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^2. 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.[7] 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.[8]

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.[9–13] 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.[6,9,10,12,14,15] 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 that that reported by others. According to one long-term follow-up study,[16] 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.[17] Another study reported findings of pulmonary embolisms in 4.6% of patients on chest X-rays, even though the patients were asymptomatic.[18] 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.

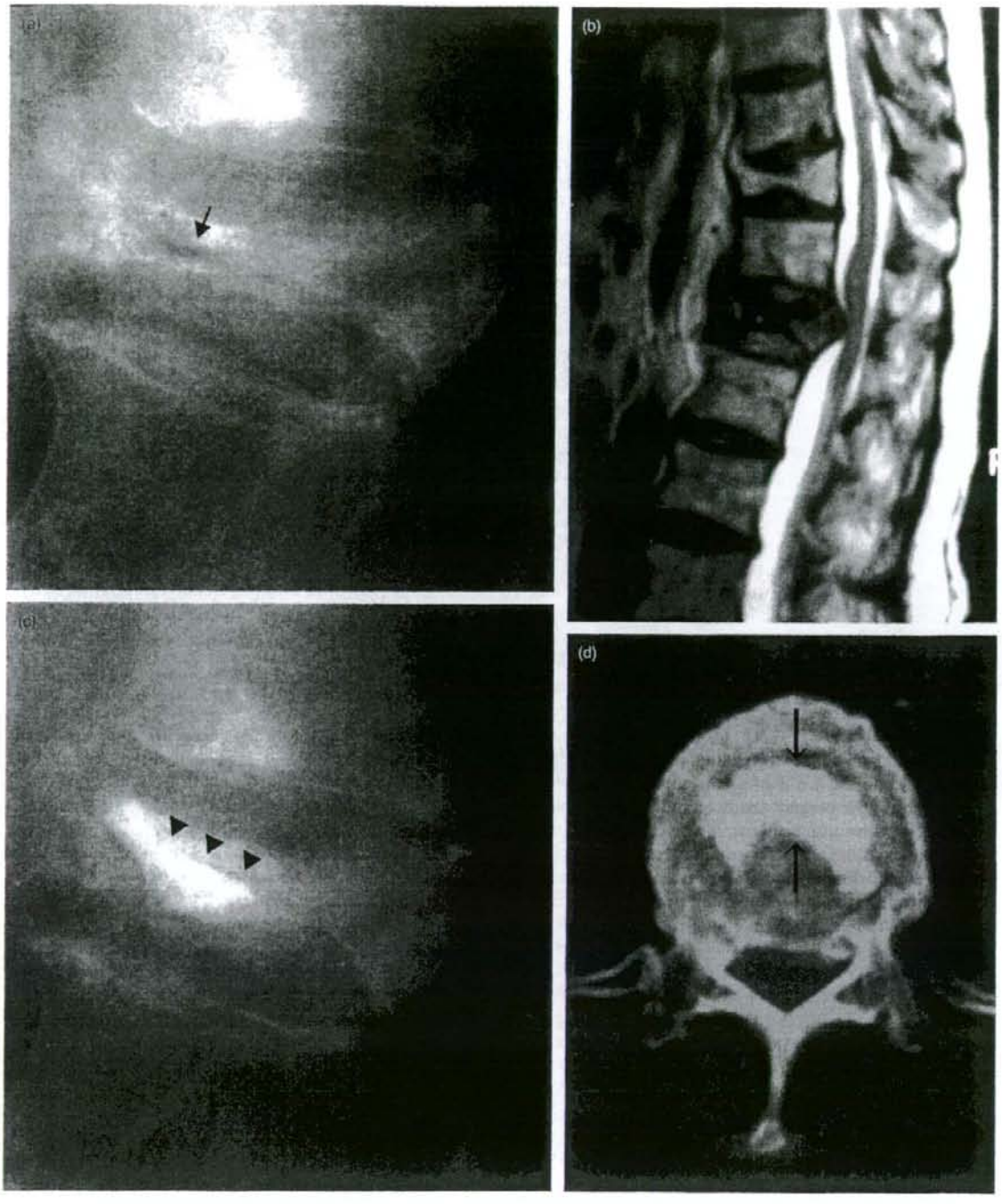

Figure 1 Case 10. (a) Preoperative lateral view of the first lumbar vertebral body. Arrow shows vacuum cleft which reduced in neutral position. (b) Preoperative magnetic resonance image. T2 weighted image shows the unhealed burst fracture of the first lumbar vertebral body and the healed fracture of 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%[19] and 21.7%[20] 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.*[1] 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.

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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

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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[1] 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 institutions, 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	3-Year total	1999	2000	2001	3-Year total	1999	2000	2001	3-Year total
Days	2.7 ± 31	3.4 ± 20.0	3.2 ± 18.0	3.1 ± 16.0	11.1 ± 31.0	12.3 ± 24.0	10.2 ± 40.0	11.2 ± 34.0	52.2 ± 55.0*	49.0 ± 41.0	48.4 ± 49.0*	49.8 ± 42.0
Cases	3656	3393	3946	10992	3428	3153	3675	10256	3365	3127	3640	10132

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

Table 3. Patients who died without surgery (3-year total)

Patients	Nonsurgical deaths (no.)	Living situation at time of fracture					Neck fracture		Trochanteric fracture	
		Average age (years)	Living alone	Living with family	Living in facility	Unknown	No.	Complications	No.	Complications
Men	31	85.5 ± 8.5	3	9	5	14	11	1.9	20	2.8
Women	38	87.5 ± 6.0	4	7	3	24	14	3.2	24	2.6
Unknown	1	87	1							

Table 4. Treatments and surgery (3-year total)

Treatment	Neck fractures (n = 4537)		Trochanteric fractures (n = 6710)		Unknown (n = 238)
	No.	%	No.	%	No.
No surgery	288	6.3	291	4.7	19
Surgery	3885	85.6	5485	88.2	194
Ender nail	3	0.1	214	3.4	3
Screw	681	15.0	52	0.8	18
Gamma nail	9	0.2	1269	20.4	15
CHS	201	4.4	3556	57.2	59
Plate	1	0	5	0.1	1
Hemiarthroplasty	1847	40.7	164	2.6	42
Total hip arthroplasty	978	21.6	22	0.4	16
Other	110	2.4	118	1.9	13
Unknown	31	0.7	21	0.3	3
Compound	24	0.5	64	1.0	24
No response	364	8.0	441	7.1	25

CHS, captured hip screw

Table 5. ADL independence before fracture

ADL independence before fracture (scores 1–8)	No.	%
1 Able to go out using public transportation	2667	24.3
2 Can go out to visit neighbors	2928	26.6
3 Can go out with assistance and spend the day out of bed	1997	18.2
4 Rarely goes out; spends the day in bed	1971	17.9
5 Uses a wheelchair and only leaves bed to eat or use the bathroom	700	6.4
6 Can get in and out of a wheelchair with assistance	469	4.3
7 Able to turn over in bed independently	67	0.6
8 Unable to turn over in bed independently	46	0.4
Unknown and other	29	0.3
Total responses	10992	100.0
No response	118	1.1

ADL, activities of daily living

neighbors independently — J2) accounted for 12.7% and 14.1%, respectively, for a total of 26.8%. This represented a decrease of 29.5 percentage points from the preoperative score ($P < 0.01$; continuity adjusted chi-squared test). However, the section for ADL independence 1 year after the initial visit was left blank by 2820 patients (25.7%), suggesting difficulties associated with conducting the prognostic survey (Table 6).

Preoperative complications (3-year period)

Many patients with hip fracture develop complications. Of the 10992 patients treated over the 3-year period, the section for preoperative complications was completed for 10908 patients and left blank for 84 patients. Only 882 patients (8.0%) experienced no complications. The most common complication was hypertension, followed by dementia, neuropathy, and heart disease, in that order.

One-year mortality rate for each surgery (3-year period)

Table 7 shows 1-year mortality rates for the various surgical methods. Mortality rate was highest for plate

fixation (14.3%, 1/7), followed by Ender nailing (14.0%) and Gamma nailing (12.3%). Apart from the "Others" category, the 1-year mortality rate was lowest for the screw method, at 7.7%. The mean postoperative mortality rate was 10.1%.

One-year survival rate for each calendar age (3-year period)

Table 8 shows 1-year survival and mortality rates for each year of age from 65 years and older. The number of hip fracture patients exceeded 300 among these 78–90 years of age. The greatest number of patients was 416, at 85 years of age. The 1-year survival rate for patients in their eighties was higher than 80%, whereas that for patients in their nineties was above 70%, confirming that the 1-year survival rate decreases with age.

Table 6. ADL independence 1 year after surgery/initial visit

ADL independence 1 year after surgery/initial visit	No.	%
1 Able to go out using public transportation	1399	12.7
2 Can go out to visit neighbors	1550	14.1
3 Can go out with assistance and spend the day out of bed	1427	13.4
4 Rarely goes out; spends the day in bed	1080	9.8
5 Uses a wheelchair and only leaves bed to eat or use the bathroom	1000	9.1
6 Can get in and out of a wheelchair with assistance	1034	9.4
7 Able to turn over in bed independently	167	1.5
8 Unable to turn over in bed independently	174	1.6
Unknown and other	341	3.1
Total responses	10992	100.0
No response	2820	25.7

Table 8. One-year survival rate for each year of age

Age (years)	Alive (no.)	Deceased (no.)	Survival rate (%)
65	91	3	96.8
66	117	4	96.7
67	109	4	96.5
68	122	3	97.6
69	144	10	93.5
70	150	8	94.9
71	167	10	94.4
72	189	13	93.6
73	172	20	89.6
74	212	23	90.2
75	234	13	94.7
76	250	26	90.6
77	266	15	94.7
78	325	29	91.8
79	333	31	91.5
80	287	35	89.1
81	323	40	89.0
82	318	49	86.6
83	321	42	88.4
84	355	58	86.0
85	356	60	85.6
86	344	66	83.9
87	338	65	83.9
88	344	58	85.6
89	254	61	80.6
90	265	53	83.3
91	198	56	78.0
92	160	50	76.2
93	111	38	74.5
94	107	22	82.9
95	51	26	66.2
96	50	14	78.1
97	43	11	79.6
98	18	3	85.7
99	36	8	81.8
100	13	7	65.0
101	9	4	69.2
102	0	2	0
103	0	0	0
111	1	0	100.0

Table 7. One-year mortality rate for each surgery method

Method	Alive	Deceased	Unknown	Total count	Mortality rate (%)
Surgery					
Ender nail	108	31	81	220	14.0
Screw	512	58	181	751	7.7
Gamma nail	762	159	372	1293	12.3
CHS	2300	381	1134	3815	10.0
Plate	4	1	2	7	14.3
Artificial head replacement	1302	146	604	2052	7.1
Total hip replacement	670	77	269	1016	7.6
Others	162	17	62	241	7.1
Unknown	322	171	506	999	17.1
Nooperation	509	70	19	598	11.7
Total	6651	1111	3230	10992	10.1 (average)

Table 9. Discharge status and 1-year mortality

Discharge status		Alive	Deceased	Unknown	No response	One-year total
Well	9012	6367	555	1122	968	9012
No change	503	282	87	59	75	503
Deceased	397					
Others	1080	2	72	220	786	1080
Total	10992	6651	714	1401	1829	10595

Table 10. Complications and 1-year mortality

		Alive		Deceased		Unknown	
Complications	Total	No.	%	No.	%	No.	%
No	698	583	83.5	41	5.8	74	10.6
Yes	7794	5700	73.1	1045	13.4	1049	13.4
No response	2500	368	14.7	25	1.0	2107	84.2
Total	10992	6651	67.9	1111	16.8	3230	15.1

Table 11. One-year mortality rate and sex

	1999		2000		2001		Total	
Sex	No.	%	No.	%	No.	%	No.	%
Male	115		127		117		145	
Female	270		220		237		242	
No response	16		6		3		10	
Total	401		353		357		1111	
Total patients (mortality rate)	3656	10.9*	3393	10.4	3943	9.0*	10992	10.1

* $P < 0.01$ (continuity adjusted chi-squared test)

Outcomes at discharge and the 1-year prognosis

The 1-year prognosis was investigated based on discharge status for the 10992 patients treated over the 3-year period. Of the 9012 patients discharged in good health, 503 (4.6%) were discharged with unchanged condition, and 396 (4.4%) were dead at discharge. Of the 9012 patients in good health at discharge 555 (6.2%) were dead, and 87 (17.3%) of 503 patients with an unchanged condition were dead, 1 year postoperatively. Of the 1081 patients whose condition at discharge was unknown or left blank, 72 (6.7%) were dead 1 year postoperatively (Table 9).

Comparison of 1-year survival and mortality in relation to complications

The 1-year mortality rate for the 698 patients without complications was 5.8%, compared to 13.4% for the 7794 patients with complications and 1.0% for the 2500 patients for whom the section on complications was left blank (Table 10).

Comparison of 1-year mortality during 3-year period for men and women

The 1-year mortality rate for each year of age among men was 17.3% for the 664 patients in 1999, 19.7% for the 646 patients in 2000, and 16.2% for the 724 patients in 2001. The 1-year mortality rate for the women was 9.4% for the 2858 patients in 1999, 8.1% for the 2716 patients in 2000, and 7.5% for the 3176 patients in 2001. The mortality rate of both sexes was 10.9% for 3656 patients in 1999, 10.4% in 2000, and 9.0% in 2001. The 1-year mortality rate showed a tendency to decrease year by year. ($P < 0.01$, continuity adjusted chi-squared test) (Table 11).

Discussion

In Japan, the first epidemiological study on hip fracture was conducted in 1987 by Orimo et al.,[2] and about 52300 cases of hip fracture were estimated to occur annually each year in Japan. The JOA then took a leadership role and the Committee has conducted annual epidemiological studies on hip fracture since 1997. Between 1998 and 2000, a total of 110747 hip fractures were reported[3] and about 90000 hip fractures are estimated to occur each year in Japan. To supplement these studies, a hip fracture project was started in 1999 at selected hospitals in Japan in an attempt to clarify the 1-year prognosis following hip fracture. Comparing the JOA study and the fixed-point observation project, the project studied about 10% of the number of patients enrolled in the epidemiological study in 1999 and 2000, and the types, laterality, and causes of femoral neck fracture were comparable.

The mean hospitalization for patients with hip fracture in various countries is reportedly 10 days for the Ullevaal hip screw in Norway, 12 days for the Hansson hook-pin in Norway,[4] 10 days for internal fixation in Sweden, 12 days for arthroplasty in Sweden,[5] 17.8 days in England,[6] 18 days in Austria,[7] 20.6 days in Thailand,[8] 24 days in Denmark,[9] 35 days in Italy,[10] and 23.3 days in the United States.[11] In Japan, the mean length of hospitalization is 83.6 days for pinning, 53.0–58.8 days for hemiarthroplasty,[12,13] 83.9 days for CHS,[14] 2.4 months for the Ender procedure, and 1.9 months for DHS or the Gamma nail.[15] Compared to other countries, the length of hospitalization following surgery for hip fracture is longer in Japan. In other countries, once acute-phase surgery for hip fracture is performed, patients are transferred to institutions specializing in rehabilitation, such as nursing homes. As a result, the duration of stay in the orthopedic department is low. In Japan, many hospitals are capable of handling both acute- and chronic-phase care, including rehabilitation, thus resulting in longer stays in the orthopedic department.

Based on data obtained from the fixed-point observation project, the number of days from surgery to discharge decreased each year, from 52.2 days ($P < 0.01$, t-text) in 1999 ($n = 3365$) to 49.0 days in 2000 ($n = 3127$) and 48.4 days ($P < 0.01$, t-test) in 2001 ($n = 3640$). As for the decrease at the hospitalization period, advances in the treatment method and the expansion of facilities after discharge are suspected.

Zückerman et al. developed the functional recovery score (FRS) as a disease-specific health assessment tool.[16] Using this system, they reported that FRS for patients with hip fracture was 88.1 points before fracture, decreasing by 15.8 points to 72.3 points 1 year later.[17] To assess patient function, we used the assessment criteria established by the Ministry of Health, Labour, and Welfare of Japan.[1] Thus, ADL independence was classified into eight grades, from (1) able to go out freely by utilizing public transportation, to (2) able to visit immediate neighbors independently, and (3) able to go out with assistance and spend the day out of bed to (8) unable to turn over in bed independently. ADL independence was assessed preoperatively and 1 year after the initial visit (within 6 months in some cases). Over the 3-year period, grade 1 and 2 patients accounted for 24.3% and 26.6%, respectively, of the patients preoperatively. Thus, 50.9% of patients were able to walk without assistance, but at 1 year after the initial visit grade 1 and 2 patients accounted for 12.7% and 14.1%, respectively, for a total of 26.8%. This represented a decrease of 24.1 percentage points. Of the various types of functional disabilities experienced by patients with hip fracture, the degree of disability in stair climbing is marked.[18] In the Baltimore Hip Study, among 804 patients with hip fracture who were ≥65 years old, 55.6% required assistance climbing five stairs preoperatively, and 89.9% required assistance with the same task 12 months postoperatively. Many studies have documented decreases in independent walking following hip fracture,[4,7,11,12,14,19] and one found that the ratio of patients requiring assistance walking one block was 42.4% preoperatively and 55.2% at 12 months postoperatively. However, the degree of decrease in independence was lower when compared to stair climbing, and degree of decrease in walking 10 feet remained low, at 9.2 percentage points.[19]

Because many elderly patients with a hip fracture experience complications, mortality rates for these patients are markedly higher than in the general cohort.[20,21] The 1-year mortality rate for hip fracture has decreased over the last few decades, from 21.6%,[22] 24.0%,[23] and 27.0%[9,24] during the 1970s and 1980s, to 16.8%,[19] 18.0%,[25] 20.0%[10,25,26] during the 1990s and 10.9%[11] during the 2000s. In the present study, the 1-year mortality rate for the entire patient population decreased every year over the 3-year period, from 10.9% in 1999 to 10.4% in 2000 and 9.0% in 2001 (3-year average 10.1%; 1111 of the 10992 patients were dead 1 year after the initial visit — $P < 0.01$, continuity adjusted chi-squared test). Compared to other countries, the duration of hospitalization is longer in Japan, but the mortality rate is lower.

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Original article

Effects of unipedal standing balance exercise on the prevention of falls and hip fracture among clinically defined high-risk elderly individuals: a randomized controlled trial

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Abstract
Background. The aim of this study was to assess the effectiveness of the unipedal standing balance exercise for 1 min to prevent falls and hip fractures in high-risk elderly individuals with a randomized controlled trial. This control study was designed as a 6-month intervention trial.
Subjects. Subjects included 553 clinically defined high-risk adults who were living in residences or in the community. They were randomized to an exercise group and a control group.
Methods. Randomization to the subjects was performed by a table of random numbers. A unipedal standing balance exercise with open eyes was performed by standing on each leg for 1 min three times per day. As a rule, subjects of the exercise group stood on one leg without holding onto any support, but unstable subjects were permitted to hold onto a bar during the exercise time. Falls and hip fractures were reported by nurses, physical therapists, or facility staff with a survey sheet every month. This survey sheet was required every month for both groups.
Results. Registered subjects were 553 persons ranging in age from 37 to 102 years (average, 81.6 years of age). Twenty-six subjects dropped out. The number of falls and hip fractures for the 6-month period after the trial for 527 of the 553 subjects for whom related data were available were assessed. The exercise group comprised 315 subjects and the control group included 212 subjects. The cumulative number of falls of the exercise group, with 1 multiple faller omitted, was 118, and the control group recorded 121 falls. A significant intergroup difference was observed. However, the cumulative number of hip fractures was only 1 case in both groups. This difference was not statistically significant.
Conclusions. The unipedal standing balance exercise is effective to prevent falls but was not shown to be statistically significant in the prevention of hip fracture in this study.

Introduction

Injurious falls constitute an important health problem. Changes in the sensory, neurological, and musculoskeletal systems in older adults affect several motor tasks, including postural balance and gait. Various studies have examined the effects of specific exercises on balance in older people with conflicting results.[1,2] Postmenopausal or involutional osteoporosis in elderly people affects the fragility of the proximal femur and may ultimately lead to hip fractures. To prevent hip fracture, there are three methods: (1) prevention of falls,[3,4] (2) treatment of osteoporosis, and (3) hip protectors.[5,6] The unipedal standing exercise is useful for improvement of the proximal femoral bone density and postural balance.[7] To ascertain the effects of unipedal standing training on the prevention of falls and femoral neck

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fracture, the Japanese Orthopaedic Association Osteoporosis Committee conducted a randomized study on individuals clinically defined as high-risk adults, including residents of nursing homes and nursing care facilities and users of outpatient rehabilitation centers.

Subjects

Initially, orthopedic surgery departments at medical schools and universities across Japan were contacted to ask for their recommendations of special nursing homes for the aged and nursing care facilities at which motion exercise training might be accepted and carried out. Subsequently, a questionnaire was mailed to each recommended facility to ask for their participation in the present randomized study. Subjects defined as high-risk adults were residents of special nursing homes for the aged or nursing care facilities who could stand on their own while holding onto a bar, and users of outpatient rehabilitation centers. Dementia patients who had agreement from their family were also enrolled in this study, but severe dementia patients or patients without agreement provided by themselves or family were not enrolled.

Methods

Because the present study was a human trial, the study protocol was reviewed and approved by the Medical Ethics Review Board of Showa University School of Medicine in November 2002. Before participation in this study, all subjects were required to have an institutionally approved informed consent form signed by themselves, family, or the patient's guardians in accordance with the Helsinki Declaration. This form involved agreeing to be randomized to an exercise or a control group. Randomization of the subjects into an exercise group or a control group was performed by the Department of Information Science of our university.

In general, the unipedal standing balance exercise was carried out as follows. With their eyes open, subjects were instructed to stand on their right leg for 1 min and then their left leg for another minute, for a total of 2 min, three times in a day. If a subject was unable to stand on one leg continuously for 1 min and required several breaks, he or she was instructed to stand on either leg until the total duration of one-leg standing reached 1 min. A single set of this one-leg standing balance exercise consisted of standing on the right leg for 1 min and the left leg for 1 min. Each day, subjects performed three sets, one in the morning, one at noon, and one in the afternoon. A control group was observed without exercise in the follow-up period.

The unipedal standing balance exercise was carried out under the guidance of a physical therapist or a similarly qualified individual. The individuals who prescribed and monitored the unipedal standing exercise (or facility staff) were asked to complete a survey sheet every month and mail the survey to the study office (Department of Orthopaedic Surgery in Showa University School of Medicine).

Investigated items

The survey sheet was designed to collect information regarding clinical diagnosis, age, frequency of falls, and fracture site. In addition, the survey sheet also included items that assessed compliance with performance of the exercise as already described. Simultaneously, we ascertained the number of falls over the 6-month period immediately before the study (as indicated by patients' survey responses or ascertained from medical charts). A prospective, randomized, controlled clinical trial with the unipedal standing balance exercise was designed by the Department of Information Science of Show University.

Results

Participating institutions and participants

Before February 2005, survey sheets were received from a total of 32 institutions comprising 24 nursing care facilities, 3 special nursing homes for the aged, and 5 outpatient rehabilitation centers. A total of 553 (142 men and 411 women) subjects were enrolled in the present study. Of these subjects, 397 (94 men and 303 women) were residents of nursing care facilities, 38 (5 men and 33 women) were residents of special nursing homes for the aged, and 118 (43 men and 75 women) were users of outpatient rehabilitation centers.

Age of subjects

Subjects ranged in age from 37 to 102 years. The mean ages of male and female subjects were 77.2 and 83.1 years, respectively. For the exercise and control groups, the mean ages were 81.2 and 82.3 years, respectively. The overall mean age of the subjects was 81.6 ± 9.0 years (mean ± SD). Table 1 shows the age distribution of all subjects.

Medical conditions among subjects

Residents of nursing care facilities and special nursing homes for the aged, and the users of outpatient rehabilitation centers, had various underlying diseases and many patients had multiple diseases and ailments.

Table 2 summarizes the primary underlying diseases of the subjects in the present study.

Unipedal standing balance exercise and fall prevention

Even though grouping was carried out according to the randomized method (table of random numbers), the number of survey sheets received was lower for the control group and the number of falls before the study was higher for the exercise group. Table 3 shows the results at 3 months after the start of the investigation. Subjects ($n = 553$) included 337 individuals who underwent training to stand on one leg with eyes open (training group) and 216 individuals who did not undergo this training (control group). The number of falls over a 3-month period ranged from 0 (training group, $n = 302$; control group, $n = 189$) to 19 (training group, $n = 1$; control group, $n = 0$). Table 4 shows the distribution of the number of falls for the 6-month period after training of the 527 subjects for whom the related data were available. The exercise group comprised 315 subjects and the control group comprised 212 subjects.

Effects on the number of falls

A statistical comparison was conducted on the differences in the number of falls between the exercise and control groups. At 3 months, a total of 79 falls were observed for the training group, whereas 58 falls were recorded for the control group. A Fisher's probability test showed no significant difference between the training group ($n = 337$, 79 falls) and the control group ($n = 216$, 58 falls) ($P = 0.4959$). However, after excluding 1 subject in the training group who had multiple falls, the same test showed a significant difference (training group, $n = 336$, 60 falls; control group, $n = 216$, 58 falls) ($P = 0.0500$). At 6 months after training, 1 subject in the

Table 1. Age distribution

Age (years)	Men ($n = 142$)	Women ($n = 411$)	Total ($n = 553$)
37–39	2	0	2
40–44	0	0	0
45–49	3	0	3
50–54	1	2	3
55–59	6	1	7
60–64	3	9	12
65–69	13	9	22
70–74	11	29	40
75–79	35	66	101
80–84	29	104	133
85–89	22	107	129
90–94	16	74	90
95–99	1	8	9
100–	0	2	2

Table 2. Primary underlying disease of subjects

Underlying disease	Number of subjects
Cerebrovascular disorder	204
Dementia	91
Fracture	71
Spinal disease	66
Cardiovascular disease	38
Motor organ disease	32
Diabetes	16
Respiratory organ disease	7
Neuropsychiatric disorder	7
Others	21
Total	553

Table 3. Exercise training and number of falls at 3 months

			Exercise group		Control group			
Number of falls (a)	Number of subjects	Percent	Number (b)	Cumulative number of falls (a × b)	Number (b′)	Cumulative number of falls (a × b′)	Men	Women
0	488	88.2	300	0	188	0	126	362
1	40	7.2	25	25	15	15	9	31
2	12	2.2	7	14	5	10	2	10
3	5	0.9	1	3	4	12	1	4
4	3	0.5	1	4	2	8	0	3
5	1	0.2	0	0	1	5	0	1
6	1	0.2	1	6	0	0	1	0
8	2	0.4	1	8	1	8	2	0
11	0	0.0	0	0	0	0	0	0
12	0	0.0	0	0	0	0	0	0
13	0	0.0	0	0	0	0	0	0
19	1	0.2	1	19	0	0	0	1
Total	553	100	337	79	216	58	141	412

Table 4. Exercise training and number of falls at 6 months

Number of falls (a)	Subjects	Percent	Exercise group		Control group		Men	Women
			Number (b)	Cumulative number of falls (a × b)	Number (b′)	Cumulative number of falls (a × b′)		
0	408	77.4	247	0	161	0	108	300
1	68	12.9	42	42	26	26	13	55
2	20	3.8	14	28	6	12	5	15
3	20	3.8	8	24	12	36	5	15
4	4	0.8	0	0	4	16	0	4
5	1	0.2	1	5	0	0	0	1
6	0	0.0	0	0	0	0	0	0
7	2	0.4	1	7	1	7	1	1
11	1	0.2	0	0	1	11	0	1
12	1	0.2	1	12	0	0	1	0
13	1	0.2	0	0	1	13	1	0
29	1	0.2	1	29	0	0	0	1
Total	527	100	315	147	212	121	134	393

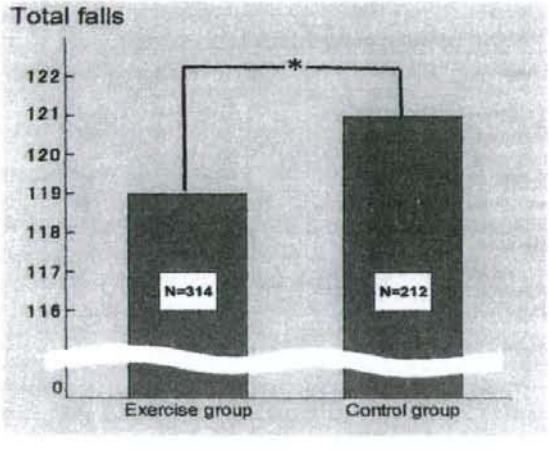

Fig. 1. Relationship of intervention to falls (*Fisher's exact probability test: $*P = 0.0067$; $P < 0.01$)

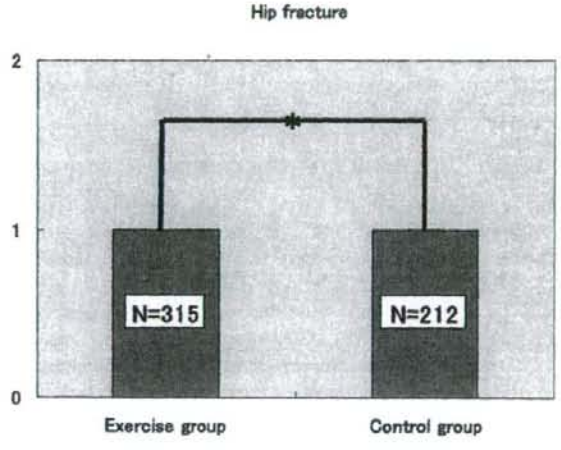

Fig. 2. Relationship of intervention to hip fractures (*Fisher's exact probability test: $P > 0.999$; *NS)

exercise group fell 60 times before the study and a total of 29 times after training; therefore, this subject was excluded from the statistical analysis. A Fisher's exact probability test was used to compare the cumulative number of falls between the exercise and control groups. A significant intergroup difference was observed ($P < 0.01$) (Fig. 1).

At 3 and 6 months after the start of the investigation, individuals who received a longer intervention tended to have lower P values, thus suggesting that the assessment of the effects of the intervention (training to stand on one leg with eyes open) was highly reliable.

Effects of unipedal standing balance exercise on hip fracture

At 1 month after the start of the study, a 61-year-old woman with Recklinghausen's disease in the control group had a femoral neck fracture. At 2 months after the start of the study, an 84-year-old woman with dementia in the exercise group had a femoral neck fracture. This fracture did not occur while the woman was exercising.

The incidence of hip fracture in the exercise group was 0.3% (1/315) whereas the incidence in the control group was 0.5% (1/212). However, this difference was not statistically significant (Fig. 2).

Discussion

The primary causes of hip fracture are osteoporosis of the femoral neck and falls.[8–11] According to an epidemiological study of hip fracture conducted by the Japanese Orthopaedic Association Osteoporosis Committee, a total of 110747 cases of femoral neck fracture were recorded from 1998 to 2000.[12] Of these, 74814 cases (74.0%) were caused by simple falls. Although the prevention of hip fracture using drugs is important,[13–16] these medications are very expensive.[17] From the point of view of cost-to-benefit ratio, a more effective way to prevent hip fracture would be to prevent falls.[3,4,18–20]

The following interventional exercise therapy programs have been demonstrated to be effective for preventing falls: muscle strengthening three times a week, balance training, and walking for 2 months[21]; 1 h muscle strengthening and endurance training three times a week for 6 months[21]; and a group Tai Chi class twice a week with two 15-min sessions of daily individual Tai Chi practice.[22] Although these exercise programs are effective for preventing falls, to remain effective they must be carried out continuously. However, it is difficult to administer an exercise program to elderly residents of nursing homes and nursing care facilities because of the difficulty faced by residents of these facilities in consistently carrying out the exercises. Therefore, it is necessary to design an exercise program that is more convenient for elderly individuals with various diseases who are at a higher risk for falls.

Several studies have reported that standing on one leg for 1 min with eyes open three times a day increases the bone mineral density of the femoral neck region.[23] Furthermore, it has been shown that unipedal standing for 1 min is equivalent to the amount of exercise gained through walking for approximately 53 min.[7]

In the present study, we investigated the effects of unipedal standing for 1 min with the eyes open on the prevention of falls and hip fracture in 553 residents of nursing homes and nursing care facilities. The cumulative number of falls over a 6-month period was 118 for the exercise group ($n = 314$) and 121 for the control group ($n = 212$). A Fisher's exact probability test showed a significant difference ($P = 0.0062$). Accordingly, with statistical significance established at the level of $P < 0.01$, the present exercise program was shown to prevent falls. However, as a single case of hip fracture was observed in each group, we could find no statistically significant intergroup difference for hip fracture incidence.

Conclusions

The results of the present study suggest that standing on one leg for 1 min with the eyes open is effective in preventing falls. Therefore, we believe that facilities should adopt this exercise program to prevent hip fracture among high-risk individuals.

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Urinary γ-glutamyltransferase (GGT) as a potential marker of bone resorption

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Abstract

We recently identified γ-glutamyltransferase (GGT) as a novel bone-resorbing factor. The present study was undertaken to determine whether GGT is a marker of bone resorption in two genetic models of hyper- and hypo-function of osteoclasts, as well as in postmenopausal women with accelerated bone resorption, using type I collagen N-telopeptide (NTX) and deoxypyridinoline (DPD) as established biochemical markers. Urinary excretion of GGT, corrected for creatinine, was found to be increased in osteoprotegerin (OPG)-deficient osteoporotic mice as well as in patients with postmenopausal osteoporosis (67–83 years of age); in both cases the urinary level decreased after treatment of patients or mice with alendronate, a selective inhibitor of bone resorption, concomitantly with a reduction in DPD and NTX. Conversely, in osteopetrotic *op/op* mice, urinary GGT increased in parallel with DPD after induction of osteoclasts with M-CSF injection. Constant infusion of parathyroid hormone (PTH) also increased urinary GGT along with DPD. In a survey of 551 postmenopausal women (50–89 years of age) at their regular health checkup, urinary GGT excretion exhibited a high correlation with DPD ($\rho = 0.49$, $p < 0.0001$). The calculated sensitivity and specificity for diagnosing elevated bone resorption, as determined by a DPD value higher than 7.6 nM/mM Cr, were 61% and 92%, respectively, when a cut-off value of 40 IU/g Cr was assigned for urinary GGT. Since GGT activity can be measured inexpensively in large numbers in a very short time, the measurement of urinary level may provide a convenient and useful method for mass screening to identify those with increased bone turnover and hence at increased risk for bone fracture.

Keywords: Osteoclast; Bone resorption; GGT

Introduction

Osteoporotic fractures are a major cause of morbidity and mortality in the aging population [1]. The annual incidence of hip fractures has been increasing and exceeded one hundred thousand cases in the most recent 2002 survey in Japan. The diagnosis of osteoporosis is made on the basis of bone mineral density (BMD) measurement, as in other countries [9]; however, due to the limited availability of devices for dual X-ray absorptiometry (DXA), the number of those who actually receive medical treatment is estimated to be only 20–30% of the more than 10 million patients with osteoporosis in our country. Thus, it is of utmost importance to develop a noninvasive, simple and inexpensive method to estimate bone fragility and the associated increased risk of fractures.

Although low BMD is the most reliable surrogate for the assessment of fracture risk, other traits, referred to collectively as "bone quality", entailing size, architecture, turnover, damage accumulation and mineralization, contribute to bone strength as well [1,21]. Among these, biochemical markers of bone turnover have been shown to predict the risk of fractures independently of BMD [5,6]. Bone undergoes continuous remodeling, in which bone resorption always precedes formation. Elevated

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