

## 研究成果の刊行物・別刷

## Can you diagnose for vertebral fracture correctly by plain X-ray?

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**Abstract** *Introduction:* A wrong diagnosis of latent vertebral fracture is often made when it is based on plain X-ray imaging. Magnetic resonance imaging (MRI) has a high degree of accuracy for the definite diagnosis. This study was designed to identify ways to support improvements in the diagnostic accuracy of plain X-ray (X-P). *Methods:* We studied X-P and MRI images of 120 women and men (age range: 50–96 years). Five orthopedists and two radiologists interpreted front and lateral thoracolumbar X-Ps and MRI images. The correct diagnosis rate for the presence and location of incident vertebral fractures and the correct diagnosis rate according to morphological classifications were analyzed. *Results:* A correct diagnosis of incident fractures was made in 51.5% of cases overall. Diagnoses of non-incident fracture based on X-P in those cases with incident fracture based on MRI (false positive) occurred in 24.8% of the patients, while diagnoses of incident fracture based on X-P in those cases without incident fracture based on MRI (false

negative) occurred in 6.5% of the patients. The application of morphological classifications (the primary osteoporosis diagnostic criteria and Yoshida's classification) resulted in the correct diagnosis rate being significantly higher in the group without prevalent fracture even when there were morphological changes (wedge, indented, protruding type) in the anterior bone cortex. Odds ratios were investigated for factors that would affect the correct diagnosis rate, including age, body weight, lumbar vertebrae bone mineral density, and examiner ability. In an overall investigation, age (OR=0.660), body weight (OR=2.082), and examiner ability ( $p=0.0205$ ) affected the correct diagnosis rate. *Conclusion:* The correct diagnosis rate for incident vertebral fractures with X-Ps was low (24.8%) and in cases with prevalent fractures, the rate was even lower (16.8%), but the number of prevalent fractures and BMD did not exert an effect. One key improving the correct diagnosis rate may be to pay attention to morphological changes in the anterior bone cortex.

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### Introduction

Elderly outpatients with complaints of severe lumbar back pain in almost all cases undergo plain X-ray (X-P), from which a diagnosis of the underlying condition should be made. At such times an existing lesion of vertebral disk degeneration or osteoporosis can often conceal a latent incident spinal fracture, with the result that a delayed diagnosis can make it difficult to prevent post-fracture sequelae or other problems [1]. However, reports are occasionally received that an accurate diagnosis of the existence or location of the incident fracture is difficult with X-P images only and that X-P screening images are not effective for low back pain [2, 3]. Meanwhile, many reports have stated that magnetic resonance imaging (MRI) has a high degree of accuracy for the definite diagnosis of incident spinal fracture, and it continues to be used as the

more useful tool [4–6]. However, due to limitations in equipment and considerations that must be given to the economics of medical treatments, it is not possible to use MRI with all patients. In the present study, therefore, with diagnosis by MRI taken to be the correct diagnosis, we conducted a multi-lateral analysis of the diagnostic accuracy of several orthopedic surgeons and radiologists who based their diagnoses on X-P images, in order to identify ways to support improvements in diagnostic accuracy. This is a cross-sectional study.

## Materials & methods

### Participants

The subjects were patients above the age of 50 who were examined at the authors' hospitals between May 1999 and January 2004, and who had undergone MRI within 4 weeks of the initial examination. A non-incident fracture group consisted of patients without incident vertebral fractures, while an incident fracture group consisted of patients with incident vertebral fragility fractures caused by weak external force, such as that sustained in falls from a standing position. One hundred twenty-three patients had these conditions. After excluding patients who had a history of primary or metastatic bone tumor, infectious disease, hematological disorders, or compression fracture within the previous year, which would leave spots with high signal intensity on the MRI images (three patients), the final number of subjects for the study was 120, of whom 112 were women and eight were men, with ages ranging from 50 to 96 years (mean age: 75.6 years).

### Measurements

Five orthopedists and two radiologists from our hospital interpreted anteroposterior (A-P) and lateral thoracolumbar X-Ps taken during the initial examination. They did not question the patients or have access to physiological

findings, and the images were arranged by a third party with the patients' IDs and names concealed. The correct diagnoses were taken to be those of two radiologists not involved in the treatment of the patients who, in consultation with each other, reached the same conclusion based on MRI [1.5T, T1-weighted images (SE: TR/TE = 400/15 ms); T2-weighted images (SE: TR/TE = 2500/120 ms)]. In this study, a definition of a fracture based on the MRI image also included a bone bruise without deformity as an incident fracture. Differences in the ability of the five orthopedists to interpret spinal X-P images were investigated in advance. The subjects of this investigation were 89 healthy community residents who underwent thoracolumbar spine X-P for the purpose of a long-term longitudinal epidemiological study at out hospital. Each orthopedist classified the vertebral spines (Nathan's classification [7]) on an A-P thoracolumbar image, after which intraclass correlation coefficients were calculated using SAS (Statistical Analysis Software, Cary N.C.) ver. 8.2, and the level of coincidence was observed. The results revealed no significant difference in the ability of the orthopedists to interpret radiographs, with intra-class correlation (ICC) = 0.739 [95%CI for ICC: 0.679–0.799]. Accordingly, assuming that there was no difference in the ability to interpret spinal X-P images, the correct diagnosis rate for the presence and location of incident spinal fractures and the correct diagnosis rate according to the morphological classifications (classifications of Genant et al. [8] and Yoshida [9]) of the incidental fractured vertebral body were analyzed, and subjects were divided into three groups for the analysis of factors affecting correct diagnosis: (1) non-incident fracture group with and without prevalent fractures (non-incident fracture group); (2) incident fracture group without prevalent fractures; (3) incident fracture group with prevalent fractures. Bone mineral density (BMD) was measured using dual energy x-ray absorptiometry (DPX; Lunar, GE Healthcare, UK) in bones of the entire body, the lumbar vertebrae, and the femoral neck. The density for the lumbar vertebrae (L2–4) was adopted for the present study.

Table 1 Baseline data (means  $\pm$  standard deviation)

1	Fracture group	Incident fracture group		Non-incident fracture group <sup>a</sup>	
		Without prevalent fracture	With prevalent fracture		
<sup>a</sup> Number	67	24	43	53	
Age (year)	79.9 $\pm$ 7.9	76.8 $\pm$ 7.2	81.1 $\pm$ 7.9	68.9 $\pm$ 9.6	
Weight (kg)	43.4 $\pm$ 8.3	46.1 $\pm$ 9.1	42.2 $\pm$ 7.7	49.9 $\pm$ 7.3	
Height (cm)	146.3 $\pm$ 7.1	148.1 $\pm$ 5.5	145.5 $\pm$ 7.6	148.39 $\pm$ 6.2	
Lumbar BMD(g/cm <sup>2</sup> )	0.74 $\pm$ 0.19	0.84 $\pm$ 0.18	0.70 $\pm$ 0.27	0.90 $\pm$ 0.24	
One new fracture	50	21	29	-	
Two new fractures	9	2	7	-	<i>p</i> <0.0001
Three new fractures	7	1	6	-	
More new fractures	1	0	1	-	

Values are means $\pm$ SD

<sup>a</sup>Significant differences were seen in age, height, weight, and lumbar vertebrae BMD

## Statistical analysis

SAS ver. 8.2 was used for the accumulation and analysis of data. In comparing the correct diagnosis rate for fractured vertebral body morphology, adjustments were made using the Cochran-Mantel-Haenszel method for variations in age, body weight, lumbar spine bone mineral density, and examiner ability, and analysis was conducted with ANOVA, Tukey's multiple comparison test, and logistic regression analysis.

## Results

### Number of patients and fractured vertebrae

Of the 120 patients, 67 patients were diagnosed with incident fractures with and without prevalent fractures in 95 vertebrae, including single incident fractures in 50 patients and two or more incident fractures in 17 patients. There was non-incident fracture with and without prevalent fractures in 53 patients. The group of incident fractures without prevalent fractures consisted of 24 patients and 28 vertebrae, and with prevalent fractures, of 43 patients and 67 vertebrae. Significant differences were seen in age, height, weight, and lumbar vertebrae BMD ( $p < 0.0001$ ) (Table 1).

### A breakdown of correct and incorrect diagnoses

A correct diagnosis of incident fracture was made in 51.5% of cases overall. A breakdown shows that in cases when non-incident fracture was seen by MRI the correct response of non-incident fracture (true negative) was made in 37.7% of cases and the correct diagnosis of incident fracture (true positive) was judged to have occurred in 13.8% of cases. The location of incident fracture was mistaken in 17.2% of the cases. Responses of non-incident fracture on X-P images in cases with incident fracture (false negative) occurred in 24.8% of the cases, while responses of incident fracture on X-P images in cases of non-incident fracture (false positive) occurred in 6.5% of the cases (Table 2).

### The overall rate of correct diagnosis

#### *Non-incident fracture group*

We next compared the correct diagnosis rate of incident fractures by the five examiners in each of the three groups. The correct diagnosis rate of the five examiners was high overall, reaching 85.3% (73.6–92.5%) in the non-incident fracture group. The overall diagnosis rate was also high with no significant variation between the five examiners ( $p = 0.486$ ).

#### *Incident fracture group without prevalent fractures*

The overall correct diagnosis rate for the incident fracture group without prevalent fractures was 39.3% (21–58.3%), and significant variation was seen between the five examiners ( $p = 0.04$ ).

#### *Incident fracture group with prevalent fractures*

Despite the low overall correct diagnosis rate of 16.8% (9.3–21%) in the incident fracture group with prevalent fractures, no significant difference was seen in the correct diagnosis rate between the five examiners, and overall the diagnosis rate was low ( $p = 0.432$ ).

Thus, the correct diagnosis rate for incident fractures decreased significantly in the non-incident fracture group followed by the incident fracture group without prevalent fractures, and the incident fracture group with prevalent fractures, in that order. However, a second investigation after adjusting for differences in age, weight, and lumbar vertebrae BMD revealed significant variation in all three groups (Fig. 1).

#### *The kappa score of interexaminers*

The median kappa-score of all examiners was 0.65 [0.51 (min.) to 0.81 (max.)]. The median kappa-score of inter-orthopedists was 0.65 (0.51–0.72), while the kappa-score of inter-radiologists was 0.69. The median kappa-score of orthopedists-radiologists was 0.63 (0.54–0.81) (Fig. 1).

Table 2 A breakdown of correct and incorrect diagnoses<sup>a</sup>

	Fracture - (MRI)	Fracture +	Total	Diagnosis rate
Fracture-(X-P)	37.68%	24.83%	62.51%	→ Fx-/Fx-: 37.68%
Fracture +	6.49%	31%	37.495%	Fx+/Fx+: 13.83%
		(Correct: 13.83%, level mistake: 17.17%)		
Total	44.17%	55.83%	100%	Total: 51.51%

<sup>a</sup>Fracture with a -/+ (MRI) means the correct diagnosis; fracture with a -/+ (X-P) means the examiners' answers

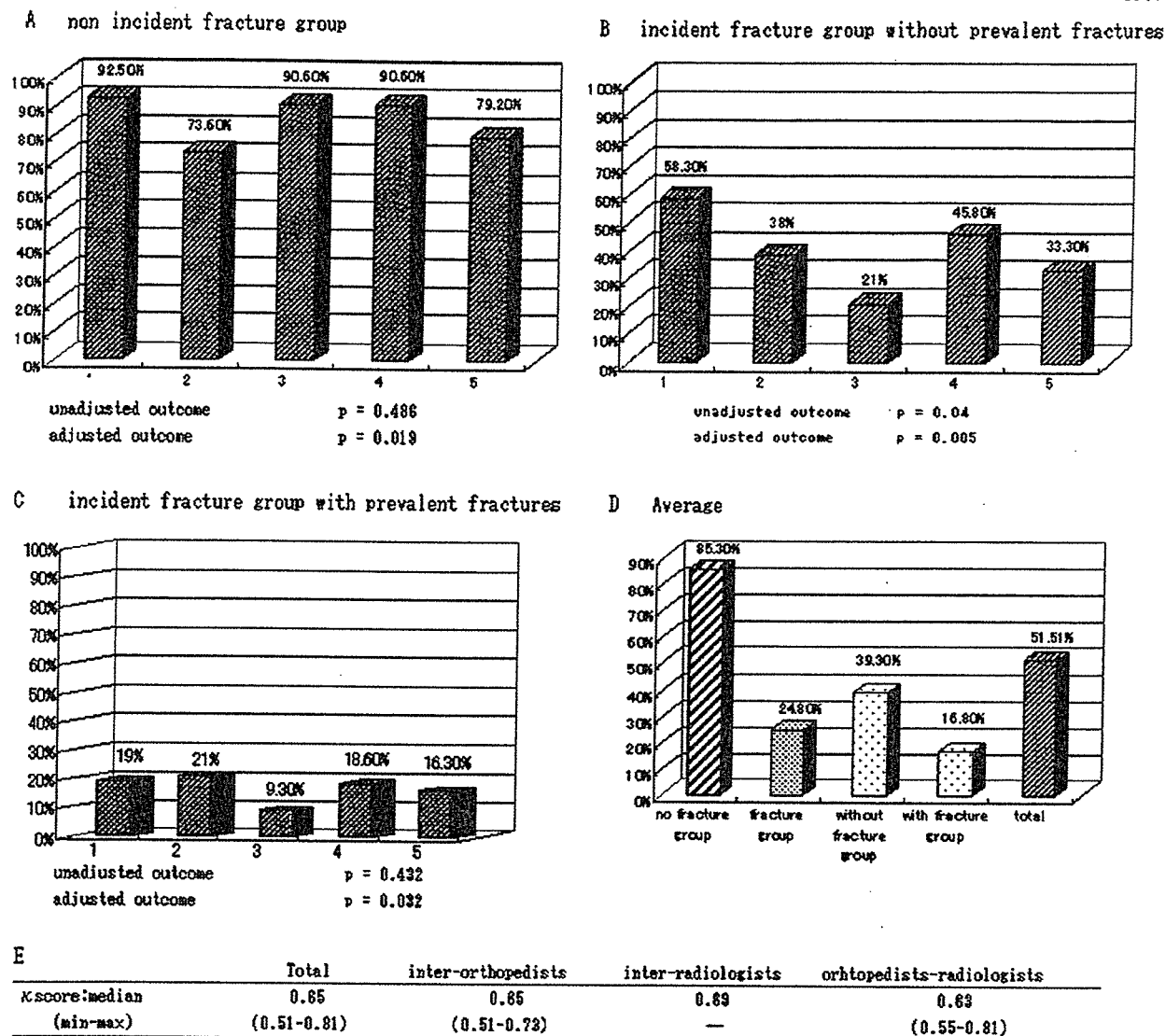


Fig. 1 Diagnosis rate by the five examiners. a Significant variation was seen in the non-incident fracture group after adjustment. b Significant variation was seen in the incident fracture group without prevalent fractures. c Significant variation was seen in

the incident fracture group with prevalent fractures after adjustment. d Average of diagnosis rate. e The kappa score of interexaminers. These results were moderate

The rate of correct diagnosis based on the number of prevalent fractures

The rate of correct diagnosis by morphological classification

The next variable investigated was the correct diagnosis rate by number of prevalent fractures in the incident fracture group with prevalent fractures. No correlation was found between the correct diagnosis rate and the number of complicating prevalent fractures when the subjects were divided into either six groups according to the number of prevalent fractures (one fracture to six or more fractures) or two groups (one fracture vs. two or more fractures) ( $p=0.139, 0.284$ , respectively; Fig. 2).

#### *The primary osteoporosis diagnostic criteria*

We then looked at the correct diagnosis rate for incident fractures by morphological classification of the vertebral body in the incident fracture groups with and without prevalent fractures. The morphological classifications used were the primary osteoporosis diagnostic criteria of Genant et al. [8] and Yoshida's classification [9] (Fig. 3). Using the primary osteoporosis diagnostic criteria of Genant, the correct diagnosis rate was high for wedge-type fractures in the combined results for the incident fracture groups with and without prevalent fractures (fracture group)

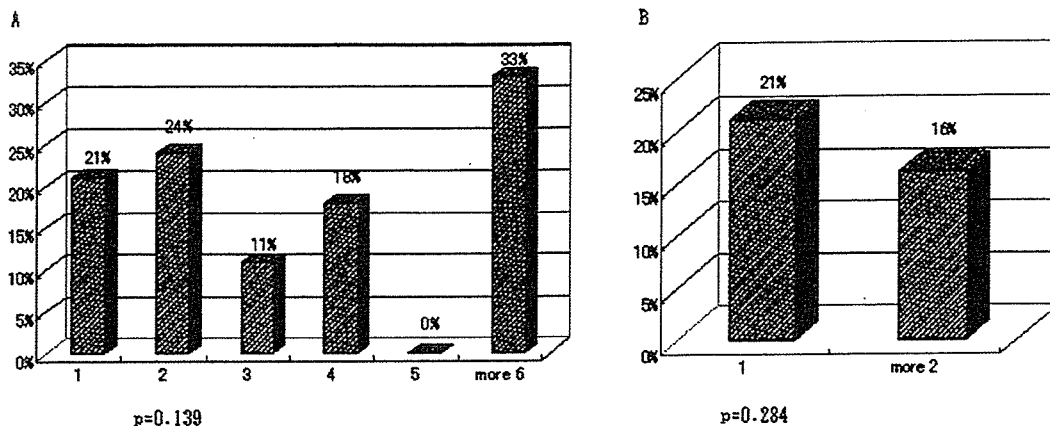


Fig. 2 No correlation was found between correct diagnosis rate and the number of complicating prevalent fractures. a Diagnosis rate when divided into one of six groups. b Diagnosis rate when divided into one of two groups

( $p<0.0001$ ). Similar results were obtained even after adjustment had been made for variation between the examiners. However, this significant difference disappeared after age, body weight, and lumbar BMD had been adjusted for. The same results were obtained in the incident fracture group with prevalent fractures, but in this case a significant difference was seen after correction in the incident fracture group without prevalent fractures ( $p=0.0455$ ) (Table 3).

*Yoshida's classification*

When Yoshida's classification was applied, the correct diagnosis rate was high for intended and protruding types of fractures ( $p<0.0001$ ). The correct diagnosis rate was significantly higher in the incident fracture group without prevalent fractures even when there were morphological changes (wedge, intended and protruding type) in the anterior bone cortex. Conversely, the correct diagnosis rate was low in the incident fracture group with prevalent fractures, end plate compression and slippage type fractures with no morphological changes in the anterior bone cortex, and in "miscellaneous" cases that belonged to no category and had almost no morphological change.

**The primary osteoporosis diagnostic criteria**

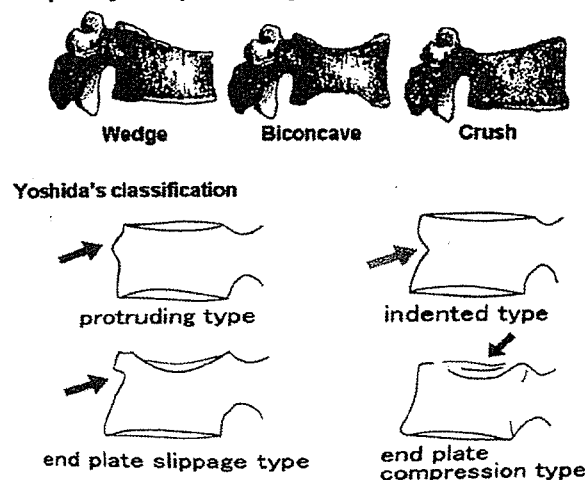


Fig. 3 The morphological classifications used were the primary osteoporosis diagnostic criteria of Genant [8] and Yoshida's [9] classification. Yoshida's criteria is for incident fractures and classified in four types as follows: protruding type, the anterior bone cortex disrupted protrudes anteriorly; indented type, the anterior bone cortex disrupted indents posteriorly; end plate slippage type, the anterior edge of the end plate disrupted displaces anteriorly; end plate compression type, the center of the end plate disrupted indents and depressed

Odds ratios affected the rate of correct diagnosis

Odds ratios (ORs) were investigated for factors that would affect the correct diagnosis rate, including age, body weight, lumbar vertebrae BMD, and examiner ability. In an overall investigation, age ( $OR=0.660$ ), body weight ( $OR=2.082$ ), and examiner ability ( $p=0.0205$ ) affected the correct diagnosis rate. A younger age and greater body weight resulted in higher correct diagnosis rates, and results were also affected by the examiner's ability. None of these factors had an effect in the non-incident fracture group. Significant variation is seen in examiner's ability in Fig. 1, but not to the extent that results were affected ( $p=0.0709$ ). In the fracture groups, both body weight ( $OR=2.206$ ) and examiner ability ( $p=0.0039$ ) affected the results. This was also seen in the incident fracture group without prevalent fractures alone, but in the incident fracture group with prevalent fractures alone only lumbar BMD had an effect ( $OR=1.574$ ) (Table 4).

**Discussion**

The prevalence rate of spinal fracture is thought to be 117 people per 100,000 in the population [10], and the lifetime

**Table 3** Diagnosis rate<sup>a</sup> according to the morphological classifications

Genant classification						
Fracture type	Numbers	Diagnosis rate – total fracture group	Numbers	Diagnosis rate – without prevalent fractures	Numbers	Diagnosis rate without prevalent fractures
Wedge	22	40.90%	6	63.30%	16	32.50%
Crush	9	26.70%	3	53.30%	6	13.30%
Biconcave	17	24.70%	4	40.00%	13	20.00%
Other	40	18%	12	30%	28	12.80%
a <sup>b</sup>	$p < 0.0001$		$p = 0.0011$		$p < 0.0011$	
b	$p < 0.0001$					
c	$p = 0.9123$		$p = 0.0455$		$p = 0.9516$	
Yoshida's classification						
Fracture type	Numbers	Diagnosis rate – total fracture group	Numbers	Diagnosis rate – without prevalent fractures	Numbers	Diagnosis rate without prevalent fractures
End plate slip-page	17	29.40%	7	45.71%	10	18.00%
Intended	8	46.70%	2	90.00%	6	40.00%
protruding	9	60%	4	80.00%	5	44.00%
End plate compression	6	10%	2	10%	4	10.00%
Other	48	16.20%	10	22.91%	38	14.21%
a <sup>b</sup>	$p < 0.0001$		$p = 0.0016$		$p = 0.0173$	
b	$p < 0.0001$					
c	$p = 0.4708$		$p = 0.0455$		$p = 0.6953$	

<sup>a</sup>The correct diagnosis rate was higher in the incident fracture group without prevalent fractures even when there were morphological changes in the anterior bone cortex. In seven cases, we were unable to classify the morphology because of indistinctness

<sup>b</sup>a, Unadjusted  $p$  value; b,  $p$  value adjusted with examiners; c  $p$  value adjusted with age, weight, BMD and examiners

risk of spinal fracture in women over the age of 50 rises to about 40% [11]. Vertebral body fractures result in pain and functional restrictions, and provoke a marked decrease in quality of life [12, 13]. Therefore, early prevention of spinal fractures and accurate diagnosis and treatment are crucial. There are various reports on the diagnosis of incident spinal fracture [14], but a diagnostic gold standard has yet to be established. Nearly all institutions first take X-P images for patients presenting with lumbar pain. However, it is difficult to determine from X-P images the presence and location of incident fragility fractures in elderly patients with osteoporosis at the time of injury; it is even more difficult when the patient has prevalent fractures. Furthermore, incident fractures are defined as those vertebral bodies that show distinct morphologic changes or osteosclerosis change on the follow-up X-P

images. Consequently, we usually cannot detect incident fractures at the early stage of diagnosis.

With respect to the effectiveness of X-Ps for lumbar pain disease in general, David et al. reported that 17.8% of patients in an emergency department received unnecessary lumbar X-Ps [15], while Khoo et al. reported that 90.5% of AP views on X-Ps have no benefit and were effective only in assessing the sacroiliac joint [16]. Thus, establishing a diagnosis for lumbar pain is difficult with X-P alone, and most cases require MRI. Many reports attest to the high diagnostic accuracy of MRI, and it continues to be more useful tool in diagnosing spinal fracture [4–6]. In MRI images, fractures are defined so that an acute fracture associated with hemorrhage and edema increases the focal water content and thus increases the signal on T2-images. With an osteoporotic fracture, the hemorrhage will be organized and the edema will decrease, giving a low to

**Table 4** Odds ratios of factors that would affect the correct diagnosis rate

Factors	Total		Non-incident fracture group		Total fracture group		Without prevalent fractures		With prevalent fractures	
	Odds ratio	$p$ value	Odds ratio	$p$ value	Odds ratio	$p$ value	Odds ratio	$p$ value	Odds ratio	$p$ value
Age	0.66	<0.001	0.781	0.2817	1.053	0.7098	1.02	0.9291	1.254	0.1966
Body weight	2.082	<0.001	0.661	0.0876	2.206	<0.001	3.002	<0.0001	1.42	0.1303
Lumbar BMD	1.246	0.072	1.108	0.676	1.043	0.7873	0.65	0.0584	1.574	0.0478
Ability of the examiner	-	0.0205	-	0.0709	-	0.0039	-	0.0349	-	0.1163

Results were affected by examiner ability, age and body weight

intermediate signal intensity on T2-weighted images. It has already been reported that femoral neck fractures cannot be judged on X-P images and that MRI diagnosis is useful in cases of occult fracture. Pandey et al. reported that fractures are not discovered on X-P images and that even on MRI images, 30% show no fracture [17], while Rizzo et al. reported that occult fractures were detected on MRI in 36 of 62 patients (58%) [18].

With respect to spinal disease as well, Nakano et al. investigated the diagnostic accuracy of MRI for incident vertebral fractures. They took vertebral bodies showing signs of crush and bone sclerosis on follow-up X-P images to indicate true incident fractures and reported that the diagnostic sensitivity and specificity of MRI were 99.0% and 98.7%, respectively [19, 20]. They also reported that based on diagnosis with MRI it was possible to diagnose with precision a fracture in the early period of onset. In addition, Kanchiku et al. reported that the diagnostic rate of the fractured vertebral body was 98% by MRI, which was higher than the 87% for plain radiography ( $p=0.006$ ); in patients for whom no posterior wall injury was seen on X-P imaging at the time of the injury, intraspinal protrusion of the posterior wall of the vertebral body was diagnosed in 37% using MRI [21]. Eugene et al. reported that twice as many spinal diseases were detected when using MRI as when diagnosis was made from X-P imaging [2]. Thus, MRI is considered to be reliable in the diagnosis of incident fragility fracture. However, this high diagnostic accuracy also gives rise to some problems. Rupp et al. reported that in distinguishing between tumor and compression fracture on MRI images, compression fracture can only be diagnosed in those patients that have completely maintained normal marrow within the vertebrae and that it is difficult to make a distinction, due to changes in contrast effect and intensity, over multiple vertebrae or invasion to the posterior vertebral body wall [22]. In addition, Cuenod et al. reported that at 2 months after a spinal fracture is sustained, changes in brightness on MRI images have completely returned to normal in only 13% of the cases [23], indicating the possibility that old fractures can be mistaken for incident fractures. Equipment limitations at some institutions and economic problems make it impossible to conduct MRI with all patients. Jefferey et al. compared MRI in the acute phase of lumbar pain with X-P over the clinical course and concluded that no cost benefit was achieved [24]. Thus, several problems are also encountered with the use of MRI in diagnosis.

Based on all of the points raised above, we re-examined X-P diagnosis and investigated whether the correct diagnosis rate with X-P in the initial examination could be improved. To our knowledge, this type of comparison has not been carried out to date, however, a search of the literature has revealed that various data sets are available on diagnosis rates for incident fractures with X-P. In a comparison of local and central readings, Pierre et al. reported a correct diagnosis rate of 95% in the non-fracture group and 66% in the fracture group [25]. Hachiya et al. reported a correct diagnosis rate of 43%, false positives in 41% of the cases, and false negatives in 16% [26]. Nakano

et al. reported a correct diagnosis rate of 51.5% [27], while Kanchiku et al. reported a high correct diagnosis rate of 87% [21]. However, factors such as unspecified measurement conditions, a small number of examiners, or non-uniform skill levels of examiners in these studies make them inadequate for the establishment of a correct diagnosis rate.

In the present study, a strict diagnosis was made together with radiologists, the ability of five orthopedists to interpret X-Ps was determined in advance to be uniform, and three groups were compared. The results of this analysis showed the correct diagnosis rate to be 51.5%, which did not differ greatly from the reports of previous investigators. However, the mean correct diagnosis rate for incident vertebral fracture group was 24.8%, and it was even lower – 16.8% – in the group with prevalent fractures. The correct diagnosis rate decreased in order of non-incident fracture group (highest), the incident fracture group without prevalent fractures, and the incident fracture group with prevalent fractures (lowest), a result which demonstrates anew the difficulty of diagnosing the location of fractures in the daily clinical setting. Moreover, after correcting for various factors, we found that there was a significant inter-examiner variation in all groups. This seems to indicate that the ability of an examiner to interpret radiographs is reflected in the correct diagnosis rate. In an examination based on the number of prevalent fractures, the correct diagnosis rate did not drop as the number of prevalent fractures increased, and no correlation was found. This finding that the number of prevalent fractures does not exert an effect is intriguing. Thus, even with prevalent fractures over multiple vertebrae, it is assumed that with diligence, incident fractures can be detected.

The previously mentioned criteria of Genant et al. were used in the analysis by morphological classification [8]. These criteria are commonly used in the diagnosis of osteoporotic vertebral body fractures. However, 45.5% of the cases in our study did not fit any type in these classifications, bringing some doubt to the judgments that have been made to date. We therefore conducted the investigation using these criteria in conjunction with Yoshida's classifications [9]. A high correct diagnosis rate was obtained for wedge type fractures with the diagnostic criteria for primary osteoporosis, and for protruding and indented type fractures with Yoshida's criteria; however, the correct diagnosis rate was low with the remaining types of fractures. Thus, a key to raising the correct diagnosis rate for incident fragility fractures may be to focus sufficient attention on morphological changes in the anterior bone cortex when diagnosing from X-P images.

In this investigation of factors influencing the correct diagnosis rate of osteoporotic vertebral body fractures, we found age, body weight, and examiner ability had an overall effect. The negative correlation seen with age, in which the correct diagnosis rate decreased as age increased, and the decrease in the correct diagnosis rate with lower body weight are understandable, but the finding that BMD did not exert an effect was intriguing. Moreover, the



finding that the ability of the examiner to interpret radiographs was reflected in the correct diagnosis rate indicates the importance of continuing efforts to improve ability.

Several points remain for future study, including the facts that the present study was a retrospective study and that the diagnosis was made without questioning the patients or pathological findings. Based on the results presented here, an investigation of how repeat readings will change the correct diagnosis rate should also be made. In any case, the finding that the correct diagnosis rate was low, even when made by orthopedists experienced in reading radiographs, is a finding that should be taken into consideration in the normal diagnosis of incident spinal fragility fractures with X-Ps only, and may be important in identifying keys for the development of new diagnostic criteria and more accurate diagnoses. The present study indicates the importance of not only improving the ability of examiners to interpret radiographs but also of the attention that should be paid to morphological changes in the anterior bone cortex during examinations.

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## References

- Majumdar SR, Kim N, Colman L, Chahal AM, Raymond G, Jen H, Siminoski KG, Hanley DA, Rowe BH (2005) Incidental vertebral fractures discovered with chest radiography in the emergency department: prevalence, recognition, and osteoporosis management in a cohort of elderly patients. *Arch Intern Med* 165:905-909
- Gibson ES, Martin RII, Terry CW (1980) Incidence of low back pain and pre-placement x-ray screening. *J Occup Med* 22:515-519
- Simmons ED, Guyer RD, Graham-Smith A, Herzog R (2003) Radiograph assessment for patients with low back pain. *Spine J* 3:3S-5S
- Rankine JJ, Gill KP, Hutchinson CE, Ross ER, Williamson JB (1998) The therapeutic impact of lumbar spine MRI on patients with low back and leg pain. *Clin Radiol* 53:688-693
- McNally EG, Wilson DJ, Ostlere SJ (2001) Limited magnetic resonance imaging in low back pain instead of plain radiographs: experience with first 1000 cases. *Clin Radiol* 56: 922-925
- Shih TT, Tsuang YH, Huang KM, Chen PQ, Su CT (1996) Magnetic resonance imaging of vertebral compression fractures. *J Formos Med Assoc* 95:313-319
- Nathan H (1962) Osteophytes of the vertebral column. An anatomical study of their development according to age, race, and sex with consideration as to their etiology and significance. *J Bone Joint Surg* 44-A:243-268
- Genant HK, Wu CY, van Kuijk C, Nevitt MC (1993) Vertebral fracture assessment using a semiquantitative technique. *J Bone Miner Res* 8:1137-1148
- Yoshida T, Nanba H, Mimatsu K, Kasai T (2000) Treatment of osteoporotic spinal compression fractures. Conservative therapy and its limitation (in Japanese). *Clin Calcium* 10:53-58
- Cooper C, Atkinson EJ, O'Fallon WM, Melton LJ 3rd (1992) Incidence of clinically diagnosed vertebral fractures: a population-based study in Rochester, Minnesota, 1985-1989. *J Bone Miner Res* 7:221-227
- Fujiwara S (2004) Degeneration of lumbar spine and QOL (in Japanese). *Ther Osteoporos* 3:32-37
- Nevitt MC, Ettinger B, Black DM, Stone K, Jamal SA, Ensrud K, Segal M, Genant HK, Cummings SR (1998) The association of radiographically detected vertebral fractures with back pain and function: a prospective study. *Ann Intern Med* 128:793-800
- O'Neill TW, Cockerill W, Matthis C, Raspe HH, Lunt M, Cooper C, Banzer D, Cannata JB, Naves M, Felsch B, Felsenberg D, Janott J, Johnell O, Kanis JA, Kragl G, Lopes Vaz A, Lyritis G, Masaryk P, Poor G, Reid DM, Reisinger W, Scheidt-Nave C, Stepan JJ, Todd CJ, Woolf AD, Reeve J, Silman AJ (2004) Back pain, disability, and radiographic vertebral fracture in European women: a prospective study. *Osteoporos Int* 15:760-765
- Ross PD, Davis JW, Epstein RS, Wasnich RD (1992) Ability of vertebral dimensions from a single radiograph to identify fractures. *Calcif Tissue Int* 51:95-99
- Isaacs DM, Marinac J, Sun C (2004) Radiograph use in low back pain: a United States Emergency Department database analysis. *J Emerg Med* 26:37-45
- Khoo LA, Heron C, Patel U, Given-Wilson R, Grundy A, Khaw KT, Dundas D (2003) The diagnostic contribution of the frontal lumbar spine radiograph in community referred low back pain-a prospective study of 1030 patients. *Clin Radiol* 58:606-609
- Pandey R, McNally E, Ali A, Bulstrode C (1998) The role of MRI in the diagnosis of occult hip fractures. *Injury* 29:61-63
- Rizzo PF, Gould ES, Lyden JP, Asnis SE (1993) Diagnosis of occult fractures about the hip. Magnetic resonance imaging compared with bone-scanning. *J Bone Joint Surg Am* 75: 395-401
- Nakano T, Inaba D, Takada K, Tsurugami H (2003) Rate of correct diagnosis for vertebral fracture by MRI and natural history (in Japanese). *Osteoporos Jpn* 11:25-28
- Nakano T, Ochi R, Miyazono K, Inaba D, Tsurugami H (2004) Diagnosis precision of MRI for fresh osteoporotic vertebral body fracture and a diagnosis by follow-up roentgenogram (in Japanese). *Osteoporos Jpn* 12:89-90
- Kanchiku T, Taguchi T, Kawai S (2003) Magnetic resonance imaging diagnosis and new classification of the osteoporotic vertebral fracture. *J Orthop Sci* 8:463-466
- Rupp RE, Ebraheim NA, Coombs RJ (1995) Magnetic resonance imaging differentiation of compression spine fractures or vertebral lesions caused by osteoporosis or tumor. *Spine* 20:2499-2503
- Cuenod CA, Laredo JD, Chevret S, Hamze B, Naouri JF, Chapaux X, Bondeville JM, Tubiana JM (1996) Acute vertebral collapse due to osteoporosis or malignancy: appearance on unenhanced and gadolinium-enhanced MR images. *Radiology* 199:541-549
- Jarvik JG, Hollingworth W, Martin B, Emerson SS, Gray DT, Overman S, Robinson D, Staiger T, Wessbecher F, Sullivan SD, Kreuter W, Deyo RA (2003) Rapid magnetic resonance imaging vs radiographs for patients with low back pain: a randomized controlled trial. *JAMA* 289:2810-2818
- Delmas PD, van de Langerijt L, Watts NB, Eastell R, Genant H, Grauer A, Cahall DL; IMPACT Study Group (2005) Underdiagnosis of vertebral fractures is a worldwide problem: the IMPACT study. *J Bone Miner Res* 20:557-563
- Hachiya Y (1994) MRI of compression and osteoporotic fracture (in Japanese). *MB Orthop* 7:173-185
- Nakano T, Abe Y, Shimizu Y, Ochi R, Seike I, Iwamoto K, Fujiwara K, Takagi K (1999) Rate of correct diagnosis for vertebral fracture by plain roentgenograms (in Japanese). *Fracture* 21:586-588

ORIGINAL ARTICLE

# Percutaneous vertebroplasty for elderly patients with unhealed osteoporotic spinal fractures

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**Background:** Vertebroplasty is a procedure in which bone cement is injected percutaneously into the vertebral body.

**Methods:** We used this technique with 15 patients who had pseudarthrosis or delayed union of osteoporotic spinal fractures with vacuum clefts, and in whom conservative treatment did not relieve persistent pain. The procedure was performed in a short time with little blood loss, and no generic complications, leakage of bone cement to blood vessels or the spinal canal, or neural compression.

**Results:** At 1 week after the operation, pain was eliminated in seven patients, alleviated in seven patients, unchanged in one patient, and worsened in none. The rate of alleviation or elimination of pain after 1 week and 6 months was 93% and 85%, respectively. Recurrence of the pain was seen in four cases, but this was caused by new spinal fractures in separate locations, confirmed with magnetic resonance imaging, in three patients, and by multiple myeloma in one patient.

**Conclusion:** Thus, vertebroplasty, which alleviates pain rapidly and with low invasiveness, is a new and promising therapy for osteoporotic spinal fractures in which conservative treatment has failed. It seems to provide a large benefit to elderly patients if performed with prudent care with regard to complications at the time of bone cement injection, and in conjunction with treatment for osteoporosis.

**Keywords:** osteoporosis, pain, spinal fracture, vacuum cleft, vertebroplasty.

## Introduction

Many elderly people with osteoporosis suffer from spinal fracture, and are troubled by pain and disability. Seventy-three percent of osteoporotic spinal fractures are morphometrical fractures, with the remainder

considered to be clinical fractures.<sup>1</sup> With morphometrical fractures there is no traumatic disruption of bone and symptoms tend to slight, such as decreased height. Treatment of the fracture itself is therefore unnecessary for most morphometrical fracture patients. With clinical fractures, however, symptoms tend to be severe, including strong back pain and high level of disability due to traumatic disruption of bone with intraosseous bleeding. Therefore, most patients require some type of conservative orthopedic treatment for more than 4 weeks. Afterwards, symptoms gradually improve, and patients can return to their normal daily lives by 12 weeks. Bone union is also obtained over the course of several months.<sup>2</sup>

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However, if conservative treatment fails to result in adequate bone union, the spinal fracture progresses to pseudarthrosis with persistent pain.<sup>3,4</sup> This is one of the worst clinical courses for an osteoporotic spinal fracture. Until recently, the treatment for delayed union or pseudarthrosis of osteoporotic spinal fracture was either surgery, which is highly invasive, or no intervention if it was judged that the patient's health condition was too poor to withstand surgery. As a result, there are many elderly patients with osteoporotic spinal fractures who have had chronic pain and decreased activities of daily living (ADL) over a long term. Development of more appropriate therapy for such patients has been eagerly awaited.

Vertebroplasty is a procedure that was begun in France,<sup>5,6</sup> in which bone adhesion and fixing is obtained in a short time by percutaneous injection of bone cement (polymethylmethacrylate [PMMA]) into the fractured vertebral body through the pedicles under monitoring by X-ray fluoroscopy. This procedure may be of great benefit for these elderly patients.<sup>5,6</sup> It can be used even with frail elderly patients because of the low level of invasion. However, the outcome with this method has not yet been sufficiently investigated in Japan.

We performed vertebroplasty using PMMA for patients with pseudarthrosis or delayed union of osteoporotic spinal fractures, and in the present study examined the effectiveness and safety of this method.

## Methods

### *Subjects*

Selection criteria for vertebroplasty, regardless of sex or age, were that the patient have pseudarthrosis or delayed union of an osteoporotic spinal fracture with a vacuum cleft,<sup>3</sup> persistent pain that was resistive to conservative treatment, and reduced ADL.

### *Vertebroplasty procedure*

PMMA (Stryker, Limerick, Ireland) was used as the bone cement. Patients were given local or epidural anesthesia in an operating room. The first step after the anesthesia was a reduction maneuver by Bohler's method; high pads were placed under precordia and pelvic region of the patient in the prone position, and fracture reduction was achieved with the patient's own weight. Under close monitoring by X-ray fluoroscopy, 11-G or 13-G bone marrow biopsy needles (Accura Biopsy Systems, Gainesville, FL, USA) were inserted percutaneously to within the vacuum cleft of the vertebral body through the pedicles on both sides. After aspirating the fluid within the cleft, it was lavaged while confirming that the physiological saline injected from one side flowed easily to the

biopsy needle on the other side. Next, contrast medium was injected under fluoroscopic guidance, and it was confirmed that there was no leakage outside the vertebral body or into the blood vessels. If this could not be confirmed, the procedure was stopped at that point. If there was no leakage, bone cement polymerization was started and when it reached a certain hardness the bone cement was injected through the biopsy needle on one side until the vertebral body vacuum cleft was filled. If it was insufficiently filled, additional cement was injected from the opposite side. During this procedure, several doctors carefully and frequently checked for bone cement leakage outside the vertebra or into the blood vessels, and blood pressure fluctuations were regulated. After the bone cement had completely hardened, the patient was allowed to change body positions, and to walk starting on the same day.

### *Background data*

We assessed the physical condition and osteoporosis status of patients at baseline. Bone mineral density in the lumbar spine and femoral neck were measured using dual energy X-ray absorptiometry (DPX; Lunar, Madison, WI, USA). Roentgenograms of the thoracic and lumbar spine were also evaluated to identify prevalent spinal fractures.

### *Outcomes*

Major assessment items were the effect on pain, evaluated on four levels of eliminated, alleviated, no change, and worsened at 1 week, 6 months, and 12 months after the procedure, and the recurrence of pain. We evaluated invasiveness in terms of operation time, blood loss and amount of bone cement injected, as well as complications related to the injection of bone cement in addition to general postoperative complications.

### *Ethical considerations*

A protocol detailing the above procedure was approved by the ethics committee of our hospital, and written informed consent was obtained from all patients.

## Results

Between January 2001 and November 2004 there were 17 patients who met the selection criteria and consented to vertebroplasty. One patient withdrew his consent, so that the procedure was conducted with 16 patients. They included two males and 14 females with ages ranging 60–88 years and a mean age of 76.7 years. Mean bodyweight and height were 46.8 kg (range 32–58 kg) and 148 cm (range 133–165 cm), respectively. Mean bone mineral density in the lumbar spine and femoral

**Table 1** Patient characteristics before vertebroplasty

No.	Age	Sex	Body weight (kg)	Height (cm)	Lumbar spine BMD (g/cm <sup>2</sup> )	Femoral neck BMD (g/cm <sup>2</sup> )	Number of prevalent spinal fractures including surgical site	Treatment for osteoporosis
1	60	Male	58	165	0.612	0.589	1	Alendronate
2	66	Female	53	160	1.114	0.809	3	None
3	70	Female	48	140	0.837	0.64	1	None
4	74	Female	53	160	0.855	0.727	2	None
5	74	Female	44	146	1.056	0.767	3	None
6	75	Female	45	146	0.958	0.708	3	Vitamin D <sub>3</sub>
7	76	Female	53	147	0.875	Not examined	2	Vitamin D <sub>3</sub>
8	78	Female	54	145	Not examined	Not examined	3	None
9	79	Female	43	133	0.739	0.531	4	None
10	80	Female	53	158	1.014	Not examined	3	None
11	80	Female	32	135	0.862	0.563	1	None
12	82	Female	45	150	0.766	0.471	3	Vitamin D <sub>3</sub>
13	84	Female	37	147	0.649	0.373	3	Alendronate
14	85	Female	41	140	0.695	Not examined	3	Vitamin D <sub>3</sub> + etidronate
15	88	Male	43	148	Not examined	Not examined	3	None

BMD, bone mineral density; Vitamin D<sub>3</sub>, alfa-Calcidol.

**Table 2** Operative data

No.	Surgical site	Operation time (min)	Volume of bone cement injected (mL)	Blood loss (mL)	Anesthesia	Complications
1	T12	31	2	10	Epidural	None
2	T12	103	8	10	Epidural	None
3	T12	98	1.5	10	Local	None
4	L1	45	8	Negligible	Epidural	None
5	L1	60	6	Negligible	Epidural	None
6	T12	20	4	10	Epidural	None
7	L2	121	4	10	Epidural + Local	None
8	T12	24	8	10	Epidural	None
9	T11 & T12	36	Unclear	Negligible	General	None
10	L1	69	1.5	30	Epidural + Local	None
11	L2	22	Unclear	Negligible	Epidural	None
12	T12	67	5	Negligible	Epidural	None
13	T12	97	1	10	Local	None
14	L2	135	3.3	30	Local	None
15	T12 & L1	65	2.8□A 6	10	Epidural	None

L1, first lumbar vertebra; L2, second lumbar vertebra; T11, 11th thoracic vertebra; T12, 12th thoracic vertebra.

neck was 0.849 g/cm<sup>2</sup>, or 75.4% of young adult mean, and 0.618 g/cm<sup>2</sup>, or 68.3% of young adult mean, respectively. Six patients had already received alendronate, etidronate, or vitamin D<sub>3</sub> for their osteoporosis before the vertebroplasty, and continued the same medication thereafter (Table 1). The main complaint was long-term persistent pain in all patients, with only one who had complications with neural symptoms of the

legs. The mean number of prevalent spinal fractures including the surgical site was 2.5, ranging 1–4 (Table 1). Fourteen patients had a painful fracture in a single vertebra, and two patients in two vertebrae. The affected painful region was two 11th thoracic vertebrae, nine 12th thoracic vertebrae, four first lumbar vertebrae, and three second lumbar vertebrae; thus, the fractures were concentrated in the thoracolumbar spine (Table 2).

The vacuum cleft of the vertebral body fractures seen in all patients was opened with a reduction maneuver by Bohler's method and showed abnormal movement. Pseudarthrosis or delayed union was thus confirmed in these patients.

The anesthesia was epidural anesthesia in three patients, local anesthesia in two patients, and general anesthesia in one patient. The blood pressure of one patient who was thin and had strong kyphosis dropped at the point when the needle was inserted into the vertebral body under epidural anesthesia. In this case, the procedure was discontinued and the blood pressure recovered rapidly with just a change of body position. There was no vascular damage, and the cause was thought to be painful shock from the distress of Bohler's position. Vertebroplasty was not attempted again in this patient, so the final number of patients that underwent the procedure was 15 (Table 2). The biopsy needles used were 13-G in the initial period, with a switch later to 11-G needles.

### *Invasiveness*

The operation time ranged 20–135 min, with a mean of 66.2 min. The mean time per vertebra was 58.4 min, but with experience the time was clearly shortened. The mean time per vertebra for the most recent seven patients was 30.6 min. With patients three and 14, an intraoperative navigation system was tried, and manipulation of this system required extra time. Blood loss ranged from negligible to 30 mL, with a mean of 9.3 mL, and the amount of bone cement injected was from 1 mL to 8 mL, with a mean of 4.4 mL (Table 2).

### *Complications*

There was no impairment to circulation, respiration or consciousness during or after injection of bone cement, nor any leakage of cement into blood vessels or the spinal canal, or neural compression. There were also no wound infections. Postoperative computed tomography (CT) scans were examined closely for leakage of bone cement, but there were no leaks into the spinal canal and no clear leaks toward the lateral or anterior portions of the vertebral bodies. In one patient, however, who received injection of 8 mL of bone cement, there was a slight anterior swelling of bone cement in the vertebral body. The only other adverse event was the drop in blood pressure described above, but that patient did not reach the stage of injection of bone cement (Table 2).

### *Effect on pain*

Vertebroplasty was performed for 15 patients, who were then followed postoperatively for periods ranging 2–

29 months (mean follow-up period: 11.6 months). Improvements in pain from the preoperative state were seen in 93% of patients, including elimination of pain in seven patients, alleviation in seven, no change in one, and worsening in none. The one patient with no change had severe cognitive disorder, and the lack of a better result is thought to have been caused by insufficient injection of bone cement, because we could not obtain sufficient cooperation from the patient under epidural anesthesia. Of the 13 patients who could be evaluated 6 months after the operation, pain was eliminated in eight patients, alleviated in three and unchanged in two. Six patients were followed for 12 months, and among them pain was eliminated in four and alleviated in two. Recurrence of pain that had been alleviated after this procedure was seen in four patients. In three of them the cause was thought to be a new spinal fracture in a separate location, confirmed by magnetic resonance imaging, and in the other to be a complication of multiple myeloma (Table 3). The occurrence of new spinal fractures was not related to bone mineral density, the number of prevalent spinal fractures, or whether osteoporosis was treated or not.

### *Case 10*

This patient was an 80-year-old woman with a main complaint of low back pain. The patient had a history of severe liver cirrhosis and mild cognitive impairment. After a fall in March 2003, the patient was treated at another hospital for intense low back pain, but was referred to our hospital and hospitalized in June of the same year. A vacuum cleft was found in the first lumbar vertebra with radiography. After hospitalization, the patient was treated for a further 2 months with a corset and bed rest, but the intense pain continued with the patient requiring assistance even to change positions in bed. Therefore, vertebroplasty was performed for the purpose of alleviating the pain. Bone cement was injected into the vacuum cleft in the first lumbar vertebra, and immediately afterward the low back pain disappeared. The following day the patient could move to a sitting position without assistance, and at 20 months there was still no recurrence (Fig. 1). Bone mineral density of the lumbar spine was 1.014 g/cm<sup>2</sup>. This is 91% of the young adult mean, and so with consideration also of the severe liver cirrhosis, no osteoporosis treatment was given.

### **Discussion**

Vertebroplasty using bone cement was begun in France in the late 1980s to treat osteoporotic spinal fractures and malignant neoplasms.<sup>7</sup> Results with this procedure were gradually reported, but it did not spread rapidly. It began to be used in the USA in 1994 and it has only

**Table 3** Effect of vertebroplasty on pain

No	Follow-up duration (months)	1 week	6 months	12 months	Time of pain recurrence	Cause of pain recurrence
1	16	Elimination	Elimination	ND	None	–
2	6	Alleviation	Alleviation	ND	None	–
3	12	Elimination	Elimination	Elimination	None	–
4	2	Elimination	ND	ND	None	–
5	23	Alleviation	Alleviation	Alleviation	After 13 months	New spinal fracture
6	6	Alleviation	Pain recurrence	ND	After 2 months	New spinal fracture
7	29	Elimination	Elimination	Elimination	None	–
8	9	Alleviation	Elimination	ND	None	–
9	8	Elimination	Elimination	ND	None	–
10	20	Elimination	Elimination	Elimination	None	–
11	7	Alleviation	Elimination	ND	None	–
12	12	Alleviation	Alleviation	Alleviation	None	–
13	24	Elimination	Elimination	Elimination	After 20 months	New spinal fracture
14	4	Alleviation	Pain recurrence	ND	After 4 months	Multiple myeloma
15	2	No change	ND	ND	None	–

ND, no data.

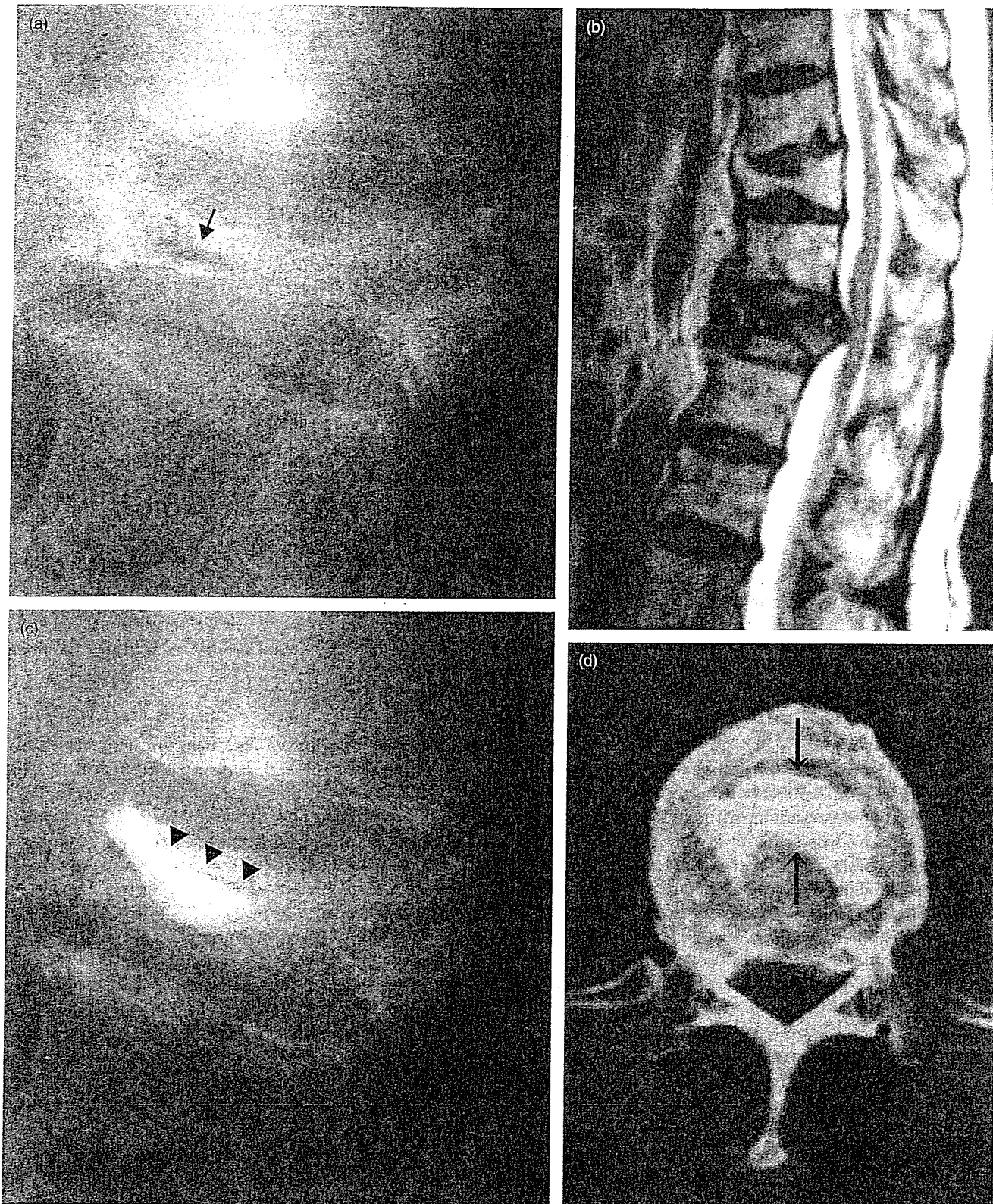
been recently that occasional reports have been seen in Japan.<sup>8</sup>

The biggest advantage of this technique is the speed with which pain alleviation can be obtained. Among reports of vertebroplasty using bone cement with 10 or more patients, those that give the pain alleviation rate soon after the procedure report that 60–97% of patients had less pain within 24 h.<sup>9–13</sup> This is a time in which there are still effects from the anesthesia and the wound itself, but we have also experienced cases in which the strong pain induced by movements that place a large load on the spine, such as changing position in bed or standing up, have disappeared soon after this procedure. It is conjectured that there is rapid alleviation of pain from the point when the bone cement that fills the pseudarthrotic area hardens completely, which is after approximately 10 min. In the end, more than 90% of patients attain pain relief in nearly all reports.<sup>6,9,10,12,14,15</sup> The patients in the present study had had intense pain continuing in some cases for more than a year, but 93% obtained relief of either pain alleviation or elimination at 1 week postoperatively. This is a good result in which the level of relief was no less than that reported by others. According to one long-term follow-up study,<sup>16</sup> the pain relief effect was significantly maintained for a mean time of as long as 35 months, indicating that the effect with this technique is not temporary but is stable over a long period.

Another advantage of vertebroplasty is its low invasiveness. This technique can be performed in a short period with very little blood loss. No matter how superior a technique may be in relieving pain, if it is highly

invasive it will not be suitable for a good number of elderly people. Especially in frail elderly people in the final stages of life who tend to put off invasive treatments, this method has an acceptable level of invasiveness and is therefore of great benefit.

While this method has major advantages, it also carries risk of major complications, although their occurrence is rare. As vertebroplasty is used increasingly around the world, there are a gradually increasing number of reports of serious complications. The complication requiring the greatest vigilance, as it is potentially fatal, is bone cement leaking into blood vessels. One case was reported in which this caused a pulmonary embolism during the operation and the patient died.<sup>17</sup> Another study reported findings of pulmonary embolisms in 4.6% of patients on chest X-rays, even though the patients were asymptomatic.<sup>18</sup> Fortunately, no pulmonary embolisms occurred in our patients, including those who were asymptomatic, and there were none of the other complications that need to be watched for, such as leakage of bone cement from the fracture area, damage to large surrounding blood vessels, and neural compression. There was also no inhibition of circulation, such as known drops in blood pressure. However, while remaining alert to the possibility that these could happen at any time and monitoring for leakage of contrast medium into veins or the spinal canal, precautions were taken by estimating the amount of cement needed for injection, leaving one of the two biopsy needles inserted through the pedicles open and injecting the bone cement from the other, and not raising the internal pressure excessively.



**Figure 1** Case 10. (a) Preoperative lateral view of the first lumbar vertebral body. Arrow shows vacuum cleft which reduced in neutral position. (b) Preoperative magnetic resonance image. T2 weighted image shows the unhealed burst fracture of the first lumbar vertebral body and the healed fracture of the 11th thoracic vertebral body. (c) Postoperative lateral view of the first lumbar vertebral body. Arrowheads show the bone cement injected into the vacuum cleft which spread in intraoperative extended position. (d) Postoperative computed tomography of the first lumbar vertebral body. Arrows show the bone cement injected.

Vertebroplasty is also limited in that it is a local treatment. Because it cannot prevent the occurrence of new osteoporotic fractures, it is sometimes taken by patients to be a failed treatment if pain recurs. After pain had been alleviated or eliminated with vertebroplasty, pain from a new spinal fracture in a different location was seen in three (or 20%) of our patients. This was not a problem of the vertebra that underwent vertebroplasty in any of these three cases. Reported rates of new spinal fractures in a different location following vertebroplasty are 22.6%<sup>19</sup> and 21.7%<sup>20</sup> within 1 year, which is similar to the frequency among our patients. This frequency is no different from the rate of new spinal fractures over one year in osteoporosis patients, which was reported by Lindsay *et al.*<sup>1</sup> to be 19.2% in people with an existing fracture in a single vertebra, and 24% in people with existing fractures in two or more vertebrae. Thus, it seems that new spinal fractures are not induced by vertebroplasty, but occur in the natural course of the underlying disease of osteoporosis itself. Therefore, with patients who undergo this procedure it is very important to provide concurrent osteoporosis treatment in order to reduce the risk of new spinal fracture, although the medication for osteoporosis could not inhibit the occurrence of fractures in our patients.

Problems with the present study are that pain was the only item used to assess the treatment effect and that the assessment was not done using a method with a high level of reliability, such as a visual analog scale (VAS). The goal of medical care for the elderly is survival accompanied by a high quality of life (QOL), and assessment should not be limited to pain but consider overall QOL. Because the present study included patients who also had cognitive impairments, it would have been difficult or impossible to conduct an assessment by QOL or VAS in a considerable number of patients. Only seven patients could be followed for more than a year, so this study is also limited in that overall it reports only short-term results.

## Conclusion

We selected elderly patients with pseudarthrosis or delayed union, who are those with the worst outcome among osteoporotic spinal fracture patients, and conducted vertebroplasty using bone cement. A good pain relief effect was obtained in a short time with no major complications. With this technique, pain relief is obtained quickly with little invasiveness, so it seems to be a promising new treatment option for osteoporotic spinal fracture patients in whom conservative treatment has failed. If conducted with close attention to complications during the injection of the bone cement, this technique in conjunction with osteoporosis treatment can bring great benefit to elderly patients.

## References

- Lindsay R, Silverman SL, Cooper C *et al.* Risk of new vertebral fracture in the year following a fracture. *JAMA* 2001; 285: 320–323.
- Tamayo-Orozco J, Arzac-Palumbo P, Peon-Vidales H, Mota-Bolfeta R, Fuentes F. Vertebral fractures associated with osteoporosis: patient management. *Am J Med* 1997; 103: 44S–50S.
- Maldague BE, Noel HM, Malghem JJ. The intervertebral vacuum cleft: a sign of ischemic vertebral collapse. *Radiology* 1978; 129: 23–29.
- Browner AC, Downey EF. Kummel disease: report of a case with serial radiographs. *Radiology* 1981; 141: 363–364.
- Gangi A, Kastler BA, Dietemann JL. Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. *Am J Neuroradiol* 1994; 15: 83–86.
- Jensen ME, Evans AJ, Mathis JM, Kallmes DF, Cloft HJ, Dion JE. Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. *Am J Neuroradiol* 1997; 18: 1897–1904.
- Galibert P, Deramond H, Rosat P, Le Gars D. Note préliminaire sur le traitement des angiomes vertébraux par vertébroplastie percutanée. *Neurochirurgie* 1987; 33: 166–168.
- Ebara S, Narasaki K, Takahashi J *et al.* Vertebroplasty. *Clin Calcium* 2004; 14: 1757–1763.
- Deramond H, Depriester C, Galibert P, Le Gars D. Percutaneous vertebroplasty with polymethylmethacrylate. Technique, indications, and results. *Radiol Clin North Am* 1998; 36: 533–546.
- Zoarski GH, Stallmeyer MJ, Obuchowski A. Percutaneous vertebroplasty: A to Z. *Tech Vasc Interv Radiol* 2002; 5: 223–238.
- Ryu KS, Park CK, Kim MC, Kang JK. Dose-dependent epidural leakage of polymethylmethacrylate after percutaneous vertebroplasty in patients with osteoporotic vertebral compression fractures. *J Neurosurg* 2002; 96: 56–61.
- McGraw JK, Lippert JA, Minkus KD, Rami PM, Davis TM, Budzik RF. Prospective evaluation of pain relief in 100 patients undergoing percutaneous vertebroplasty: results and follow-up. *J Vasc Interv Radiol* 2002; 13: 883–886.
- Liliang PC, Su TM, Liang CL, Chen HJ, Tsai YD, Lu K. Percutaneous vertebroplasty improves pain and physical functioning in elderly osteoporotic vertebral compression fracture patients. *Gerontology* 2005; 51: 34–39.
- Barr JD, Barr MS, Lemley TJ, McCann RM. Percutaneous vertebroplasty for pain relief and spinal stabilization. *Spine* 2000; 25: 923–928.
- Peh WC, Gilula LA, Peck DD. Percutaneous vertebroplasty for severe osteoporotic vertebral body compression fractures. *Radiology* 2002; 223: 121–126.
- Legroux-Gerot I, Lormeau C, Boutry N, Cotten A, Duquesnoy B, Cortet B. Long-term follow-up of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. *Clin Rheumatol* 2004; 23: 310–317.
- Chen HL, Wong CS, Ho ST, Chang FL, Hsu CH, Wu CT. A lethal pulmonary embolism during percutaneous vertebroplasty. *Anesth Analg* 2002; 95: 1060–1062.
- Choe du H, Marom EM, Ahrar K, Truong MT, Madewell JE. Pulmonary embolism of polymethyl methacrylate during percutaneous vertebroplasty and kyphoplasty. *Am J Roentgenol* 2004; 183: 1097–1102.



- 19 Harrop JS, Prpa B, Reinhardt MK, Lieberman I. Primary and secondary osteoporosis' incidence of subsequent vertebral compression fractures after kyphoplasty. *Spine* 2004; 29: 2120-2125.
- 20 Syed MI, Patel NA, Jan S, Harron MS, Morar K, Shaikh A. New symptomatic vertebral compression fractures within a year following vertebroplasty in osteoporotic women. *Am J Neuroradiol* 2005; 26: 1601-1604.

*Original article*

## Report on the Japanese Orthopaedic Association's 3-year project observing hip fractures at fixed-point hospitals

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### Abstract

**Background.** The aim of this study was to assess the disability and mortality of hip fractures 1 year after initial visit (postoperatively) at fixed-point hospitals selected by the Japanese Orthopaedic Association Committee on Osteoporosis.

**Method.** A total of 158 core orthopedic hospitals were selected for participation in this research. Subjects were all aged 65 years and older with hip fractures at the selected hospitals between January 1, 1999 and December 31, 2001. A prognostic survey of activities of daily living (ADL), assessed by the long-term care insurance criteria established by the Ministry of Health, Labour, and Welfare of Japan was performed 1 year after the initial visit.

**Results.** A total of 10992 hip fractures in patients aged 65 to 111 years were treated over the 3 years from 1999 to 2001. Among the 10992 patients, 4537 had femoral neck fractures and 6217 had trochanteric fractures. Surgical treatment was chosen for 85.6% of the femoral neck fractures and 88.2% of the trochanteric fractures. The mean duration from fracture to admission was 3.1 days, and the mean duration from admission to surgery was 11.2 days. The mean duration from surgery to discharge over the 3-year period was 49.8 days. Before hip fracture, the ratio of patients with J1 ("able to go out freely utilizing public transportation") or J2 ("able to visit immediate neighbors independently") on the long-term care insurance criteria was 50.9%. At 1 year after the initial visit, that result represented a decrease of 24.1 percentage points before hip fracture. A total of 70 patients died before undergoing surgery. In the present study, the 1-year mortality rate

for the entire patient population over the 3-year period was 10.1%.

**Conclusions.** Hip fracture patients show a decrease in the ADL score 1 year after the initial visit. Compared to other countries, the duration of hospitalization is longer in Japan, but the mortality rate is lower.

### Introduction

Hip fracture is an important cause of morbidity and mortality among the elderly. For the first time, under the leadership of the Japanese Orthopaedic Association (JOA), an epidemiological study on hip fracture was commenced in 1997 by the Committee on Osteoporosis of the JOA (hereafter referred to as the Committee). Because the number of investigated items is limited in this annual epidemiological study, a fixed-point observation project involving core orthopedic hospitals was started in 1999 (including patients treated between January 1 and December 31) to examine a larger number of factors including the 1-year prognosis. Herein, we report the results of fixed-point observation for hip fractures occurring over the 3-year period from 1999 to 2001.

### Selection of institutions for fixed-point observation

In October 1999, the Committee began selecting core orthopedic hospitals at which to observe and analyze

treatments for hip fracture in Japan. After taking into account the regional factors, a total of 160 institutions were identified in February 2000. These institutions were contacted for participation in the fixed-point observation project, with only two institutions declining. Subsequently, a total of 158 institutions were designated fixed-point observation institutions.

## Subjects and methods

Subjects were all patients with hip fracture and aged 65 years old and older treated at one of the participating institutions between January 1 and December 31, 1999. A prognostic survey was performed 1 year postoperatively (hereafter referred to as the 1-year prognosis survey). Survey sheets for hip fractures occurring over the 3-year period were collected.

The survey ascertained the following information: sex; height; body weight; cause of fracture; living situation at the time of fracture; date of fracture; date of admission; date of surgery; location where fracture occurred; discharge status; outcomes; side and type of fracture; treatment; independence in activities of daily living (ADL) both before fracture and 1 year postoperatively (at the time of the 1-year prognosis survey, and assessed according to the long-term care insurance<sup>1</sup> criteria established by the Ministry of Health, Labour, and Welfare of Japan); preoperative complications; and past history of fracture. The study was designed to ensure patient anonymity.

Data were analyzed using of variance with the *t*-test and the continuity adjusted chi-squared test. Statistical significance was set at 0.01.

## Results

### *Number of responding institutions for each year*

Of the 158 participating institutions, 76 institutions (48.1%) responded during the first year (fractures occurring in 1999), 69 institutions (43.7%) during the second year (fractures occurring in 2000), and 75 institutions (46.2%) during the third year (fractures occurring in 2001). Over the 3-year period, a total of 220 institutions responded, with an annual average of 73.3 institutions (46.4%).

### *Number of patients over the 3-year period*

A total of 12250 hip fractures in patients 0–111 years of age were treated during the 3 years from 1999 to 2001. Among these patients, those 65 years and older (65–111 years of age) were analyzed. At the responding institu-

tions, a total of 3656 patients were treated in 1999, 3393 patients in 2000, and 3943 patients in 2001, for a 3-year total of 10992 patients with an annual average of 3664 patients using those criteria.

### *Background factors (age at time of fracture)*

Among the 10992 patients with known sex and age, the mean age was 81.8 years (79.8 years for male patients, 82.3 years for female patients).

### *Laterality and type of hip fracture*

The incidence of left and right fractures was analyzed for all 3 years. The total numbers of right and left hip fractures over the 3-year period were comparable, at 5414 and 5497, respectively. Over the 3-year period, 3 male patients and 28 female patients presented with bilateral hip fractures. A total of 6217 trochanteric fractures, 4537 femoral neck fractures, 13 patients with both fractures, and 225 with no-response fractures were treated.

### *Cause of fracture*

Among the 10992 patients treated over the 3-year period, the most common cause was "simple fall (fall from a standing level)", accounting for 76.1% ( $n = 8362$ ) (Table 1), followed by a "staircase accident" and "downfall (fall from a high level)", in that order (5.9% and 5.0%, respectively). Most of the hip fractures were caused by falls from a standing level.

### *Time after fracture*

The mean interval from fracture to admission was 2.7 days in 1999, 3.4 days in 2000, and 3.2 days in 2001 (3-year average 3.1 days). The mean duration from admission to surgery was 11.1 days in 1999, 12.3 days in 2000,

**Table 1.** Causes of fracture (3-year period)

Cause of fracture	No.	%
Body movement while lying down	89	0.8
Fall while standing	8362	76.1
Staircase accident	645	5.9
Downfall	545	5.0
Traffic accident	341	3.1
No recollection	78	0.7
Diaper-related fracture	27	0.2
Spontaneous fracture	102	0.9
Unknown	540	4.9
Other	65	0.6
No response	198	1.8
Total	10992	100

and 10.2 days in 2001 (3-year average 11.2 days). The mean duration from surgery to discharge over the 3-year period was 50.4 days, with a tendency to decrease each year: 52.2 days in 1999 ( $P < 0.01$ ), 49.0 days in 2000, and 48.4 days in 2001 ( $P < 0.01$ ) (Table 2).

#### *Patients who died before undergoing surgery (3-year period)*

A total of 70 patients died before undergoing surgery (31 men, 38 women, 1 patient of unknown sex). Table 3 shows living situations and hip fracture types for these patients. The mean age was 85.5 years for the 31 men and 87.5 years for the 38 women. The incidence of trochanteric fracture was about double that of femoral neck fracture, and mean number of complications ranged from 1.9 to 3.2. Although we suspect that more complications arose, only the complications listed on the survey sheets were analyzed.

#### *Treatments and surgery (3-year period)*

Among the 10992 patients, 4537 had femoral neck fractures, 6217 had trochanteric fractures, and these was no response for 238 cases. Table 4 shows the breakdown of treatments for femoral neck fracture and trochanteric fracture. Surgical treatment was chosen for 85.6% of femoral neck fractures and 88.2% of trochanteric fractures. Among patients with femoral neck fractures, hemiarthroplasty was performed in 40.7%, total hip arthroplasty in 21.6%, and screw fixation in 15.0%. Among patients with trochanteric fractures, captured hip screw (CHS) fixation was performed in 57.2% and Gamma nailing in 20.4%. These two methods thus accounted for 77.6% of surgeries performed for trochanteric fracture.

#### *ADL independence before hip fracture*

In accordance with ADL independence assessment criteria established by the Ministry of Health, Labour, and Welfare of Japan, patients were classified in eight grades, from (1) able to go out freely by utilizing public transportation (J1) to (8) unable to turn over in bed independently (C2). Over the 3-year period, the section for ADL independence was left blank for only 118 patients (1.1%). Preoperatively, the ratio of grade 1 or 2 patients was relatively high, accounting for 50.9% of the total (Table 5).

#### *ADL independence 1 year after initial visit*

At 1 year (6 months) after the initial visit, grade 1 patients (able to go out freely by utilizing public transportation) and grade 2 patients (able to visit immediate

**Table 2.** Time parameters

Parameter	From fracture to admission			From admission to surgery			From surgery to discharge		
	1999	2000	2001	1999	2000	2001	1999	2000	2001
Days	2.7 ± 31	3.4 ± 20.0	3.2 ± 18.0	11.1 ± 31.0	12.3 ± 24.0	10.2 ± 40.0	52.2 ± 55.0*	49.0 ± 41.0	48.4 ± 49.0*
Cases	3656	3393	3946	3428	3153	3675	3365	3127	3640
				3-Year total	3-Year total	3-Year total	3-Year total	3-Year total	3-Year total
				10 992	10 256	10 256	10 256	10 256	10 132

Results are averages  
\*  $P < 0.01$  (*t*-test)