cement required for a therapeutic effect is not exactly known. In a series of 37 patients, Cotten observed a reduction of pain after filling vertebral bodies with between 5.5 and 7 cc cement, but no correlation between the volume of filling and the amount of pain relief was found [5]. The antalgic effect of PMMA is most probably based on its mechanical effect, through reinforcement of the trabecular pattern at the fracture site [18]. A thermal or chemical destruction of nerve endings also seems feasible. In our series, pain was reduced with a mean of 5.9 cc PMMA per vertebral body and, with the exception of one vertebra, further collapse was prevented. This single case of collapse may have been due to an insufficient filling, of 2.5 cc PMMA. Thirty-four of the 40 vertebrae were injected through one pedicle only. We did not see any collapse of the non-injected side, which confirms the results of a recent biomechanical study reporting a comparable biomechanical efficacy of unipedicular versus bipedicular vertebroplasties [17].

A further question to be discussed is whether the reinforcement of the affected and already fractured vertebrae alone is sufficient, or whether a more extensive treatment including the adjacent levels should be performed. The reported experience in the literature is based on the treatment of fractured vertebrae – in most cases a single vertebra – only, and focusses on acute pain relief. So far, long-term follow-up and consequences of vertebroplasties on the overall alignment of the spine have not been addressed. At 1 year follow-up, two of our patients showed vertebral fractures adjacent to the augmentation area. We do not know whether these fractures were caused by the underlying disease or whether an increased stiffness and stress arising adjacent to an augmented area plays a role.

Also, limits and timing of cement augmentation are difficult to determine. As a consequence of the present study, we started to augment acute osteoporotic fractures as well, in order to prevent collapse and achieve immediate pain relief. However, if the patient's pain seems more related to an advanced kyphotic deformation and loss of spinal balance, more aggressive measures, such as multisegment correction and stabilization may be indicated. In these cases, as with already collapsed single vertebrae, the technique of vertebroplasty reaches a limit, as the cement injection does not restore vertebral height. In addition, in advanced kyphosis, we recommend magnetic resonance imaging (MRI) evaluation of the thoracic spinal canal before considering cement augmentation. In cases of narrowing of the spinal canal, any indication for vertebroplasty should be considered very cautiously, as cement leakage posteriorly may have severe consequences. In order to define these factors more clearly, a randomised controlled trial is planned to analyse the effect of preventive reinforcement.

At present, the only suitable material for injection is a low-viscosity PMMA. Injectable calcium phosphate (CaP) cements are already available, but for percutaneous application in the spine, their radio-opaqueness is insufficient and does not allow a safe procedure. The corresponding adaptations seem technically difficult to achieve. However, once available, these materials could represent an improved solution for patients at risk of osteoporotic spine fractures, as the potential disadvantages of PMMA, e.g. toxicity, heat generation, etc, can be avoided. Also, the osteoconductive properties of CaP materials could bear potential benefits in the long term. This should be investigated further, including long-term assessment of augmentation materials in vivo.

The results of the present study justify the generous use of PMMA percutaneous vertebroplasty as a complementary therapy to standard medical therapy for patients suffering from severe pain on the basis of osteoporotic compression fractures.

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