

- [27] J. S. Bauer, S. Kohlmann, F. Eckstein, D. Mueller, E. M. Lochmüller, and T. M. Link, "Structural analysis of trabecular bone of the proximal femur using multislice computed tomography: a comparison with dual X-ray absorptiometry for predicting biomechanical strength in vitro," *Calcified Tissue International*, vol. 78, no. 2, pp. 78–89, 2006.
- [28] L. M. Havill, M. C. Mahaney, T. L. Binkley, and B. L. Specker, "Effects of genes, sex, age, and activity on BMC, bone size, and areal and volumetric BMD," *Journal of Bone and Mineral Research*, vol. 22, no. 5, pp. 737–746, 2007.
- [29] N. Masunari, S. Fujiwara, Y. Nakata, K. Furukawa, and F. Kasagi, "Effect of angiotensin converting enzyme inhibitor and benzodiazepine intake on bone loss in older Japanese," *Hiroshima Journal of Medical Sciences*, vol. 57, no. 1, pp. 17–25, 2008.
- [30] J. M. P. Soriano, E. Ioannidou, J. Wang et al., "Pencil-beam versus fan-beam dual-energy X-ray absorptiometry comparisons across four systems: body composition and bone mineral," *Journal of Clinical Densitometry*, vol. 7, no. 3, pp. 281–289, 2004.
- [31] H. H. Bolotin and H. Sievänen, "Inaccuracies inherent in dual-energy x-ray absorptiometry in vivo bone mineral density can seriously mislead diagnostic/prognostic interpretations of patient-specific bone fragility," *Journal of Bone and Mineral Research*, vol. 16, no. 5, pp. 799–805, 2001.
- [32] H. H. Bolotin, H. Sievänen, J. L. Grashuis, J. W. Kuiper, and T. L. N. Järvinen, "Inaccuracies inherent in patient-specific dual-energy X-ray absorptiometry bone mineral density measurements: Comprehensive phantom-based evaluation," *Journal of Bone and Mineral Research*, vol. 16, no. 2, pp. 417–426, 2001.
- [33] H. H. Bolotin, H. Sievänen, and J. L. Grashuis, "Patient-specific DXA bone mineral density inaccuracies: quantitative effects of nonuniform extraosseous fat distributions," *Journal of Bone and Mineral Research*, vol. 18, no. 6, pp. 1020–1027, 2003.

# Why not use your own body weight to prevent falls? A randomized, controlled trial of balance therapy to prevent falls and fractures for elderly people who can stand on one leg for $\leq 15$ s

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## Abstract

**Background** Maintaining or improving motor (balance) ability is essential to extending the healthy lifespan of elderly people, and developing effective and efficient strategies to prevent falls of elderly people is an urgent. The purpose of this study was to determine the effects of balance exercise on fall and fracture prevention for elderly people with poor balance.

**Methods** A 6-month, randomized controlled trial was conducted to verify whether one-leg standing with eyes open for a total of 1 min, three times a day (dynamic flamingo exercise) prevents falls and fractures. Setting and

participants were elderly people  $\geq 75$  years of age and one-leg standing time  $\leq 15.0$  s living in their own home. They were visiting orthopaedic clinics for orthopaedic handicaps. Subjects with poor balance were allowed to hold on to something. If a subject's lifted leg touched the ground during the exercise, they were allowed to lift it again and continue so that they stood on one leg for a total of 60 s. **Results** The dynamic flamingo exercise group (410 people; 86 men, 324 women) and the no exercise group (455 people; 78 men, 377 women) were compared. After dynamic flamingo exercise for 6 months, significant differences were seen in the increase in one-leg standing time with eyes open (men right/left, women right/left), in the improvement in independence in daily living (women), number of people who fell during the 6 months (women),

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and adverse events (women). The number of fractures was not significantly different for men or women.

**Conclusions** Dynamic flamingo exercise prevents falls but no significant difference was demonstrated in fracture prevention in elderly women with poor balance.

## Introduction

As the aging of society accelerates, a very important question is how to maintain daily living functions in elderly people so that they can spend their remaining life comfortably. Elderly people with underlying osteoporosis are susceptible to fractures of the proximal femur, and their mortality 1 year after a fracture is high (10–27 %) [1–3]. Prevention of proximal femur fractures is believed to be beneficial for extending the healthy life span of elderly people. One-third of elderly people  $\geq 65$  years of age are said to fall once a year [4], and more than half of these need to be hospitalized for trauma accompanying the fall [5]. Strategic development and implementation of effective and cost-efficient means of preventing falls of elderly people is a pressing global health challenge. Sherrington et al. [6], conducted a systematic review and meta-analysis of the most effective methods for fall prevention, and concluded that effective methods are training for  $\geq 50$  h during trials, training in standing on both legs with narrow bases of support, or center of gravity balance control training standing on one leg. Walking training was not included among the most effective methods. Selection of methods with superior cost performance must also be considered in exercise training [7].

Haeney [8] listed three elements related to the growth and deterioration of bone: genetics, endocrine activity, and mechanical stress. As seen from this, mechanical stress is a crucial element for bone metabolism. Bone density of the proximal femur of astronauts returning to earth after a space flight of 6 months, during which time there is little mechanical stress, requires a long period of approximately 900 days to return to its original level [9]. Various kinds of exercise therapy are recommended, but this exercise therapy must combine three basic rules:

1. dynamic loading;
2. short duration; and
3. customary mechanical loading environment [10].

To prevent fractures of the proximal femur caused by minor trauma when osteoporosis is a background factor, it is necessary not only to prevent falls but also to apply loads to the proximal femur to increase its density and to improve bone quality and strengthen the bone.

Standing on one leg with the eyes open for 1 min 3 times a day (dynamic flamingo (DF) therapy [11]), uses the fact that one-leg standing places a load on the femoral head that is 2.75 times greater than the load on one leg when standing on two legs. This exercise theory is based on the finding, for the elderly, that the total load on the femoral head when standing on one leg with eyes open for 1 min is equivalent to the total load placed on the femoral head on one side from walking for 53.3 min (160/3 min) [12]. DF therapy has points in common with Tai Chi exercise, which is reported to be effective in preventing falls [13, 14]. It is also reported to be effective in increasing bone density in the proximal femur [15, 16]. DF therapy is exercise that uses the body's own weight as mechanical stress, and it requires no special equipment. It is also a very simple exercise therapy that does not require special exercise instruction. A randomized trial was conducted for 6 months to determine whether this DF therapy is, in general, effective in preventing falls and fractures for elderly people with an orthopedic handicap who live at home. If this therapy were to be effective in fall prevention, it may be beneficial in preventing femoral neck fractures by increasing bone density in the femoral neck and preventing falls.

## Subjects

The subjects were men and women  $\geq 75$  years of age who lived at home and visited an orthopedic clinic or hospital for an orthopedic handicap and who could stand on one leg, both right and left, with the eyes open for  $\leq 15$  s (the Ministry of Health, Labor, and Welfare of Japan designates men and women  $\geq 75$  years of age who can stand on one leg with eyes open for  $\leq 15$  s as having musculoskeletal ambulation disability symptom complex). The time of one-leg standing with eyes open for the left and right legs is measured with the subject standing on one leg with both hands placed at the hips until the subject takes a hand off his or her hip or the other leg hits the floor. The subject is first allowed one attempt as practice, and the second attempt is measured using a stopwatch to the first decimal place. The time of one-leg standing with eyes open was measured for up to 20 s for each leg for elderly individuals

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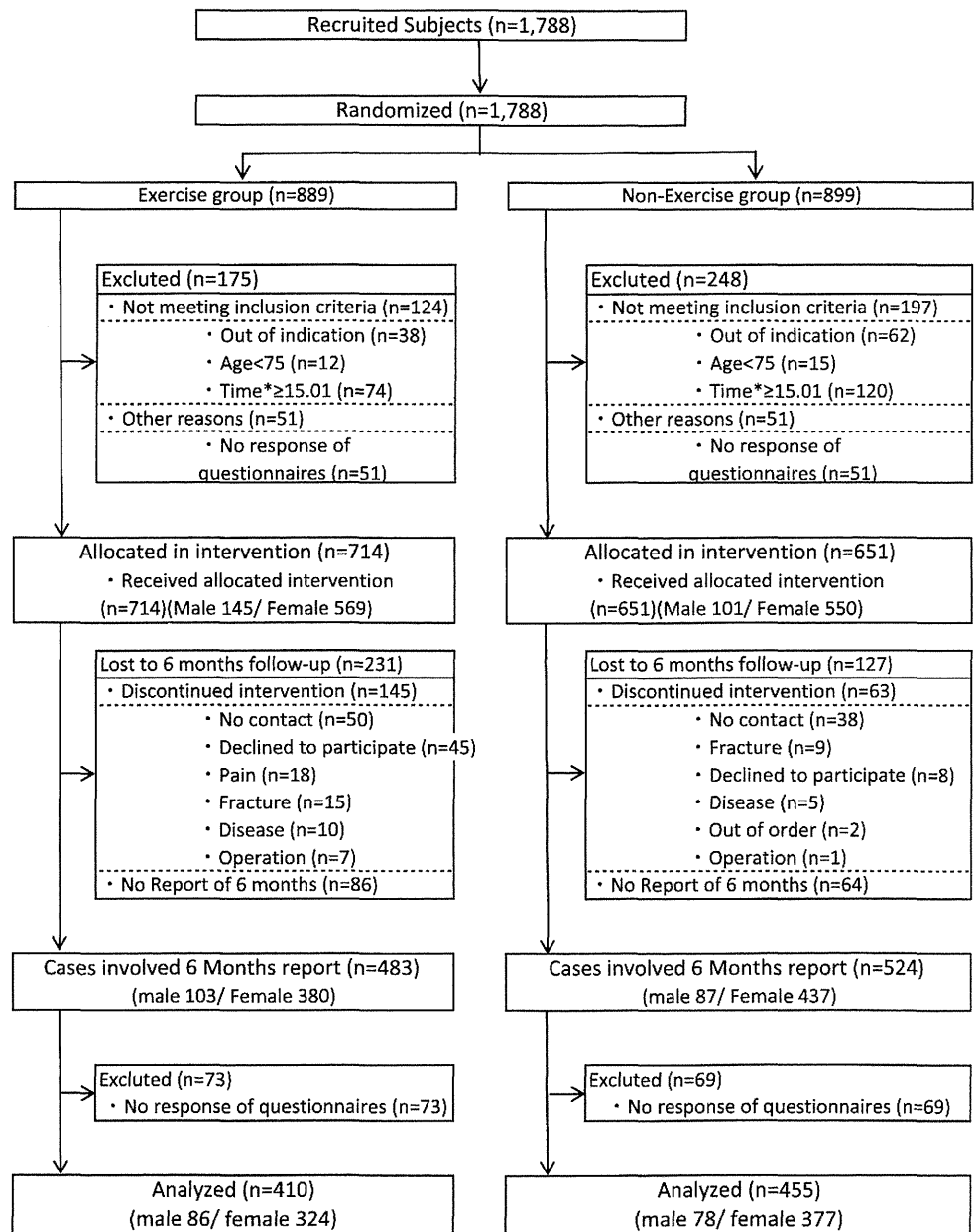
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aged  $\geq 75$  years, and those with a time  $\leq 15$  s for both legs were allocated to the Entry group. To ensure accuracy in judgments of the effect of one-leg standing exercise training, subjects were usually people with the ability to communicate and those who could continue training. It had been recommended to these people that they participate in exercise without DF therapy. After presenting a written explanation, consent was obtained from the subjects in writing for participation in the clinical study. People with Parkinson's disease or other conditions that made them susceptible to falls, people with artificial joints, and people

with cognitive disorders were excluded. From April 2007 until March 2010, 1,788 subjects were recruited (exercise group 889, non-exercise group 899; Fig. 1; flow diagram: trial profile [17]). Those who did not meet the stipulations were excluded, as were subjects with no responses for dominant leg, weight, height, and other items on a questionnaire. Next, those for whom there was no report at the end of the 6 months were excluded. Final reports were collected for 483 people in the exercise group and 524 in the no exercise group. Of these, those with items with no responses in the report were excluded. The comparative

**Fig. 1** Flow diagram trial profile



\*Time: Unipedal standing time

**Table 1** Diagnosis of subjects at baseline survey between exercise group and non-exercise group (the first diagnosis name described on report sheet)

Female		Non-exercise group		Male	
Exercise group		Diagnosis	N	Exercise group	
Diagnosis	N	Diagnosis	N	Diagnosis	N
OA (knee)	97	OA (knee)	97	Spondylosis deformans	24
Osteoporosis	72	Osteoporosis	90	LCS	14
LSD	31	LCS	45	OA (knee)	13
LCS	30	LSD	40	Osteoporosis	6
Spondylosis deformans	18	Vertebral fracture	22	Cervical spondylosis	5
Painful shoulder	10	Cervical spondylosis	21	LDD	4
Cervical spondylosis	8	Non-vertebral fracture	12	Diabetes meritis	4
Hypertension	7	Rheumatic arthritis	10	Lumbar spondylosis	3
Vertebral fracture	6	Painful shoulder	8	Painful shoulder	3
MAD	5	LDD	7	Vertebral fracture	2
Low back pain	4	Heart disease	4	etc.	8
CTS	4	OA (shoulder)	3	Total	86
Non-vertebral fracture	4	MAD	2		
LDD	3	OA (hip)	2	Non-exercise group	
Lumbar disc hernia	3	Low back pain	2	Diagnosis	N
Cranial infarct	3	etc.	13	LCS	16
Rheumatic arthritis	2	Total	378	OA (knee)	15
CDD	2			Spondylosis deformans	13
Scoliosis	2			Osteoporosis	8
Rotator cuff injury	2			Cervical spondylosis	8
etc.	11			Painful shoulder	4
Total	324			Lumbar disc hernia	3
				Rheumatic arthritis	3
				Gout	2
				etc.	6
				Total	78

## Exercise group versus non-exercise group

OA osteo arthritis, LSD lumbar spondylosis deformans, LCS lumbar canal stenosis, MAD musculoskeletal ambulation disability symptom complex, CTS carpal tunnel syndrome, LDD lumbar disc degeneration, CDD cervical disc degeneration, N number

analysis was finally conducted with 410 people from the exercise group (86 men, 324 women) and 455 people from the no exercise group (78 men, 377 women).

The ailments diagnosed in each group are listed in Table 1. Among women in both groups, osteoarthritis of the knee was the most common ailment (97 subjects). Among men, spondylosis deformans was the most common in the exercise group (24 subjects), and lumbar canal stenosis was the most common in the no exercise group (16 subjects).

## Methods

Application for approval of this study was made to the Ethics Committee of the School of Showa University, and

the randomized, controlled trial (RCT) was conducted for 6 months after approval was obtained. To prevent feelings of unfairness among participants, random allocation to the intervention group (exercise group) or control group (non-exercise group) was conducted at the institution level, meaning that all participants attending the same institution belonged to the same group. The following randomization method was applied. The  $10 \times 5 (= 50)$  random number tables with  $5 \times 5 (25)$  numbers were prepared and 2 ten-faced dice (one green, one yellow) were thrown to decide which table to use. Two six-faced dice were then thrown to select the number within the chosen random number table to decide whether the institution would be designated an exercise or non-exercise institution. Dice were repeatedly thrown in this manner until the target number of facilities had been allocated to each group.

Subjects were recruited with the cooperation of the Japanese Orthopaedic Association and the Japanese Society for Musculo-skeletal Rehabilitation over 3 years from April 2007 to March 2010. They were patients undergoing outpatient orthopedic treatment or rehabilitation who could stand on one leg with eyes open for  $\leq 15$  s with both the left and right leg. They were divided into a group that did one-leg standing exercise with eyes open for 1 min 3 times a day and a group that did not do this exercise. The effectiveness of exercise training in preventing falls and fractures was then examined.

In the DF exercise, people with poor balance held on to a table, chair, bar, or other object while standing on one leg (when they became accustomed to this, they stood on one leg without holding on to anything). If their free leg touched the ground, they lifted it once more so the total one-leg standing time was 60 s. They stood on one leg for a total of 1 min in this way 3 times a day with each leg. The basic position for one-leg standing was to have one leg swung slightly forward with the knee bent, but the subjects were free to adopt any one-leg standing position. However, when standing on one leg, precautions such as a table, chair, or bar were in place to prevent falls, in case the person lost his or her balance. The exercise was done as a home exercise so that it could be continued daily. To confirm the exercises were done, every day subjects were asked to complete a “Flamingo Record” with a “●” when the exercises were done 3 times a day, a “Δ” on days of falls, and an “x” for fracture (fracture was confirmed and recorded by a doctor). Exercises were continued every day, but 2 days off a week were allowed, and the Flamingo Record was checked at the time of examination at a clinic once a month.

The initial survey items for the subjects were: 1. sex, 2. date of birth, 3. dominant leg, 4. age at the start of exercise, 5. weight, 6. height, 7. one-leg standing time with eyes open (right, left), 8. name of primary disease, 9. medical history, 10. history of fracture, 11. complications, 12. presence or absence of osteoporosis, 13. medications, 14. number of falls in past year, 15. exercise habit, 16. use of cane or walking aid, and 17. level of ADL independence\*. At the end of 6 months, items 5, 6, 7, 10 (fracture), 14 (falls or no falls, and number), 19 (ADL\*), and 20 (adverse events) were surveyed.

\*ADL: by Long-Term Care Insurance Act (The Ministry of Health, Labor and Welfare of Japan, December 17th 1997) (Table 2).

Statistical analysis was conducted by consulting statisticians (Hamano Statistical Analysis). The software used was SAS System 91.3 (SAS Institute), with the paired *t* test used for means and McNemar’s test used for proportions.

**Table 2** Classification of the disability of elderly people

ADL independent (people have some disability but ADL are independent and they go out without help)
J1: Able to go out using public transport
J2: Able to go out to visit neighbors only
ADL dependent (requires assistance to leave home)
A. Lives independently indoors but requires assistance to go out
A1: Goes out with assistance, stays out of bed most of the day
A2: Seldom goes out, has several rests in bed during the day (Nearly bedridden)
B. Requires some assistance living indoors and spends most of the day in bed, although sitting up
B1: Uses a wheelchair to move about, but gets up for meals and to go to the toilet
B2: Moves about in a wheelchair with assistance (Completely bedridden)
C. Spends all day in bed requires assistance to urinate/defecate
C1: Can turn over in bed unassisted
C2: Cannot turn over in bed unassisted

By Long-Term Care Insurance Act (The Ministry of Health, Labor and Welfare of Japan, December 17th 1997)

## Results

A comparison of men and women in the DF exercise group and the no exercise group at the start of the RCT (Table 3) revealed that, in men, there were more users of canes and aids in the no exercise group. Other than that, there were no significant differences in items from dominant leg to level of ADL independence. In women, one-leg standing time was increased with both legs, number of falls in the past year was greater, level of independence in activities of daily living (ADL) was higher in the exercise group. No significant differences were seen in other items between the groups. No significant differences were seen between the groups other than in sex, height, weight, and history of fracture. In a comparison of the DF exercise group and the no exercise group at the completion of the 6-month RCT (Table 4), one-leg standing time on both the right and left legs was clearly and significantly increased in the exercise group. However, no significant difference was seen other than in one-leg standing time in men. In women, on the other hand, in the exercise group, one-leg standing time with both the right and left legs was increased, there were fewer people who fell, and the level of ADL independence was higher. However, no significant difference was seen between the groups in the mean number of falls. There were also significantly more adverse events in the exercise group.

Data for men at the time of baseline for the RCT and after 6 months were compared (Table 5). In the DF exercise group, body weight decreased after 6 months of exercise training, and one-leg standing time with both the right and left legs was increased approximately 3 times. In

**Table 3** Comparison of clinical data at baseline survey between exercise group and the non-exercise group

	Male			Female		
	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value
Number	86	78		324	377	
Dominant leg: right	77 (89.5)	72 (92.3)	0.538 <sup>#</sup>	283 (87.3)	331 (87.8)	0.856 <sup>#</sup>
Age (years)	80.5 ± 4.1	80.7 ± 4.0	0.3548 <sup>§</sup>	80.1 ± 4.0	80.5 ± 4.1	0.199 <sup>§</sup>
Weight (kg)	58.8 ± 9.8	58.5 ± 10.6	0.849 <sup>§</sup>	49.8 ± 8.2	49.6 ± 8.9	0.755 <sup>§</sup>
Height (cm)	158.9 ± 6.1	159.7 ± 6.7	0.458 <sup>§</sup>	147.0 ± 5.9	146.4 ± 6.1	0.191 <sup>§</sup>
One leg time (right)	5.8 ± 4.2	5.6 ± 3.8	0.836 <sup>§</sup>	5.9 ± 4.1	5.1 ± 3.8	0.013 <sup>§</sup>
One leg time (left)	5.2 ± 3.7	5.4 ± 3.6	0.731 <sup>§</sup>	5.9 ± 4.0	5.2 ± 3.8	0.025 <sup>§</sup>
History of fracture	25 (29.1)	27 (34.6)	0.446 <sup>#</sup>	134 (41.4)	167 (44.3)	0.433 <sup>#</sup>
Complication	78 (90.7)	73 (93.6)	0.446 <sup>#</sup>	285 (88.0)	318 (84.4)	0.169 <sup>#</sup>
Osteoporosis	17 (19.8)	14 (17.9)	0.766 <sup>#</sup>	251 (77.5)	276 (73.2)	0.193 <sup>#</sup>
Falls yes/no	23 (26.7)	27 (34.6)	0.274 <sup>#</sup>	120 (37.0)	114 (30.2)	0.057 <sup>#</sup>
No. of falls	0.5 ± 1.3	1.3 ± 3.8	0.09 <sup>§</sup>	1.1 ± 2.2	0.6 ± 2.0	0.005 <sup>§</sup>
Exercise habit yes/no	41 (47.7)	39 (50.0)	0.766 <sup>#</sup>	127 (39.2)	186 (49.3)	0.007 <sup>#</sup>
Use of aids yes/no	16 (18.6)	31 (39.7)	0.003 <sup>#</sup>	114 (35.2)	159 (42.2)	0.059 <sup>#</sup>
ADL Independence	81 (94.2)	71 (91.0)	0.438 <sup>#</sup>	310 (95.7)	344 (91.2)	0.019 <sup>#</sup>

Dominant leg, leg to kick a ball, number of right leg (%); age, average (Av) years ± standard deviation (SD); weight, Av ± SD; height, Av ± SD; one leg time, one leg standing time (seconds) with eyes open, Av ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); No. of falls, number of falls in 1 year, Av ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J\*1 + J\*2)

J\*1, J\*2: criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

<sup>#</sup> The paired *t* test for means

<sup>§</sup> McNemar's test used for proportions

the no exercise group, on the other hand, one-leg standing time on the left side increased significantly, but there were no other significant differences.

In a comparison of the data at the time of RCT registration and after 6 months for women (Table 6), after 6 months, weight and height decreased and one-leg standing time with both the right and left leg increased significantly in the DF exercise group. Because the survey period differed for fractures (history), number of people who fell, and number of falls, tests of significance were not conducted. For the women in the no exercise group, on the other hand, one-leg standing time with both the right and left legs was significantly increased, but the increase in the number of seconds was small. It was supposed all participants had some physical treatment at their clinics or hospitals and their therapy was apparent as good effects on time dependence. For both men and women, the one-leg standing time with eyes open in the no exercise group increased significantly after 6 months compared with the time of entry, but the increase in the one-leg standing time with eyes open was much larger in the DF exercise group. The number of fractures, which is viewed as the most important outcome, was 10 in the no exercise group in women

(5 compression fractures of the spine, 3 rib fractures, 1 fracture of the scaphoid bone, and 1 fracture of the proximal femur) versus 3 in the DF exercise group (2 fractures of the distal radius and 1 fracture of the fifth metacarpal bone). The number was larger in the no exercise group, but there was no significant difference. Among men, there was one compression fracture of the spine in the DF exercise group and one fracture of the distal radius in the no exercise group. No significant difference was seen between the groups. There was one adverse event (knee pain) in men and four (knee pain 1, lower limb pain 1, palpitations 1, fall during training 1) in women in the DF exercise groups.

## Discussion

Methods to prevent proximal femur fractures include treatment for osteoporosis, which is a background factor that is a risk for proximal femur fractures, and fall prevention. Currently, many drugs, including bisphosphonates [18, 19], alfacalcidol [20, 21], and selective estrogen receptor modulators (SERM) [22, 23], are widely used for treatment of osteoporosis. Many reports on exercise

**Table 4** Comparison of clinical data at 6-month survey between exercise group and non-exercise group

	Male			Female		
	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value	Exercise group (%)	Non-exercise group (%)	Statistical <i>p</i> value
Number	86	78		324	377	
Weight (kg)	58.4 ± 9.8	58.8 ± 10.9	0.815 <sup>§</sup>	49.3 ± 7.9	49.6 ± 9.1	0.641 <sup>§</sup>
Height (cm)	158.2 ± 7.9	159.4 ± 6.8	0.290 <sup>§</sup>	146.6 ± 6.1	146.2 ± 6.1	0.401 <sup>§</sup>
One leg time (right)	17.7 ± 35.1	6.4 ± 5.0	0.004 <sup>§</sup>	16.2 ± 21.6	7.2 ± 7.9	<0.000 <sup>§</sup>
One leg time (left)	19.3 ± 44.4	6.7 ± 6.0	0.011 <sup>§</sup>	15.0 ± 21.2	6.1 ± 6.1	<0.000 <sup>§</sup>
Cases of fracture	1 (1.2)	1 (1.3)	0.945 <sup>#</sup>	3 (0.9)	10 (2.7)	0.091 <sup>#</sup>
Falls yes/no	10 (11.6)	14 (17.9)	0.253 <sup>#</sup>	46 (14.2)	78 (20.7)	0.025 <sup>#</sup>
No. of falls	0.2 ± 0.8	0.5 ± 1.7	0.183 <sup>§</sup>	0.3 ± 1.2	0.3 ± 0.7	0.687 <sup>§</sup>
ADL independence	82 (95.3)	72 (92.3)	0.416 <sup>#</sup>	313 (96.6)	345 (91.5)	0.005 <sup>#</sup>
Adverse event	1 (1.2)	0 (0.0)	0.339 <sup>#</sup>	4 (1.2)	0 (0.0)	0.031 <sup>#</sup>

Weight, average ± standard deviation (Av ± SD); height, Av ± SD; one leg time, one leg standing time (seconds) with eyes open, Av ± SD; cases of fracture, number of fracture cases (%); falls yes/no, number of people (yes) who had a fall in past 6 months (%); No. of falls, number of falls in 6 months, Av ± SD; ADL independence, number of people who are independent in activities of daily living (J\*1 + J\*2), (%); adverse event, number of adverse events, (%)

J\*1, J\*2: criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

# The paired *t* test for means

§ McNemar's test used for proportions

therapy with the objective of preventing falls have also been published. However, they include reports that such therapy is both ineffective [24, 25] and effective [13, 26, 27]. A common point among reports that exercise therapy is effective in preventing falls is that the exercise is not short, vigorous exercise but slow, sustained mechanical load. Balance control by standing on both legs with a narrow base of support or standing on one leg is also recommended [6, 10].

Although DF exercise is a method of repeating one-leg standing exercise with eyes open for the short time of 1 min, 3 times a day, it is thought to satisfy the three basic rules stated by Turner [10]. DF exercise is a profoundly superior exercise in that it is a means of placing a mechanical load on the femoral head. It is also useful in balance training. In this RCT, the increase in one-leg standing time in the DF exercise groups in both men and women compared with the time of entry (men 3.1–3.7 times, women 2.5–2.7 times longer) was striking. In a study using Cybex II [28], the one-leg standing time with eyes open for elderly people ≥65 years of age reflected the strength of the quadriceps femoris muscle of that person. When knee extensor muscle strength dropped below 0.60 Nm/kg, one-leg standing for 30 s was impossible, and when it dropped below 0.40 Nm/kg, one-leg standing for 5 s was impossible. The increase in one-leg standing time with eyes open resulted in strengthening of that person's quadriceps femoris muscle. One-leg standing with eyes

open also reflects a person's ADL and mortality [29]. Elderly people who can stand on one leg for ≥30 s are judged to be active people. For elderly people ≥70 years old, those who can stand for a long time on one leg with eyes open are reported to have high bone density [30]. Increase in one-leg standing time with eyes open leads to a larger total mechanical stress load on the femoral head, and is advantageous for improving bone density of the proximal femur. There is a good correlation between one-leg standing time with eyes open and the timed up-and-go test, which is used to assess motor ability in elderly people. Measurements of one-leg standing time with eyes open can be used as a simple means of judging the vitality of elderly people.

Looking at the results of this RCT, it can be seen that, while the increase in one-leg standing time with eyes open was marked for both men and women in the DF exercise group, there was a male–female difference in the decrease in the number of people who fell. A significant difference was not seen among men, but a significant difference was seen among women. Comparison of the number of people who were independent in ADL, which is thought to best reflect improvement in the level of vitality from DF exercise, revealed no significant difference between the DF exercise group and the no exercise group in men, but showed that there were significantly more independent people in the exercise group in women. However, no significant difference was seen in either men or women in the mean number of falls.



**Table 5** Comparison of data between baseline and at 6 months (male)

	Male					
	Exercise group (%)			Non-exercise group (%)		
	Baseline	6 months	Statistical <i>p</i> value	Baseline	6 months	Statistical <i>p</i> value
Number	86	86		78	78	
Dominant leg: right	77 (89.5)	–	–	72 (92.3)	–	–
Age (years)	80.5 ± 4.1	–	–	80.7 ± 4.3	–	–
Weight (kg)	58.8 ± 9.8	58.4 ± 9.8	0.028 <sup>§</sup>	58.5 ± 10.6	58.8 ± 10.9	0.353 <sup>§</sup>
Height (cm)	158.9 ± 6.1	158.2 ± 7.9	0.246 <sup>§</sup>	159.7 ± 6.7	159.4 ± 6.8	0.313 <sup>§</sup>
One leg time (right)	5.8 ± 4.2	17.7 ± 35.1	0.002 <sup>§</sup>	5.6 ± 3.8	6.4 ± 5.0	0.089 <sup>§</sup>
One leg time (left)	5.2 ± 3.7	19.3 ± 44.4	0.004 <sup>§</sup>	5.4 ± 3.6	6.7 ± 6.0	0.019 <sup>§</sup>
History of fracture	25 (29.1)	1 (1.2)	– <sup>‡</sup>	27 (34.6)	1 (1.3)	– <sup>‡</sup>
Complication	78 (90.7)	–	–	73 (93.6)	–	–
Osteoporosis	17 (19.8)	–	–	14 (17.9)	–	–
Falls yes/no	23 (26.7)	10 (11.6)	– <sup>‡</sup>	27 (34.6)	14 (17.9)	– <sup>‡</sup>
No. of falls	0.5 ± 1.3	0.2 ± 0.8	– <sup>‡</sup>	1.3 ± 3.8	0.5 ± 1.7	– <sup>‡</sup>
Exercise habit yes/no	41 (47.7)	–	–	39 (50.0)	–	–
Use of aids yes/no	16 (18.6)	–	–	9.7	–	–
ADL Independence	81 (94.2)	82 (95.3)	0.564 <sup>#</sup>	71 (91.0)	72 (92.3)	0.564 <sup>#</sup>
Adverse event	–	1 (1.2)	–	–	0 (0.0)	–

Dominant leg, leg to kick a ball, number of right leg (%); age, average years ± standard deviation (SD); weight, average ± SD; height, average ± SD; one leg time, one leg standing time (seconds) with eyes open, average ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); no. of falls, number of fall times in 1 year, average ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J\*1 + J\*2); adverse event, number of people (%)

J\*1, J\*2: Criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

<sup>#</sup> The paired *t* test for means

<sup>§</sup> McNemar's test used for proportions

<sup>‡</sup> No statistical analysis because of different observation period

One-leg standing with eyes open for 1 min 3 times a day can be continued daily without undue effort or the use of special equipment. It is effective not only in the prevention of falls, but also in improving bone density in the femoral neck [30], and it is also expected to be effective in preventing fractures of the proximal femur. In this 6-month RCT, however, no significant difference was seen in prevention of proximal femur fractures (DF exercise group 0 fractures, no exercise group 1 fracture). From these results, it is thought that, although DF exercise is an effective exercise therapy for improving leg muscle strength in men and women who can stand on one leg with eyes open for ≤15 s, in intervention to reduce the number of people who fall, DF exercise results in too small an exercise load for men but is effective exercise therapy for preventing falls in women. In addition, one-leg standing with eyes open may tend to induce pain in the knees or legs because it increases the load on the standing side. It is necessary to prevent falls

during training, and adequate fall prevention instruction (to hold on to a bar or how to put the free leg down on the floor, to fall forward, etc.) is required before implementing the exercise training. For adverse events during DF training, it is thought that leg alignment can be corrected by providing wedge-shaped foot plates to prevent knee and leg pain.

In conclusion, DF exercise is effective exercise therapy for increasing one-leg standing time and improving leg muscle strength in men and women ≥75 years of age who can stand on one leg with eyes open for ≤15 s. DF exercise did not seem to prevent falls in elderly men, but a significant difference in falls was seen in women ≥75 years of age. However, no significant difference was demonstrated for fracture prevention. Even so, an increase in one-leg standing time with eyes open is thought to lead to prevention of fractures of the proximal femur for 75-year-old women with osteoporosis.

**Table 6** Comparison of data between baseline and 6 months (female)

	Female					
	Exercise group (%)			Non-exercise group (%)		
	Baseline	6 months	Statistic <i>p</i> value	Baseline	6 months	Statistic <i>p</i> value
Number	324	324		377	377	
Dominant leg: right	283 (87.3)	–	–	331 (87.8)	–	–
Age (years)	80.1 ± 4.0	–	–	80.5 ± 4.1	–	–
Weight (kg)	49.8 ± 8.2	49.3 ± 7.9	0.001 <sup>§</sup>	49.6 ± 8.9	49.6 ± 9.1	0.781 <sup>§</sup>
Height (cm)	147.0 ± 5.9	146.6 ± 6.1	0.001 <sup>§</sup>	146.4 ± 6.1	146.2 ± 6.1	0.011 <sup>§</sup>
One leg time (right)	5.9 ± 4.1	16.2 ± 21.6	<.000 <sup>§</sup>	5.1 ± 3.8	7.2 ± 7.9	<.000 <sup>§</sup>
One leg time (left)	5.9 ± 4.0	15.0 ± 21.2	<.000 <sup>§</sup>	5.2 ± 3.8	6.1 ± 6.1	0.002 <sup>§</sup>
History of fracture	134 (41.4)	3 (0.9)	– <sup>‡</sup>	167 (44.3)	10 (2.7)	– <sup>‡</sup>
Complication	285 (88.0)	–	–	318 (84.4)	–	–
Osteoporosis	251 (77.5)	–	–	276 (73.2)	–	–
Falls yes/no	120 (37.0)	46 (14.2)	– <sup>‡</sup>	114 (30.2)	78 (20.7)	– <sup>‡</sup>
No. of falls	1.1 ± 2.2	0.3 ± 1.2	– <sup>‡</sup>	0.6 ± 2.0	0.3 ± 0.7	– <sup>‡</sup>
Exercise habit yes/no	127 (39.2)	–	–	186 (49.3)	–	–
Use of aids yes/no	114 (35.2)	–	–	159 (42.2)	–	–
ADL Independence	310 (95.7)	313 (96.6)	0.366	344 (91.2)	345 (91.5)	0.796 <sup>#</sup>
Adverse event	–	4 (1.2)	–	–	0 (0.0)	–

Dominant leg, leg to kick a ball, number of right leg (%); age, average years ± standard deviation (SD); weight, average ± SD; height, average ± SD; one leg time, one leg standing time (seconds) with eyes open, average ± SD; history of fracture, number with fracture history (%); complication, number of people who had complications (%); osteoporosis, number of people who had osteoporosis (%); falls yes/no, number of people (yes) who had a fall in past year (%); no. of falls, number of falls in 1 year, average ± SD; exercise habit yes/no, number of people (yes) who have exercise habit (%); use of aids, number of people (yes) who use of cane or walking aid (%); level of ADL, number of people who are independent in activities of daily living (J\*1 + J\*2); adverse event, number of people (%)

J\*1, J\*2: Criteria for independence in ADL by the Ministry of Health, Labour and Welfare of Japan

<sup>#</sup> The paired *t* test for means

<sup>§</sup> McNemar's test used for proportions

<sup>‡</sup> No statistical analysis because of different observation period

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**Conflict of interest** The authors declare no conflict of interest related to this study.

## Appendix: Principal Clinical sites

Furukawabashi Hospital, Kimuramorokado Hospital, Takatsu Chuoh Hospital, Kamiitabashi Dai2 Hospital, Nishikamata Clinic, Kyoudou Clinic, Kuchiishi Hospital, Kobayashi Clinic, Tsurumaki Orthopaedic Clinic, Sawatari Clinic, Kayama Orthopaedic Clinic, Musashiyamoto

Orthopaedic Clinic, Suzuki Orthopaedic Clinic, Sekimizu Orthopaedic Clinic, Central Hospital, Sakura Orthopaedic & Rehabilitation Hospital, Fukuzawa Orthopaedic Clinic, Furuoka Orthopaedic Clinic, Maeda Hospital, Yoshimura Orthopaedic Clinic, Chouritu Ogano Central Hospital, Tomakomai Hospital, Toyooka-Central Hospital, Hirosaki City Hospital, Iwate Medical University, Tokyo Kyouzai Hospital, Yonehara-Central Hospital, Tokyo Jikeikai Medical University, Toho University Ohashi Hospital, Tokyo Metropolitan Rehabilitation Hospital, Kugayama Hospital, Washiya Hospital, Dokyou Medical University, Rounenbyo-Kenkyusyo Hospital, Shirogane Orthopaedic Hospital, Kikkouman Clinic, Shinnkawabashi Hospital, Yamanashi Prefectural Hospital, Nirasaki City Hospital, Fukui University, Gifu University, Ohgaki Central Hospital, Kouritu Morinomachi Hospital, Mie University, Yamada Orthopaedic Hospital, Maizuru Red-Cross Hospital, PL Hospital, Saiseikai Suita Hospital, Kinki University Sakai Hospital, Kobe 100 Nen Kinen Hospital, Kouritu Toyo-oka Hospital, Hyougo Medical University, Mimuro Prefectural

Hospital, Nara Rehabilitation Centre, Misasa Onsen Hospital, Sanin Rosai Hospital, Kaike Onsen Hospital, Okayama University, Cyugoku Denryoku Hospital, Kosei Sogou Hospital, Kagawa Rosai Hospital, Tosa City Hospital, University of Occupational and Environmental Health, Sinal Cord Injury Centre, Kawashima Orthopaedic Hospital, Ohita Orthopaedic Hospital, Kumamoto University, Miyazaki University, Nichinan Hospital, Komaki Hospital, Iida Hospital, Showa University, Kouritsu Tannan Hospital, Showa University Yokohama Hokubu Hospital, Hiraosaki Kinenn Hospital, Teikyuu University Chiba Medical Centre, Shiota Sogo Hospital, Sekigawara Hospital, Tsusima City Hospital, Minamikawa Orthopaedic Hospital, Isahaya Sogo Hospital, Tkachiho-Mmachi Hospital, Kusimaoto Hospital, Momotake Orthopaedic Hospital, Kumamoto Kino Hospital, Kitade Hospital, Uguisu-Yado Onsen Hospital, Hachiya Orthopaedic Hospital, Yonago Medical Centre, Seibu Shimane Medical Centre, Hiroshima Tetsudo Hospital, Moji Rosai Hospital, Kimachi Rehabilitation Hospital, Ohta Sogo Hospital, Sapporo Eikeigeka-Jyunkanki Hospital, Aomaori Prefectural Hamanasu Medical Centre, Edogawa Hospital, Gamagouri City Hospital, Suga Orthopaedic Hospital, Tamana Central Hospital, Kijima Orthopaedic Clinic, Seigo Clinic, Niigata Rehabilitation Hospital, Nakamura Orthopaedic Clinic, Murai Orthopaedic Hospital, Noto Orthopaedic Clinic, Nakayama Orthopaedic Clinic, Asai Orthopaedic Clinic, Yanagi Orthopaedic Clinic, Kojima Orthopaedic Clinic, Ishizaka Orthopaedic Clinic, YUkiyoshi Clinic, Takahashi Orthopaedic Clinic, Ohkawa Clinic, Motomachi Hospital, Iwate Medical University Hanamaki Onsen Hospital, Mizuhara-Go Hospital, Nissan Tamagawa Hospital, National Center for Geriatrics and Gerontology, Tomizawa Hospital, Sato Hospital, Ehime National Hospital, Ishikawa Prefectural Central Hospital, Chikuma Central Hospital, Ohta Hospital, Mazda Hospital, Ube Kyouritu Hospital, Yokohama City University, Kusunoki Orthopaedic Clinic, Nezu Orthopaedic Clinic, Kubota Orthopaedic Clinic, Saiseikai Otaru Hospital, National Hirosaki Hospital, Sanai Hospital, Yamanaka Onsen Hospital, Sakasita Hospital, Yoshida Orthopaedic Clinic, Jinsen Onsen-Kaigo Rehabilitation, Suzuka Central Hospital, National Kochi Hospital, Ohita Jyunkannki Hospital, Honma Orthopaedic Clinic, Ishii Clinic, Niigata Prefectural Kamo Hospital, Kuwana Hospital, Nishi Niigata Central Hospital, Akishima Hospital, Namekawa Hospital, Kita Orthopaedic Clinic, Sanyudo Hospital, Yonago Higashi Hospital, Tama Hokubu Medical Centre, Ohdate City Hospital, Mirai Orthopaedic & Pain Clinic, Saku-Daira Orthopaedic Clinic, Minano Hospital, Hiramatu Orthopaedic Clinic, Kurata Hospital, Yourou Orthopaedic Clinic, Takeda Orthopaedic Clinic, Nakane Orthopaedic Clinic, Kanematsu Orthopaedic Clinic,

Ebihara Hospital, Tama Medical Rehabilitation Clinic, Nasu Orthopaedic Clinic, Kichikawa Orthopaedic Clinic, Nagata Clinic, Hirose Clinic, Honda Orthopaedic Clinic, Mikami Orthopaedic Clinic and Mori Orthopaedic Clinic.

## References

1. Miller CW. Survival and ambulation following hip fracture. *J Bone Joint Surg Am.* 1978;60:930–4.
2. de Palma L, Rizzi L, Lorini G, Greco F. Survival after trochanteric fracture. Biological factors analyzed in 270 patients. *Acta Orthop Scand.* 1992;63:645–7.
3. Sakamoto K, Nakamura T, Hagino H, Endo N, Mori S, Muto Y, Harada A, Nakano T, Yamamoto S, Kushida K, Tomita K, Yoshimura M, Yamamoto H. Report on the Japanese Orthopaedic Association's 3-year project observing hip fractures at fixed-point hospitals. *J Orthop Sci.* 2006;11:127–34.
4. Lord SR, Ward JA, Williams P. J. An epidemiological study of falls in older community-dwelling women: the Randwick falls and fractures study. *Austr J. Public Health.* 1993;17:240–5.
5. Cripps R, Carman J. 2. Hospitalisations due to accidental falls. Falls by the elderly in Australia: trends and data for 1998. Canberra, Australia: Australian Institute of Health and Welfare, 2001;1–9.
6. Sherrington C, Whitney JC, Lord SR, Herbert RD, Cumming RG, Close JCT. Effective exercise for the prevention of falls: a systematic review and meta-analysis. *JAGS.* 2008;56:2234–43.
7. Robertson MC, Devlin N, Gardner MM, Campbell AJ. Effectiveness and economic evaluation of a nurse delivered home exercise programme to prevent falls. 1: randomised controlled trial. *BMJ.* 2001;322:697–701.
8. Haeney RP. Chapter 6 calcium, bone health, and osteoporosis (Peck WA editor). *Bone Miner Res.* 1986;4:255–301.
9. Sibonga JD, Evans HJ, Sung HG, Spector ER, Lang TF, Oganov VS, Bakulin AV, Shackelford LC, LeBlanc AD. Recovery of spaceflight-induced bone loss: bone mineral density after long-duration missions as fitted with an exponential function. *Bone.* 2007;41:973–8.
10. Turner CH. Three rules for bone adaptation to mechanical stimuli. *Bone.* 1998;23:399–407.
11. Sakamoto K, Tashiro Y, Sato Y, Sugimoto F, Kawasaki K, Honno J, Yamaguchi A, Fujimaki E. Dynamic flamingo therapy for reducing of femoral neck fracture—a preliminary study. *Bone.* 1995;16(Suppl):164S.
12. Sakamoto K, Sugimoto F, Sato Y, Fujimaki E, Tashiro Y. Dynamic Flamingo Therapy for prevention of femoral neck osteoporosis and fractures-part I: theoretical background-Showa. *Med Sci.* 1999;11:247–54.
13. Wolf SL, Bamhart HX, Kutner NG, McNeely E, Coogler C, Xu T and the Atlanta FICSIT Group. Reducing frailty and falls in older persons: an investigation of Tai Chi and computerized balance training. *JAGS.* 1996;44:489–97.
14. Campbell AJ, Robertson MC, Gardner MM, Norton RN, Tilyard MW, Buchner DM. Randomized controlled trial of a general practice programme of home based exercise to prevent falls in elderly women. *BMJ.* 1997;315:1065–9.
15. Sakai A, Oshige T, Zenke Y, Yamanaka Y, Nagaishi H, Nakamura T. Unipedal standing exercise and hip bone mineral density in postmenopausal women: a randomized controlled trial. *J Bone Miner Metab.* 2010;28:42–8.
16. Sakamoto K, Tashiro Y. Protective exercise for osteoporosis—unipedal standing exercise. *J Phys Med.* 2005;16:2–7 (in Japanese).

17. Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT. Statement: updated guidelines for reporting parallel group randomized trials. *BMJ*. 2010;2010(340):698–702.
18. Liberman U, Weiss SR, Bróil J, Minne HW, Quan H, Bell NH, Rodriguez-Portales J, Downs Jr RW, Dequeker J, Favus M, Seeman E, Recker RR, Capizzi T, Santora II AG, Lombardi A, Sah RV, Hirsch LJ, Karpf D. For the Alendronate Phase III Osteoporosis Treatment Study Group. Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal osteoporosis. *N Engl J Med*. 1995;333:1437–43.
19. Reid DM, Hughes A, Laan RFJM, Sacco-Gibson NA, Wenderoth DH, Adami S, Eusebio RA, Devogelaer J-P. Efficacy and safety of daily risedronate in the treatment of corticosteroid-induced osteoporosis in men and women: a randomized trial. *J Bone Miner Res*. 2000;15:1006–13.
20. Shiraki M, Kushida K, Yamazaki K, Nagai T, Inoue T, Orimo H. Effects of 2 years' treatment of osteoporosis with 1  $\alpha$ -hydroxy vitamin D<sub>3</sub> on bone mineral density and incidence of fracture: a placebo-controlled double-blind prospective study. *Endocr J*. 1996;43:211–20.
21. Hayashi Y, Fujita T, Inoue T. Decrease of vertebral fracture in osteoporosis by administration of 1 $\alpha$ -hydroxy-vitamin D<sub>3</sub>. *J Bone Miner Metab*. 1992;10:184–8.
22. Kanis JA, Johansson H, Oden A, McCloskey EV. Bazedoxifene reduces vertebral and clinical fractures in postmenopausal women at high risk assessed with FRAX. *Bone*. 2009;44:1049–54.
23. Silverman S, Christiansen C, Genant HK, Vukicevic S, Zanchetta JR, de Villiers TJ, Constantine GD, Chines A. Efficacy of bazedoxifene in reducing new vertebral fracture risk in postmenopausal women with osteoporosis: results from a 3-year, randomized, placebo, and active-controlled clinical trial. *J Bone Miner Res*. 2008;23:1923–34.
24. McMurdo ME, Millar AM, Daly F. A randomized controlled trial of fall prevention strategies in old peoples' homes. *Gerontology*. 2000;46:83–7.
25. Mulrow CD, Gerety MB, Kanten D, Cornel JE, DeNino LA, Chiodo L, Aguilar C, O'Neil MB, Rosenberg J, Solis RM. A randomized trial of physical rehabilitation for very frail nursing home residents. *JAMA*. 1994;271:519–24.
26. Province MA, Hadley EC, Hornbrook MC, Lipsitz LA, Miller JP, Mulrow CD, Ory MG, Sattin RW, Tinetti ME, Wolf S, for the FICSIT Group. The effects of exercise on falls in elderly patients. *JAMA*. 1995;273:1341–7.
27. Campbell AJ, Robertson MC, Gardner MM, Norton RN, Buchner DM. Falls prevention over 2 years: a randomized controlled trial in women 80 years and older. *Age Ageing*. 1999;28:513–8.
28. Kasahara M, Yamasaki H, Aoki U, Yokoyama H, Omori Y, Hiraki K. Relationship between one leg standing time and knee extension strength in elderly patients. *Jpn J Phys Fitness Sports Med*. 2001;50:369–74 (in Japanese).
29. Michikawa T, Nishiwaki Y, Takebayashi T, Toyama Y. One-leg standing test for elderly populations. *J Orthop Sci*. 2009;14: 675–85.
30. Sakai A, Toba N, Takeda M, Suzuki M, Abe Y, Aoyagi K, Nakamura T. Association of unipedal standing time and bone mineral density in community-dwelling Japanese women. *Osteoporos Int*. 2009;20:731–6.

## 巻頭言

### ～運動器障害は 虚弱における身体的脆弱性に どこまで関与しているのか～

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高齢者において、介護が必要になった原因として、関節疾患や骨折・転倒などの運動器障害による病態が21.5%と大きな割合を占めており、この傾向は特に女性で顕著である<sup>1)</sup>。これらの運動器障害は、動物に最も根源的である“動く”能力に直接に悪影響を及ぼし、それに応じた介護を受けないと生存できない状況がもたらされる。

わが国が超高齢社会に突入した2007年に、日本整形外科学会が、この特集で主題にするロコモティブシンドロームを提唱し、直近の改訂で運動器学を学会の目的に明記したのも、このような社会の情勢に応じたものと考えられる。

ロコモティブシンドロームは、「運動器の障害による要介護の状態や要介護リスクの高い状態」と定義され、原因が運動器疾患で主要アウトカムは要介護化と明瞭である<sup>2)</sup>。要介護化の前に自分でロコモーションチェック(ロコモチェック)をし、ロコモーショントレーニング(ロコトレ)で予防を図り、進行するようなら、医療機関による診断と治療によって、運動器由来の要介護化を減らそうとするものである。基礎的組織としては、骨、軟骨、筋肉が挙げられ、これらはいずれも加齢とともに量的減少と質的劣化が進み、あるレベルを超えると、骨には骨粗鬆症、軟骨には変形性関節症、筋肉にはサルコペニアなどが基礎疾患として生じて、重大な運動機能低下をもたらす、要介護リスクを上昇させ、ロコモティブシンドロームに該当するようになる。加えて、膝痛や腰痛、あるいは転倒骨折などのイベントが生じれば、要介護化は加速する(図)。

一方、虚弱は、高齢者にとって深刻な問題で、その重要性は広く認識され、“虚弱とは、ストレスにより障害を受けやすい状態であり、相互に関連する複数の生理機構の障害に起因している”という考え方が概ね受け入れられた<sup>3)</sup>とされるが、定義や診断基準はいまだに定まっていない。したがって、実りのある議論が進めにくい状況にあるのが実情である。ただ、ロコモティブシンドロームと同じ要介護化の切り口で比較すると、介護が必要になった原因の13.6%を占めるものに高齢による衰弱があるが、この集団が虚弱該当者とかなり重複し、サルコペニアがその要因の一つである可能性は低くないと思われる。サルコペニアは、虚弱悪化の主役、かつ、ロコモティブシンドロームの基礎疾患で、両者の共通項として注目度が増すと予想される(図)。

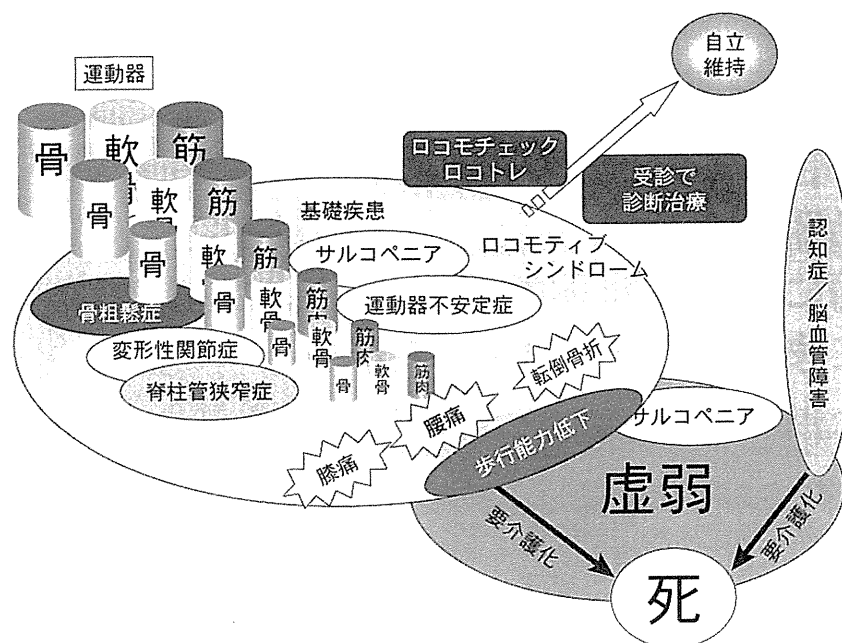


図 ロコモティブシンドロームの概念と虚弱

ロコモティブシンドロームの基礎疾患としては、骨、軟骨、筋肉由来のものが挙げられる。

ロコモティブシンドロームの基礎疾患で、かつ、虚弱悪化の主役のサルコペニアは両者の共通項として注目度が増すと予想される。

(筆者作成)

さらに、関節疾患、脊椎疾患、骨粗鬆症が虚弱における身体的脆弱性に、どこまで関与しているのかなどは、今後の大きな課題である。今回の特集が、ロコモティブシンドロームと虚弱を議論するきっかけになれば幸いである。

<文献>

- 1) 厚生労働省ホームページ 平成19年国民生活基礎調査.  
<http://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa07/4-2.html>
- 2) 中村耕三：超高齢社会とロコモティブシンドローム. 日整会誌 85：1-2, 2011.  
<http://www.ncgg.go.jp/department/ep/monograph6thj/exercise.htm#1>
- 3) Bergman H, Ferrucci L, Guralnik J, et al：Frailty：an emerging research and clinical paradigm--issues and controversies. J Gerontol A Biol Sci Med Sci 62：731-737, 2007.

## 転倒・骨折患者にみられる 虚弱 (Frailty)

原田 敦\*

転倒・骨折は老年症候群の中でも、高齢者の要介護化の主要原因となっている。大腿骨近位部骨折はその典型である。ロコモティブシンドロームからみると、基礎疾患であるサルコペニア、運動器不安定症、骨粗鬆症が転倒・骨折の発生に大きく関与している。一方、虚弱 (Frailty) からみると、臓器・器官の機能低下の主役とみなされるサルコペニアが転倒・骨折に大きく係わる。両者を繋ぐ健康障害は、歩行機能と筋力 (バランス) の低下である。ロコモティブシンドロームの基礎疾患である運動器不安定症、骨粗鬆症、変形性関節症などの、現在の虚弱の概念にはない運動器疾患群が虚弱とどう関わっているのかは、今後の重要な課題である。

**Locomotive syndrome and Frailty.**

*Frailty in patients with fall & fall-related fracture.*

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Among geriatric syndromes, fall and fall-related fractures are one of the leading causes of the elderly's need for long-term care. Hip fractures are the typical cases. The underlying diseases of locomotive syndrome, such as sarcopenia, musculoskeletal ambulation disorder symptom complex, and osteoporosis, are closely associated with fall and fall-related fractures. From the stand point of frailty, sarcopenia, which is considered the major cause of aging-associated declines in function and reserve across multiple physiologic systems, plays a role in fall and fall-related fractures. The common adverse health outcomes both in locomotive syndrome and frailty, is a decrease in walking function and muscle strength. Understanding the role of the underlying diseases of locomotive syndrome including osteoarthritis, osteoporosis within the frailty cycle is important for the future.

はじめに  
虚弱とは加齢と関連した心身の脆弱な状態であ

り、複数の臓器・器官の機能低下状態で、高齢者の普遍的な問題として、その病態成因は世界的に

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注目されている<sup>1)</sup>。しかしながら、虚弱は、いまだ研究者の合意が得られた確定した定義は存在しない。研究者によっては、認知症などの精神的病態を含めるなど、その解釈は、広い範囲にまたがり、評価基準もさまざま、いまだに独立した臨床症候群としては認知されていない<sup>2)</sup>。しかしながら、虚弱と分類された高齢者群では、健康障害のリスクが上昇し、それは、加齢およびいっそう不良な機能低下、より多い併存疾患の存在のみでは説明されないと認識されている<sup>3)</sup>。

Friedらが述べている、虚弱でリスク上昇に曝される健康障害とは、医学的不安定、身体機能障害・要介護、施設入所、外傷、転倒、急性疾患、入院、医療介護費用増加、疾患や入院での回復が遅いか不完全、治療によって医原性あるいは副作用の生じるリスクの上昇、そして、死亡である<sup>4)</sup>。彼らは、在宅住民で行った前向き観察研究 (Cardiovascular Health Study (CHS)) で、体重減少、疲労感、身体活動低下、歩行速度低下、握力低下の5指標のうち、3つ以上があつて、虚弱とみなされた人のうち1/4は、複数疾患および機能障害が共にないことを明らかにしたが、70%を超える残りの人々は、それらを有しており<sup>5)</sup>、転倒・骨折を起こす高齢者は、後者に属するものと考えられる。そして、転倒・骨折は老年症候群の症状の中でも、高齢者の自立を損じて要介護化に陥らせる主要な原因となっていることはよく知られている。

### 大腿骨近位部骨折にみられる虚弱 (Frailty)

転倒・骨折のリスクが高い高齢者のうち、背景に虚弱を有する可能性が最も高いのは、大腿骨近位部骨折患者と思われる。最近のわが国の調査で

は、この骨折は発生頻度が75歳以降で急増し、90歳以上の増加が目立つ傾向が出現しており、78%が転倒で生じている<sup>6)</sup>。

われわれの施設で治療した大腿骨近位部骨折のうち、研究対象とすることに同意を得て登録された症例群は、2001年12月から2010年10月までに635例である。その年齢は平均81.4歳(14~102歳)で、女性535例、男性100例、骨折型は転子部骨折326例、頸部骨折309例であった。これらの患者群に対して、Friedらの、意図しない体重減少、低握力、低エネルギーレベル、低歩行速度、低身体活動レベルからなるCHS指標等で虚弱を評価していないので、正確な虚弱の合併は不明であるが、典型的な症例を示す。

症例：89歳，女性  
主訴：左股関節痛  
現病歴：2005年に転倒で右大腿骨近位部骨折受傷。老人保健施設に入所して介助歩行していたが、2010年3月転倒後、主訴を訴えて歩行不能になった。  
常用薬：活性型ビタミンD<sub>3</sub>製剤のみ  
診断：左大腿骨近位部骨折 (図1a)

入院時状況は、日常生活動作 (ADL) は Barthel Index で受傷前55点、入院時0点で、骨量は二重エネルギーX線吸収測定法 (DXA) による骨密度が腰椎 0.705 g/cm<sup>2</sup> (YAM36%) で、骨粗鬆症と診断された。大腿骨頸部は、対側に骨折既往があるため測定不能であった。筋量は、DXAによる全身骨測定で得られる lean body mass より補正四肢筋量は 2.063 kg/m<sup>2</sup> であった。真田らによる日本人カットオフ値から、サルコペニアと診断された。認知機能は MMSE (Mini-Mental State Examination) 16点で、うつ状況は GDS (Geriatric Depression Scale) で8点であった。

脳 MRI 所見として、脳溝脳室拡大、側脳室周囲

CHS : Cardiovascular Health Study, ADL : activities of daily living (日常生活動作)

DXA : dual energy X-ray absorptiometry (二重エネルギーX線吸収測定法)

YAM : young adult mean (若年成人平均値), MMSE : Mini-Mental State Examination (簡易認知機能検査)

GDS : Geriatric Depression Scale



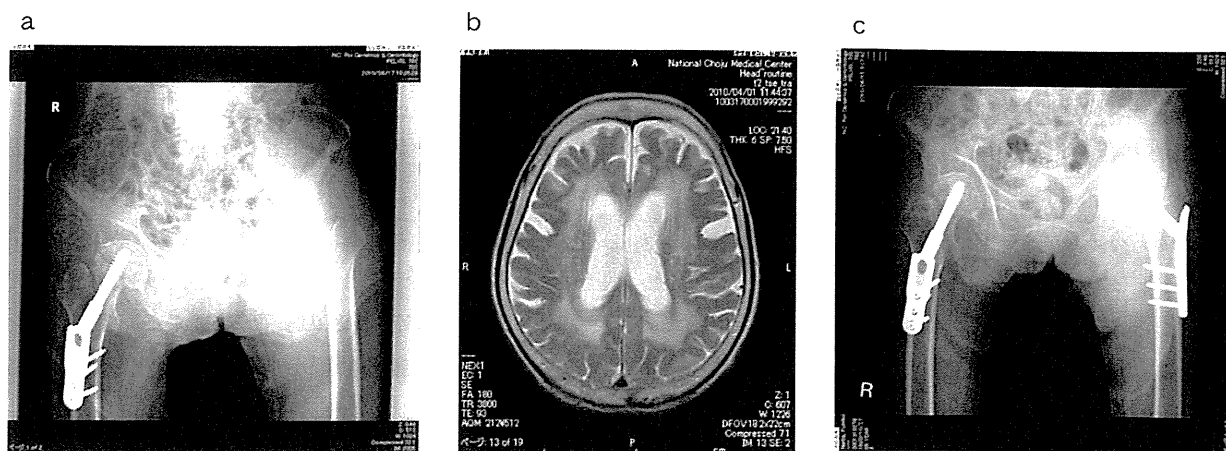


図1 左大腿骨近位部骨折の症例

- a : 今回の骨折は左側で転子部骨折。右も5年前に同じ骨折で手術されている。  
 b : 認知症合併。脳 MRI で脳溝脳室拡大, 側脳室周囲大脳白質病変, 皮質下深部白質病変。  
 c : 左に CHS 法による観血的骨折手術が施行され, 入院 35 日で退院。  
 CHS : compression hip screw

(筆者提供)

大脳白質病変, 皮質下深部白質病変が認められ (図 1b), MMSE 等と併せて, 認知症の併存が確認された。治療は, 全身状態検索後, 翌日腰椎麻酔にて観血的骨折手術を行い (図 1c), 早期リハビリを施行した。合併症はなく経過して, 入院日数は 35 日で, 退院時 Barthel Index は 35 点まで回復しており, 元の老人保健施設に戻った。

この症例は, 大腿骨近位部骨折患者に多い認知症合併例であるが, ほかの基礎疾患として, 骨粗鬆症, 転倒既往, 骨折既往 (脊椎と対側大腿骨近位部), 脊柱管狭窄症が併存しており, 受傷前から介護施設に入所しており, 介助歩行であった。CHS 指標等での虚弱評価はしてないが, この患者は, 5つの指標のうち3つ以上有していて, 受傷前から虚弱とロコモティブシンドロームに該当していた可能性は相当に高いと考えられる。ちなみに, 国立長寿医療研究センターの大腿骨近位部骨折患者群は, 97%が骨粗鬆症, 85%がサルコペニア, 49%が認知症, 72%がビタミンD不足を併存し

ていた。

このように, 複数の臓器・器官の機能低下によって, 心身の脆弱な状態となった虚弱を有する本骨折患者において, そのような背景から予想されるのは高い死亡率であるが, わが国での 753 例を 10 年追跡した調査でも, 大腿骨近位部骨折患者の死亡率は, 受傷後 2 年間劇的に上昇するだけでなく, その後も 10 年まで, 年齢, 性で調整しても, 一般人口の死亡率より高い状態が続いたと報告されている。歩行機能の回復は, 介助具の使用を問わず, 自力で屋外を歩ける人の割合は, 骨折前が 68%, 1 年で 56%と低下し, その後 10 年まで, およそ 63%ほどに維持されていた<sup>7)</sup>。

Friedらの CHS 指標と, それより簡便な Study of Osteoporotic Fractures (SOF 指標: 体重減少, 椅子から手でつかまらずに 5 回立ち上がる事が不能, エネルギーレベル減少の 3 つからなる) で虚弱を評価した平均 76.7 歳の 6,701 名による女性コホートの研究によれば, 虚弱の率は,

SOF : Study of Osteoporotic Fractures

開始時に CHS 指標で 16%、SOF 指標で 17%とほぼ同じで、9.6 年の間に 41%が死亡し、7.9 年の間に 33%が非脊椎骨折を生じ、9.3 年の間に 11%が大腿骨近位部骨折を受傷した。大腿骨近位部骨折リスクに関しては、健常人に対する虚弱を有する人のハザード比は、CHS 指標で 1.71 (1.36 ~ 2.15)、SOF 指標で 1.79 (1.46 ~ 2.19) と、どちらもほぼ一致した上昇を示した。このように白人女性における調査結果は、虚弱が大腿骨近位部骨折リスク上昇に直結していることを示すものであった<sup>81)</sup>。ただ、リスク増加の程度はとび抜けて高いものではなかった。

### 転倒にみられる虚弱 (Frailty)

世界保健機構 (WHO) のレポートによれば、転倒の頻度は年齢と虚弱の程度に伴って増加するとされ、高齢者の外傷のうちでは突出して多い<sup>91)</sup>。機能予後を悪化させ、介護を要する状態となる原因となることはよく知られている。さらには、生命予後も悪化させ、全外傷死の 40%を占めるとされる<sup>10)</sup>。高齢社会の進展に伴って、ますます大きなインパクトを有してきている。欧米の在宅高齢者では、65 歳以上では、毎年 1/4 から 1/3 が転倒しており、その頻度は 65 ~ 74 歳では 30 ~ 50/100 人年、75 歳以上では 60 ~ 90/100 人年で<sup>11)</sup>、日本の在宅高齢者も、全国 7 県での前向き調査では、10 ~ 20 数%で、前期高齢者と比して後期高齢者で有意に高いとされ、加齢との関連性は明らかである。転倒回数も、介護施設では 140 回/100 人年、病院内では 165 回/100 人年と在宅者より増加している<sup>12)</sup>。

すなわち、在宅生活者より介護施設に生活する者の方がより頻回に転倒する。長期介護施設にいる人々は、およそ 30 ~ 50%が毎年転倒し、その 40%が転倒を繰り返している<sup>13)</sup>。

わが国で転倒リスクが上昇した病態に、独自に運動器不安定症という病名がつけられた。その定義は、高齢化により、バランス能力および移動歩行能力の低下が生じ、閉じこもり、転倒リスクが高まった状態とされている。その診断は、表のようになされているが、3m Timed up and go test などの歩行パフォーマンスの低下や介護度で判定されるので、虚弱の一面をみていることになる。また、運動機能低下をきたす疾患として、転倒既往のほか、変形性関節症や骨粗鬆症、脊柱管狭窄症などのロコモティブシンドロームの基礎疾患が挙げられている<sup>14)</sup>。

鈴木らによる、転倒リスクのうちの内的因子として挙げられているもののうち、加齢変化としてまとめられた因子は、筋の持続力低下、姿勢反射の低下、深部感覚低下、平衡機能低下など筋力とバランスの低下であり、一方、身体的疾患としてまとめられた因子は、不整脈、起立性低血圧、心不全、脳血管疾患などの循環器系疾患、パーキンソン症候群、小脳障害、認知症などの神経系疾患、関節リウマチ、骨・関節炎、骨折・脱臼などの筋骨格系疾患、そして白内障などの視覚-認知系疾患が挙げられている。これらの因子が歩行能力の低下をきたし、転倒に結びつくといわれるが<sup>15)</sup>、Friedらによる CHS 指標の中の歩行速度低下および握力低下に深く関連するので、これらの内的因子を有する転倒リスクの高い高齢者は、虚弱を呈している確率は低くないと思われる。

前述の CHS 指標と SOF 指標で虚弱を評価した米国白人女性のコホート研究によれば、平均 11.9 カ月間に 11%が複数回、転倒を経験した。虚弱の占める割合は、CHS 指標で 211 名、20%、SOF 指標で 215 名、19%であった。複数回転倒リスクに関しては、健常人に対する虚弱を有する人のオッズ比は、CHS 指標で 2.44 (1.95 ~

表 運動器不安定症の診断

高齢化により、バランス能力および移動歩行能力の低下が生じ、閉じこもり、転倒リスクが高まった状態と定義され、機能評価と基礎疾患の条件から診断されている。

下記の運動機能低下をきたす疾患の既往・罹患がある者で、日常生活自立度あるいは運動機能が以下に示す機能評価基準1または2に該当する者

<p>運動機能低下をきたす疾患</p> <ul style="list-style-type: none"> <li>・ 脊椎圧迫骨折および各種脊椎変形</li> <li>・ 下肢骨折</li> <li>・ 骨粗鬆症</li> <li>・ 変形性関節症</li> <li>・ 腰椎脊柱管狭窄症</li> <li>・ 脊髄障害</li> <li>・ 神経・筋疾患</li> <li>・ 関節リウマチおよび各種関節炎</li> <li>・ 下肢切断</li> <li>・ 長期臥床後の運動器廃用</li> <li>・ 高頻度転倒者</li> </ul>	<p>機能評価基準</p> <p>1. 日常生活自立度：ランクJまたはA (要支援+要介護1, 2)</p> <p>あるいは</p> <p>2. 運動機能1)または2)</p> <p>1) 開眼片脚起立時間 15 秒未満</p> <p>2) 3m Timed up and go test 11 秒以上</p>
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(文献 14 より)

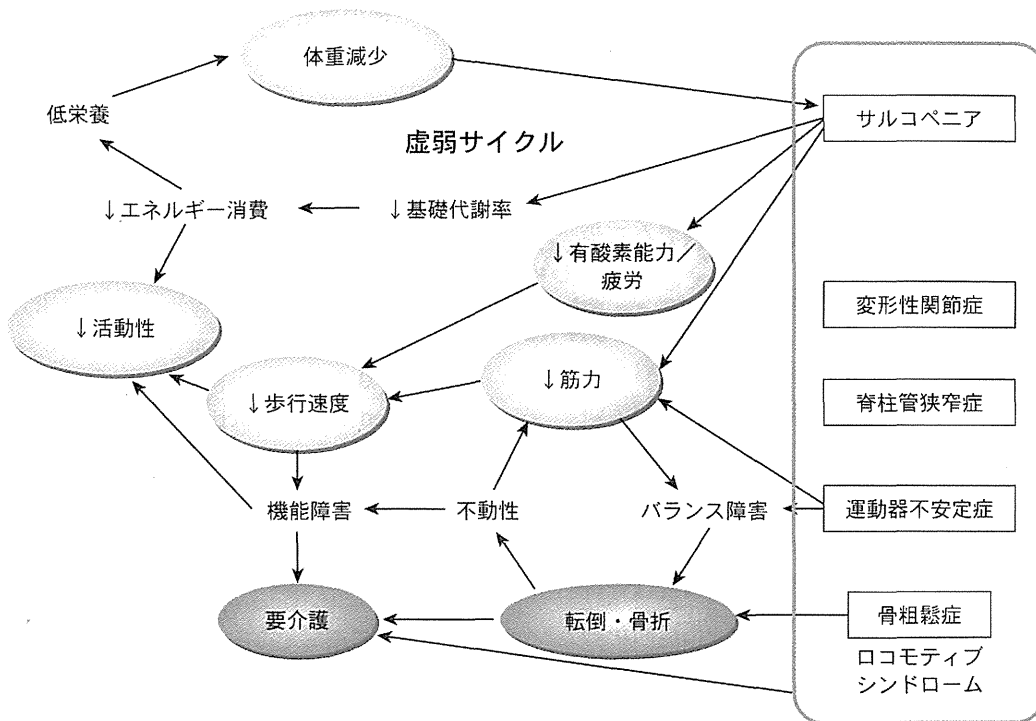


図2 虚弱サイクルとロコモティブシンドロームにおける転倒・骨折

ロコモティブシンドロームからみるとサルコペニア、運動器不安定症、骨粗鬆症が、また、虚弱 (Frailty) からみると臓器・器官機能低下の主役のサルコペニアが、転倒・骨折の発生に大きく関与している。(文献 18 より改変)

3.04), SOF 指標で 2.38 (1.94 ~ 2.92) と、どちらもほぼ一致した上昇を示した<sup>8)</sup>。しかし、同じ米国人でも 847 名のメキシコ系に対して Friedらの CHS 指標で虚弱を評価し、3年間の転倒との関連を研究によると、虚弱は 105 名で、392 名が転倒し、ポワソン回帰では、転倒と関連したのは、前虚弱 ( $p = 0.003$ ) で、虚弱は統計的には有意ではなかった ( $p = 0.06$ ) と報告されている。その理由として、虚弱の人より前虚弱の人の方が自立度は高く、より移動する機会が多いからという説明が挙げられているが、人種差もそこに影響している可能性はある<sup>16)</sup>。

#### 転倒・骨折、虚弱、ロコモティブシンドロームの関係

虚弱の背景には、複数のホメオスタシス維持機構が衰えた構造と複数の臓器・器官の機能低下状態があると考えられている。そのような状況で出現する虚弱の各症候は、相互に影響し合いながら虚弱サイクルと呼ばれる悪循環に陥る。その要因となる複数の臓器・器官の機能低下の中で、サルコペニアは中心的な役割を果たすと考えられている(図2)<sup>17)</sup>。しかし、虚弱の重要な症候である歩行速度の低下には、サルコペニアだけでなく、下肢荷重関節の変形性関節症や、頸椎や腰椎における脊柱管狭窄症も直接的な関連を有し、それらが虚弱悪化サイクルを加速し、要介護化を速めている可能性も否定できない。なかでも、サルコペニアと運動器不安定症は、筋力とバランスのさらなる低下をきたして、転倒リスクを高め、実際に転倒が起これば骨粗鬆症が併存している場合は骨折まで生じて重傷化し、より重い要介護化に向かわせることになる。

現在まで、これらのロコモティブシンドロームの基礎疾患が虚弱サイクルにどう係わり、虚弱悪化の促進に関連するののかについては、そのような観点からは検討されてこなかったため、今後の研

究が待たれるところである。

#### おわりに

転倒・骨折は老年症候群の症候の中でも、高齢者の自立を損じて要介護化に陥らせる主要な原因となっている。ロコモティブシンドロームからみると、基礎疾患であるサルコペニア、運動器不安定症、骨粗鬆症が転倒・骨折の発生に大きく関与している。一方、虚弱 (Frailty) からみると、臓器・器官の機能低下の主役とみなされるサルコペニアが転倒・骨折に大きく係わる。両者を繋ぐ健康障害は、歩行機能と筋力(バランス)の低下である。運動器不安定症、骨粗鬆症、さらに変形性関節症など、要介護の要因となると考えられ、ロコモティブシンドロームには含まれているが、現在の虚弱の概念にはない運動器疾患群が虚弱とどう係わっているのかは、定義が未定の段階ではあるが、今後の重要な課題である。

#### 文 献

- 1) 神崎恒一：高齢者の虚弱—評価と対策— 序文. *Geriatric Medicine* **49** : 283-284, 2011.
- 2) Rockwood K : Frailty and its definition : a worthy challenge. *J Am Geriatr Soc* **53** : 1069-1070, 2005.
- 3) Fried LP, Ferrucci L, Darer J, et al : Untangling the concepts of disability, frailty, and comorbidity : implications for improved targeting and care. *J Gerontol A Biol Sci Med Sci* **59** : 255-263, 2004.
- 4) Fried LP, Walston JD, Ferrucci L : Frailty. In : Hazzard's *Geriatric Medicine and Gerontology*. Sixth Ed, McGraw Hill, 2009, p631-645.
- 5) Fried LP, Tangen CM, Walston JD, et al : Frailty in older adults : evidence for a phenotype. *J Gerontol Med Sci* **56A** : M146-M156, 2001.
- 6) Hagino H, Sakamoto K, Harada A, et al : Na-