

Early and long-term outcomes of vertebroplasty for single osteoporotic fractures

Wczesne i odległe wyniki leczenia pojedynczych złamań osteoporotycznych za pomocą wertebroplastyki

Zbigniew Kotwica^{1,2}, Agnieszka Saracen¹

¹Instytut Zdrowia Politechniki Radomskiej

²Oddział Neurochirurgii, Zachodniopomorski Szpital Specjalistyczny w Gryficach

Neurologia i Neurochirurgia Polska 2011; 45, 5: 431–435

Abstract

Background and purpose: Percutaneous vertebroplasty (PVP) is a minimally invasive vertebral augmentation procedure for the treatment of recent, osteoporotic vertebral compression fractures. The aim of the study was to determine the early and late outcomes of PVP for osteoporotic vertebral compression fractures.

Material and methods: We prospectively assessed outcomes of PVP in 200 patients with single, osteoporotic vertebral compression fracture. Follow-up assessment was made 12 hours after surgery as well as after 7 days, 30 days, 3 months, 6 months, and 1 year after surgery. A subgroup of 80 patients was evaluated also 2 years after PVP. A 100-mm visual analogue scale of pain was used for outcome measurement.

Results: Twelve hours after PVP, very significant relief of pain was obtained in 85% of patients; on the 7th and 30th day a very good result of treatment was noted in 96%. The same result was noted in 92% of patients at the 6th month, and in 90% of patients at the 12th month. Among the 80 patients followed for 2 years, 3 patients reported recurrence of pain and were subsequently diagnosed with new osteoporotic fractures.

Conclusions: Percutaneous vertebroplasty is a minimally invasive method of treatment for fresh osteoporotic fractures, which provides a significant and sizeable reduction of pain in the short as well as long term after surgery. Complete relief of pain was noted 12 hours after PVP in 94% of patients, and was noted in 90% two years after treatment. Despite some

Streszczenie

Wstęp i cel pracy: Wertebroplastyka jest szeroko stosowaną, minimalnie inwazyjną metodą leczenia świeżych kompresyjnych złamań osteoporotycznych trzonów kręgow. Celem pracy była ocena wczesnych i odległych wyników leczenia świeżych złamań osteoporotycznych trzonów kręgow za pomocą przeszskórnej wertebroplastyki.

Materiał i metody: Prospektywnej analizie poddano 200 pacjentów leczonych za pomocą wertebroplastyki z powodu pojedynczego, osteoporotycznego złamania trzonu kręgu. Stan pacjentów oceniano 12 godz. po zabiegu, po upływie 7 dni, miesiąca, 3 miesięcy, 6 miesięcy i 12 miesięcy, a 80 pacjentów oceniono także po upływie 24 miesięcy. Wynik był oceniany przy użyciu 100-milimetrowej wzrokowej analogowej skali oceny bólu.

Wyniki: Po 12 godz. po zabiegu ustąpienie dolegliwości lub istotną poprawę zanotowano u 85% pacjentów, w 7. i 30. dniu bardzo dobre wyniki stwierdzono u 96% pacjentów. Po 6 miesiącach bardzo dobry wynik utrzymywał się u 92%, a po 12 miesiącach – u 90% leczonych. Spośród 80 pacjentów obserwowanych po 2 latach nawrót dolegliwości bólowych wystąpił tylko u 3 pacjentów, u których doszło do złamania kolejnego trzonu kręgu.

Wnioski: Wertebroplastyka jest minimalnie inwazyjną metodą leczenia świeżych złamań osteoporotycznych, pozwalającą na uzyskanie bardzo dobrych wyników leczenia, zarówno wczesnych, jak i późnych. Całkowite ustąpienie dolegliwości obser-

Correspondence address: dr hab. med. Zbigniew Kotwica, Oddział Neurochirurgii Zachodniopomorskiego Szpitala Specjalistycznego, ul. Niechorska 27, 72-300 Gryfice, fax +48 91 384 21 52, e-mail: zbigniew.kotwica@neostrada.pl

Received: 7.11.2010; accepted: 11.03.2011

literature data suggesting no beneficial effect of PVP, it can be concluded that PVP is the most effective and the safest method for fresh vertebral compression fracture treatment.

Key words: osteoporosis, vertebral fracture, vertebroplasty.

Introduction

Duration of life continues to increase, which leads to an increased number of patients with osteoporotic fractures, proximal femur and vertebrae being the most often noted. Vertebral compression fractures cause significant pain and some patients are debilitated by the pain due to the fracture [1-3]. Conventional surgery carries a high risk and poor outcomes and is reserved only for patients with significant neurological deficit [2,3]. Vertebroplasty involves the injection of liquid polymethylmethacrylate (PMMA) cement through a needle into the vertebral body, where it becomes hard, restores stability and diminishes pain [3-7]. This method of treatment is relatively safe, causing minimal operative trauma, and complications are rare [4,8], mainly caused by extravertebral leakage of the cement [2-4] or osteitis [9]. In 2009, two randomized trials of vertebroplasty for osteoporotic spinal fractures did not find a beneficial effect of vertebroplasty as compared to conservative treatment [1,10]. Conclusions from both trials are doubtful; the first one, from Australia [1], included 78 participants (35 treated by vertebroplasty and 36 without cement augmentation); the second one [10], from Mayo Clinic, involved 131 patients (68 treated by vertebroplasty and 63 without surgery). The number of patients included in both trials is not large, and it requires further studies, with a larger group of observed patients [6,11-13].

Compression fractures can also be treated by kyphoplasty, in which an inflated balloon increases the height of the broken vertebra, correcting the kyphotic deformation [2,5,9]. Both methods – vertebroplasty and kyphoplasty – show similar clinical results [2,5,14]. Recently, radiofrequency methods have been used for pain treatment in osteoporotic fractures with promising results [12,14]. Some authors suggest that augmentation of one vertebra can increase the probability of new fractures developing in adjacent vertebrae [15,16]. In osteoporosis, we often face the problem of multiple fractures, and

wowano już po 12 godz. u 94% chorych, taki wynik utrzymywał się przez kolejne dwa lata u 90% leczonych. Mimo pojedynczych doniesień o nieskuteczności tej metody wydaje się, że w świeżych złamaniach osteoporotycznych vertebroplastyka jest najskuteczniejszą i najbezpieczniejszą metodą leczenia dolegliwości bólowych, będących wynikiem złamań trzonów kręgow.

Słowa kluczowe: osteoporoza, złamanie trzonu kręgu, vertebroplastyka.

about 20% of patients with previously diagnosed single compression fracture develop new ones [3,14,16]. Some authors even suggest prophylactic augmentation of decalcified vertebrae [14]. The development of fractures increases mortality [2,10]; it should also be noted that almost 4% of fractures are due to neoplastic disease, which suggests the value of vertebral biopsy, which could be performed during this procedure [3,12]. In patients with pathological fractures due to malignant tumours of the vertebrae, vertebroplasty also gives satisfactory results [3,5,13].

In this paper, we analysed the results of treatment of single compression osteoporotic vertebral fractures by cement vertebral augmentation.

Material and methods

Two hundred consecutive patients with single osteoporotic vertebral fracture were included in the study. The patients were treated surgically between June 2007 and June 2009. There were 178 women and 22 men studied, and their age ranged between 58 and 89 years (114 patients were 70-80 years old). One hundred and forty-two (71%) patients had a thoracic fracture and 58 (29%) had a lumbar fracture. The highest fracture was located at Th3, and the lowest one at L5 level. The time from the onset of pain to surgery was 1 week to 7 months (mean: 4 weeks).

All the fractured vertebrae were augmented with an acrylic cement (Vertaplex, Stryker, USA). Surgical procedures were performed under local anaesthesia, and a unilateral transpedicular approach was used (Figs. 1-3). A normal 10-cm³ syringe was used for application of the cement. We did not use any application systems manufactured for vertebroplasty. The amount of PMMA injected depended on the height of the compressed vertebral body and ranged from 1 cm³ at the upper thoracic level to 3.5 cm³ in the lower lumbar part of the vertebral column. The results of treatment were eval-



Fig. 1. Plain X-ray, lateral view. Compression fracture of L1 vertebral body



Fig. 2. Intraoperative plain X-ray, lateral view. The needle is inserted transpedicularly. PMMA is injected into the vertebral body



Fig. 3. Plain X-ray, lateral view. The compressed vertebral body is augmented with PMMA

uated on the 1st, 7th and 30th day, as well as 3 months, 6 months and 12 months after surgery. In 80 patients, the results were also evaluated 2 years after performing ver-

tebroplasty. For evaluation of pain, a 100-mm visual analogue scale was used [17,18].

Results

There were no intraoperative complications. The leakage of small amounts of PMMA outside the vertebral body was noted in 8 patients, including leakage into the intervertebral space in 2 patients, and anteriorly to the vertebral body in 6 other patients. There were no clinical symptoms of leakage in any of those patients.

Just before surgery, the level of pain ranged between 56 and 100 mm (mean: 78 mm). On the first day after surgery, very significant relief of pain was noted in 170 (85%) patients; the mean value on the visual analogue scale in those 170 patients diminished to 22 mm and 101 patients (50%) were free of pain. Twenty patients noted only slight improvement, i.e. a change less than 10 mm, and in 10 patients the level of pain did not change. The same results were noted on the 7th day. The mean value of pain severity in the whole group of 200 patients was 29 mm on the visual analogue scale. On the 30th day, the pain diminished significantly in 12 of the 20 patients

with only a slight improvement after surgery (the mean pain severity among these patients changed from 52 to 34 mm on the visual analogue scale) and the value for the whole group diminished to 27 mm. All the patients who did not benefit from PVP were treated later than 3 months after the onset of pain.

The follow-up performed 3 and 6 months after surgery revealed results similar to those noted one month after vertebroplasty. One-year follow-up revealed that 21 patients, who were earlier free of pain, reported the recurrence of symptoms, with the mean value of 36 mm on the visual analogue scale (i.e. less than before surgery). In one of these patients a new fracture appeared, but not in the vertebra adjacent to the previously augmented one.

Eighty patients were examined two years after surgery. The mean pain severity in this group was 38 mm on the visual analogue scale. Results of treatment were the same as one year after surgery, except for three patients, who developed new osteoporotic fractures, one of them in a vertebra adjacent to the previously augmented one. Performing the next procedure resulted in total relief of pain in these 3 patients.

Discussion

Percutaneous vertebroplasty is widely used for the treatment of osteoporotic compressed fractures of the vertebrae [2-4,7,9,13,15]. Recently, two randomized trials put into doubt the efficiency of vertebroplasty in osteoporotic fractures [1,10], but a number of different series of patients show significant relief of pain after performing this procedure [3-5,7,12-14]. Some authors suggested an increase of the number of new fractures after performing vertebroplasty [15,16], especially in vertebrae adjacent to the augmented ones [15]. In our patients, we noted the development of new fractures during one-year follow-up in 1 of 200 patients only. Two years after surgery, however, new fractures developed in 3 of 80 examined patients, but only one patient had a fracture in a vertebra adjacent to the previously augmented one. The development of new fractures seems to be independent of augmentation.

Vertebroplasty is a relatively safe method of treatment with a small number of complications. The commonest one is extravertebral leakage outside the vertebral body. However, it does not produce any clinical symptoms. In 1-2% of cases, PMMA leaks into the vertebral canal, which can produce radicular or spinal deficits, from pain to paresis, possibly requiring open surgical intervention

and decompression of the spine [4,8,9]. Very rare systemic complications consist of pulmonary embolism and severe haemorrhage caused by the puncture of the big vessels during vertebroplasty [8,9]. Kyphoplasty gives a lower incidence of complications than vertebroplasty, but in osteoporotic fractures clinical results of both methods are similar [2,5,14]. Kyphoplasty requires a bilateral transpedicular approach. The procedure lasts much longer, which is very uncomfortable for the patients, and the costs are much higher. The authors routinely perform kyphoplasty in traumatic fractures and in some patients with pathological fractures caused by vertebral body neoplasms, but we do not find any advantages of kyphoplasty versus vertebroplasty in patients with osteoporosis.

We did not note any important complications of PVP. In 6 cases (3%), an outside leakage of cement was seen but it did not cause any clinical symptoms. This confirms the opinions of other authors [4,7,8] that the complication rate for this procedure is low. Some reviews show high rates of cement leakage, up to 40%, but it mainly depends on the amount of cement injected, as well as on the cement viscosity. We use PMMA of high viscosity and inject no more than 3 cm³, which significantly reduces cement leakage. With the development of new types of cement, especially hydroxyapatite, vertebroplasty should become safer and lead to physiological healing of the fractures. Recently, we have also performed several procedures using hydroxyapatite, but it needs time to check the efficiency of such cement. We do not find any advantages of specially designed application systems in comparison to the typical syringe, similarly to other authors [2,4,15].

The results of our study show a significant reduction in pain levels – 50 mm reduction on the 100-mm scale. This reduction of pain persisted 1 and 2 years after vertebroplasty. Satisfactory results were obtained in 85% of patients; 10% showed only slight reduction of pain level, and in 5% of patients no improvement was noted. It is difficult to say which patients have no beneficial effect of vertebroplasty, but some literature data show that the best results are obtained in patients with recent fractures. In all our patients who did not improve, the time interval between the onset of pain and PVP exceeded 3 months, which supports these observations.

Conclusions

1. Vertebroplasty provides significant reduction in pain, use of analgesics, and disability both in the short and long term.

2. The procedure is relatively safe and the number of complications is low.
3. Vertebroplasty does not increase the risk of new vertebral fractures.

Disclosure

The authors report no conflict of interest.

References

1. Buchbinder R., Osborne R.H., Ebeling P.R., et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *New Engl J Med* 2009; 361: 557-568.
2. Fuentes S., Blondel B. Vertebroplasty and balloon kyphoplasty. *Neurochirurgie* 2010; 56: 8-13.
3. Rousing R., Andersen M.O., Jespersen S.M., et al. Percutaneous vertebroplasty compared to conservative treatment in patients with painful acute or subacute osteoporotic vertebral fractures: three-months follow-up in a clinical randomized study. *Spine* 2009; 34: 1349-1354.
4. Diel P., Merky D., Roder C.H., et al. Safety and efficacy of vertebroplasty: Early results of a prospective one-year case series of osteoporosis patients in an academic high-volume center. *Indian J Orthop* 2009; 43: 228-233.
5. Schofer M.D., Efe T., Timmesfeld N., et al. Comparison of kyphoplasty and vertebroplasty in the treatment of fresh vertebral compression fractures. *Arch Orthop Trauma Surg* 2009; 129: 1391-1399.
6. Ali-Ali F., Barrow T., Luke K. Vertebroplasty: what is important and what is not. *AJNR* 2009; 30: 1835-1839.
7. Thillainadesan J., Schlaphoff G., Gibson K.A., et al. Long-term outcomes of vertebroplasty for osteoporotic compression fractures. *J Med Imaging Radiat Oncol* 2010; 54: 307-314.
8. Cosar M., Sasani M., Oktenoglu T., et al. The major complications of transpedicular vertebroplasty. *J Neurosurg Spine* 2009; 11: 607-613.
9. Patel A.A., Vaccaro A.R., Martyak G., et al. Neurologic deficit following percutaneous vertebral stabilization. *Spine* 2007; 32: 1728-1734.
10. Kallmes D., Comstock B.A., Heagerty P.J., et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009; 361: 569-579.
11. Kinkade S., Stevermer J.J. Vertebroplasty for osteoporotic fracture? Think twice. *J Fam Pract* 2009; 58: 654-656.
12. Gangi A., Clark W.A. Have recent vertebroplasty trials changed the indications for vertebroplasty? *Cardiovasc Intervent Radiol* 2010; 33: 677-680.
13. Bolster M.B. Consternation and questions about two vertebroplasty trials. *Clev Clin J Med* 2010; 77: 12-16.
14. Rollinghoff M., Zarghooni K., Dargel L., et al. The present role of vertebroplasty and kyphoplasty in the treatment of fresh vertebral compression fractures. *Minerve Chir* 2010; 65: 429-437.
15. Kulcsar Z., Marosfoi M., Berentei Z., et al. Frequency of adjacent vertebral fractures following percutaneous vertebroplasty. *Orv Heti* 2009; 150: 1744-1748.
16. Tseng Y.Y., Yang T.C., Tu P.H., et al. Repeated and multiple new vertebral compression fractures after percutaneous transpedicular vertebroplasty. *Spine* 2009; 34: 1917-1922.
17. Dixon J.S., Bird H.A. Reproducibility along a 10 cm vertical visual analogue scale. *Ann Rheum Dis* 1981; 40: 87-89.
18. Maxwell C. Sensitivity and accuracy of the visual analogue scale: a psycho-physical classroom experiment. *Br J Clin Pharmacol* 1978; 6: 15-24.