and women. Knee pain was a risk factor for falls in women. Further studies, along with continued longitudinal surveys in the ROAD study, will help elucidate the background of knee OA and LS and their relationship with falls.

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**Conflicts of interest** None.

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Original Full Length Article

# Risk factors for falls in a longitudinal population-based cohort study of Japanese men and women: The ROAD Study

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ABSTRACT

The objective of this study was to clarify the associations of physical performance and bone and joint diseases with single and multiple falls in Japanese men and women using a population-based longitudinal cohort study known as Research on Osteoarthritis/osteoporosis Against Disability (ROAD). A total of 452 men and 896 women were analyzed in the present study (mean age, 63.9 years). A questionnaire was used to assess the number of falls during the 3-year follow-up. Grip strength, 6-m walking time, and chair stand time were measured at baseline. Knee osteoarthritis (OA) and lumbar spondylosis were defined as Kellgren Lawrence = 2, 3 or 4. Vertebral fracture (VFx) was assessed with the Japanese Society of Bone and Mineral Research criteria. Osteoporosis was defined by bone mineral density using dual energy X-ray absorptiometry based on World Health Organization criteria. Knee and lower back pain were estimated by an interview. During a 3-year follow-up, 79 (17.4%) men and 216 (24.1%) women reported at least one fall, and 54 (11.9%) men and 111 (12.4%) women reported multiple falls. Knee pain was a risk factor for multiple falls in women, but not in men. VFx tended to be associated with multiple falls in women, but not in men. A longer 6-m walking time was a risk factor for multiple falls in women, whereas a longer chair stand time was a risk factor for multiple falls in men. We found gender differences in risk factors for falls.



## Introduction

Falls are one of the main causes of injury, disability, and death among the elderly [1,2]. In Japan, according to the recent National Livelihood Survey of the Ministry of Health, Labour and Welfare, falls and fractures are ranked fifth among diseases that cause disabilities and subsequently require support with activities of daily living [3]. However, few population-based studies have been performed on the incidence of falls based on sex and age. Furthermore, in terms of factors associated with falls, muscle strength, balance, vision, functional capacities, and cognitive impairment are traits that diminish with aging, and these factors have been suggested as predictive risk factors for falls and fractures [4,5]. However, the association of bone and joint diseases, especially osteoarthritis (OA), with falls remains unclear.

The representative sites of OA are the knee and lumbar spine. Knee OA and lumbar spondylosis (LS) are major public health issues because they cause chronic pain and disability [6,7]. The prevalence rates of radiographic knee OA and LS are 54.6% and 70.2%, respectively, in persons aged 40 years and older in Japan, which indicates that 25,300,000 and 37,900,000 persons aged 40 years and older are estimated to experience radiographic knee OA and LS, respectively [10]. The National Livelihood Survey ranked OA fourth among diseases that cause disabilities and subsequently require support with activities of daily living [3], but there have been few studies of the association between falls and OA [11,12]. In previous studies, knee OA was assessed only by interview and not by radiography. The principal clinical symptom of knee OA is pain [13], but its correlation with the radiographic severity of knee OA is not as strong as expected [8]. In fact, in a study in Japan, approximately 20% of persons without knee OA had knee pain, and 30% of persons with severe knee OA had no knee pain [8]. Thus, knee OA diagnosed by interview could be limited by variable accuracy. In addition, men and women were not examined separately in these previous studies, although sex differences have been found in the prevalence of knee OA [8]. Our previous study showed that knee pain is significantly associated with falls in women [14], but that study used a cross-sectional design; thus, a causal relationship remains unclear. Regarding LS, to the best of our knowledge, no population-based studies have been performed

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regarding its association with falls except for our previous cross-sectional study [14], which showed that LS is not significantly associated with falls. In addition, among fractures due to osteoporosis (OP), vertebral fracture (VFx) is the most likely to lead to marked public health problems. VFx is reportedly associated with functional impairment [15], back pain, kyphosis [16,17], esophageal reflux [18], depressive mood [19], respiratory dysfunctions [20], and mortality [21]. However, whether VFx is an independent risk factor for the incidence of falls remains unclear.

Measuring walking speed is a simple way to assess health and function in older adults [22,23]. Walking speed has been found to be associated with falls in a few studies [4,24–26], although most studies were limited by a small sample size, a cross-sectional design [24,25], or evaluation of a single sex [4,26]. In addition, although walking abnormalities indicative by a slower walking speed are significantly associated with bone and joint diseases such as knee OA, LS, and their associated pain [14], no longitudinal studies have been performed to determine the associations of falls with bone and joint diseases and walking abnormalities at the same time. Furthermore, measuring the chair stand time is also reported to be a simple and established method to assess health and function in the elderly [27,28], but to the best of our knowledge, no longitudinal studies have been performed to determine the associations of falls with chair stand time.

Previous studies have shown that associations between individual risk factors and a single fall are few in number and weak compared to risk factors for multiple falls [12], indicating that single and multiple falls may have different backgrounds. Thus, to determine factors associated with falls, single and multiple falls should be analyzed separately.

The objective of this study was to clarify the associations of physical performance and bone and joint diseases with the incidence of single and multiple falls in Japanese men and women using a population-based longitudinal cohort study known as Research on Osteoarthritis/osteoporosis Against Disability (ROAD).

## Methods

### *Participants*

The ROAD study is a nationwide, prospective study designed to establish epidemiologic indices for evaluation of clinical evidence for the development of a disease-modifying treatment for bone and joint diseases (OP and OA are the representative bone and joint diseases, respectively). ROAD consists of population-based cohorts in three communities in Japan. A detailed profile of the ROAD study has been described elsewhere [8–10,29]; a brief summary is provided here. To date, we have completed the creation of a baseline database that includes clinical and genetic information for 3,040 participants (1,061 men and 1,979 women) ranging in age from 23 to 95 years (mean, 70.6 years) who were recruited from resident registration listings in three communities: an urban region in Itabashi, Tokyo; a mountainous region in Hidakagawa, Wakayama; and a coastal region in Taiji, Wakayama.

Residents of these regions were recruited from the resident registration list of the relevant region. Participants in the urban region were recruited from a randomly selected cohort from the Itabashi-ward residents' registration database [30]. The participation rate was 75.6%. Participants in mountainous and coastal regions were also recruited from the resident registration lists, and the participation rates in these two areas were 56.7% and 31.7%, respectively. The inclusion criteria, apart from residence in the communities mentioned above, were the ability to (1) walk to the survey site, (2) report data, and (3) understand and sign an informed consent form. The baseline survey of the ROAD study was completed in 2006. All participants provided written informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo and the Tokyo Metropolitan Institute of Gerontology.

### *Assessment of falls*

Three years after the baseline data were obtained, we attempted to trace and review all 3,040 participants between 2008 and 2010; they were invited to attend a follow-up interview. All participants were interviewed with regard to falls by experienced interviewers and were asked the following questions: "Have you experienced falls during the 3-year follow-up, and if yes, how many falls did you experience"? At baseline, all participants were also interviewed regarding falls by experienced interviewers and were asked the following questions: "Have you experienced falls during the 12 months preceding baseline, and if yes, how many falls did you experience"? According to a previous study on falls [31], a fall is defined as a sudden, unintentional change in position causing an individual to land at a lower level on an object, the floor, or the ground, other than as a consequence of a sudden onset of paralysis, epileptic seizure, or overwhelming external force.

### *Pain assessment*

All participants were interviewed by experienced orthopedists regarding knee pain and lower back pain at baseline and were asked the following questions based on previous studies [8,9]: "Have you experienced knee pain on most days in the past month, in addition to now"? and "Have you experienced lower back pain on most days in the past month, in addition to now"? Those who answered "yes" were defined as having pain. Buttock pain and sciatica were not included as lower back pain in the present study.

### *Radiographic assessment*

At baseline, all participants underwent radiographic examination of both knees using anteroposterior and lateral views with weight-bearing and foot-map positioning; radiographic examination of the anteroposterior and lateral views of the lumbar spine, including intervertebral levels L1/2 to L5/S, was also performed. VFx was assessed by lateral radiographs of the lumbar spine (L1-L5) in terms of a wedge, biconcave, or crush appearance according to the Japanese Society of Bone and Mineral Research criteria [32]. The films were marked up, and morphometric measurements of anterior, middle, and posterior heights on lateral radiography of the thoracic and lumbar spine were made. Wedge appearance was defined as a site at which the anterior height of the vertebra was ≤75% of the posterior height. Biconcave appearance occurred if the height of the central part of the vertebra was ≤80% of that of the anterior or posterior parts of the vertebra. Crush appearance occurred if the height of the anterior, central, and posterior parts of an axial vertebra were all reduced to ≤80% of the normal value (Supplementary Fig. 1). Knee and lumbar spine radiographs were also read without knowledge of the participant's clinical status by a single, experienced orthopedist (S.M.) using the Kellgren Lawrence (KL) radiographic atlas [33] to determine the severity of KL grading. Radiographs were scored as grade 0–4, with higher grades associated with more severe OA. We defined knee OA and LS as KL ≥2 in at least one knee and one intervertebral level, respectively. To evaluate the intraobserver variability of KL grading, 100 randomly selected radiographs of the knee and lumbar spine were scored by the same observer more than 1 month after the first reading. One hundred other radiographs were also scored by two experienced orthopedic surgeons (S.M. and H.O.) using the same atlas for interobserver variability. The intra- and interobserver variabilities evaluated were confirmed by kappa analysis to be sufficient for assessment (0.86 and 0.80 for knee OA, and 0.84 and 0.76 for LS, respectively).

### *Bone mineral density (BMD) measurement*

BMD was measured at the lumbar spine (L2–4) and the proximal femur using dual energy X-ray absorptiometry (DXA) (Hologic

Discovery; Hologic, Waltham, MA, USA) at baseline. For quality control, the same DXA equipment was used, and the same spine phantom was scanned daily to monitor the machine's performance in study populations at different regions. The BMD of the phantom was adjusted to $1.032 \pm 0.016$ g/cm$^2$ ($\pm 1.5\%$) during all examinations. In addition, the same physician (N.Y.) examined all participants to prevent observer variability. Coefficient of variance (CV) for L2–L4 in the phantom was 0.35%, and CVs for L2–L4, the proximal femur, Ward's triangle, and the trochanter examined in five volunteers were 0.61–0.90, 1.02–2.57, 1.97–5.45, and 1.77–4.17%, respectively [34].

OP was defined based on World Health Organization (WHO) criteria in which OP was diagnosed as T-scores of BMD $\leq 2.5$ standard deviations (SDs) lower than peak bone mass [35]. Mean L2–4 BMD (SD) for young adult men and women measured using the Hologic QDR devices in Japan is reportedly 1.011 g/cm$^2$ (0.119 g/cm$^2$) [36]. Mean femoral neck BMD (SD) in Japan is reported to be 0.863 g/cm$^2$ (0.127 g/cm$^2$) for young men and 0.787 (0.109) for young women [36]. The present study therefore defined OP using these indices as lumbar spine BMD $<0.714$ g/cm$^2$ for both men and women, and as femoral neck BMD $<0.546$ g/cm$^2$ for men and $<0.515$ g/cm$^2$ for women.

### *Physical performance*

At baseline, anthropometric measurements were taken, including height and weight, and body mass index (BMI) (weight [kg]/height$^2$ [m$^2$]) was estimated based on the measured height and weight. Grip strength was measured on bilateral sides using a TOEI LIGHT handgrip dynamometer (TOEI LIGHT CO., LTD, Saitama, Japan), and the best measurement was used to characterize maximum muscle strength. To measure physical performance, the time taken to walk 6 m at normal walking speed in a hallway was recorded. Participants were told to walk from a marked starting line to a 6-m mark as if they were walking down their hallway at home. Time was measured in seconds with a stopwatch and rounded to the nearest hundredth of a second. The average of two trials was recorded. These gait-speed trial measurements are considered highly reliable in community-dwelling elderly persons [37]. The time taken for five consecutive chair rises without the use of hands was also recorded. Hands were folded in front of the chest with feet flat on the floor, following the protocol described by Guralnik et al. [27] and used by other researchers [28]. Time was measured in seconds with a stopwatch and rounded to the nearest hundredth of a second. Timing began with the command “Go” and ended when the buttocks contacted the chair on the fifth landing. The reliability of this protocol is adequate [27].

### *Cognition assessment*

At baseline, cognition was also evaluated for all participants using a Mini-Mental State Examination, and a cut-off score of <24 was used to select participants with cognitive impairment [38].

### *Statistical analyses*

The differences in age and anthropometric measurements between the responders (those who completed the study) and non-responders (those lost to follow-up or who did not complete the study as described below) and between men and women were examined with a non-paired Student's *t*-test. Differences in physical performance measurements between the responders and non-responders and between men and women were examined with Wilcoxon signed-rank test. Differences in age and anthropometric measurements, among non-fallers, single fallers, and multiple fallers, were examined with one-way analysis of variance. Differences in physical performance measurements among non-fallers, single fallers, and multiple fallers were examined with the Kruskal–Wallis test. The prevalence of bone and joint diseases and cognitive impairment was compared between men and women and among non-fallers, single fallers, and multiple fallers with the chi square test. Multinomial logistic regression analysis after adjusting for age and BMI was used to determine the association of anthropometric measurements, physical performance, bone and joint diseases, and cognitive impairment with single and multiple falls compared with the absence of falls in men and women. Further, to determine an independent association of physical performance with single and multiple falls compared with the absence of falls, we used multinomial logistic regression analysis with age, BMI, 6-m walking time, and chair stand time as explanatory variables. To determine independent risk factors for single and multiple falls, we used multinomial logistic regression analysis with age, BMI, physical performance, bone and joint diseases, and cognitive impairment as explanatory variables. Data analyses were performed using SAS version 9.0 (SAS Institute Inc., Cary, NC, USA).

## Results

Of the 1,690 participants in the mountainous and seaside cohorts at baseline in 2006 and 2007, 40 (2.4%) had died by the time of the review 3 years later, 97 (5.7%) did not participate in the follow-up study due to poor health, 16 (0.9%) had moved away, 51 (3.0%) declined the invitation to attend the follow-up study, and 47 (2.8%) did not participate in the follow-up study for other reasons. Among the 1,439 volunteers who did participate in the follow-up study, 68 (4.0%) provided incomplete fall questionnaires. In addition, six (0.4%) provided incomplete pain questionnaires; these were excluded. We also excluded eight (0.5%) participants who had undergone total knee arthroplasty before baseline. An additional nine (1.9%) participants did not perform the 6-m walking time or chair stand time, leaving a total of 1,348 (79.8%) participants (452 men and 896 women) from whom radiographs at baseline and complete fall and pain histories were obtained. The mean followup time was $2.93 \pm 0.12$ years, ranging from 2.65 to 3.22 years. Table 1 shows characterisctics of responders and non-responders. The responders were significantly younger than the non-responders (63.9 and 70.7 years, respectively). Physical performance measurements were better in responders than non-responders. Prevalence of knee OA, LS and knee pain was lower in responders (47.0, 61.6 and 9.7%,

**Table 1**
Baseline characteristics of responders and non-responders.

| | Overall | Responders | Non-responders |
|---|---|---|---|
| Number of participants | 1,690 | 1,348 | 342 |
| Female (%) | 64.7 | 66.5 | 57.9*** |
| Age (years) | $65.2 \pm 12.0$ | $63.9 \pm 11.8$ | $70.7 \pm 11.4$* |
| Height (cm) | $155.2 \pm 9.3$ | $155.6 \pm 9.0$ | $153.6 \pm 10.1$* |
| Weight (kg) | $55.6 \pm 10.8$ | $56.1 \pm 10.7$ | $53.7 \pm 10.8$* |
| BMI (kg/m$^2$) | $23.0 \pm 3.4$ | $23.1 \pm 3.4$ | $22.7 \pm 3.4$ |
| Grip strength (kg) (median [IQR]) | 26.0 [21.0–33.0] | 26.0 [21.0–34.0] | 24.0 [18.0–30.0]** |
| 6-m walking time (s) (median [IQR]) | 5.0 [4.0–7.0] | 5.0 [4.0–6.0] | 7.0 [5.0–9.0]** |
| Chair stand time (s) (median [IQR]) | 9.0 [7.0–12.0] | 9.0 [7.0–11.0] | 12.0 [8.25–15.0]** |
| Cognitive impairment (%) | 4.5 | 2.8 | 11.4*** |
| Radiographic knee OA (%) | 50.4 | 47.0 | 63.8*** |
| Radiographic LS (%) | 63.2 | 61.6 | 69.1*** |
| Radiographic VFx | 10.1 | 9.7 | 12.0 |
| Knee pain (%) | 24.3 | 22.2 | 32.6*** |
| Lower back pain (%) | 21.1 | 20.6 | 22.9 |
| Previous falls (%) | 17.3 | 16.3 | 21.0*** |

Values are mean ± SD, except where indicated.
BMI: body mass index, OA: osteoarthritis, LS: lumbar spondylosis, VFx: vertebral fracture, IQR: interquartile range.
* $p<0.05$ vs. responders by non-paired Student's *t*-test.
** $p<0.05$ vs. men by Wilcoxon signed-rank test.
*** $p<0.05$ vs. men by chi square test.

**Table 2**
Baseline characteristics of participants.

| | Men | Women |
|---|---|---|
| Number of participants | 452 | 896 |
| Age (years) | 64.9 ± 11.7 | 63.3 ± 11.8* |
| Height (cm) | 164.0 ± 7.0 | 151.3 ± 6.6* |
| Weight (kg) | 63.3 ± 10.7 | 52.5 ± 8.7* |
| BMI (kg/m$^2$) | 23.5 ± 3.2 | 22.9 ± 3.4* |
| Grip strength (kg) (median [IQR]) | 37.0 [32.0–42.5] | 23.5 [20.0–23.5]** |
| 6-m walking time (s) (median [IQR]) | 5.0 [4.0–6.0] | 5.0 [4.0–6.0] |
| Chair stand time (s) (median [IQR]) | 8.5 [7.0–11.0] | 9.0 [7.0–11.0] |
| Cognitive impairment (%) | 3.6 | 2.4 |
| Radiographic knee OA (%) | 37.4 | 51.9*** |
| Radiographic LS (%) | 76.1 | 54.2 |
| Radiographic VFx | 8.9 | 10.1 |
| Knee pain (%) | 15.3 | 25.7*** |
| Lower back pain (%) | 18.8 | 21.5 |
| Previous falls (%) | 13.1 | 18.0*** |

Values are mean ± SD, except where indicated.
BMI: body mass index, OA: osteoarthritis, LS: lumbar spondylosis, VFx: vertebral fracture, IQR: interquartile range.
* $p<0.05$ vs. men by non-paired Student's $t$-test.
** $p<0.05$ vs. men by Wilcoxon signed-rank test.
*** $p<0.05$ vs. men by chi square test.

respectively) than non-responders (63.8, 69.1 and 12.0, respectively). Prevalence of previous falls was significantly lower in responders than non-responders (16.3 and 21.0%, respectively).

Table 2 shows the age, anthropometric measurements, physical performance, and prevalence of cognitive impairment, bone and joint diseases, and previous falls of participants at baseline in men and women. Regarding physical performance, grip strength and chair stand time were significantly better in men (37.0 kg and 8.5 s, respectively) than in women (23.5 kg and 9.0 s, respectively), but the 6-m walking time was not (5.0 s and 5.0 s, respectively). The prevalence of radiographic knee OA and knee pain was significantly higher in women (51.9% and 25.7%, respectively) than in men (37.4% and 15.3%, respectively), whereas that of LS and lower back pain was not different between men and women. The prevalence of previous falls was significantly higher in women than in men (18.0% and 13.1%, respectively).

During the 3-year follow-up, 79 (17.4% [95% confidence interval [CI] 14.3–21.2]) men and 216 (24.1% [95% CI 21.4–27.0]) women reported at least one fall, and 54 (11.9% [95% CI 9.3–15.3]) men and 111 (12.4% [95% CI 10.4–14.7]) women reported multiple falls. The chi square test showed that the incidence of falls was significantly different between men and women ($p=0.0011$). The incidence of single and multiple falls was significantly higher in the mountainous regions (11.5% and 17.4%, respectively) than coastal regions (8.1% and 7.8%, respectively). With increasing age, the incidence of falls increased in women, but the incidence of falls was similar in men in their 60s and 70s (Fig. 1).

Table 3 shows the age, anthropometric measurements, physical performance, and BMD at baseline between non-fallers, single fallers, and multiple fallers. Age and BMI were significantly higher in female fallers than non-fallers, but this was not the case in men. Grip strength was worse in female fallers than non-fallers, but this was not the case in men. The 6-m walking time and chair stand time were longer in both male and female fallers than in non-fallers. LS and neck BMD were significantly lower in female fallers than non-fallers, but this was not the case in men.

We next examined the incidence rate of falls during the 3-year follow-up according to previous falls at baseline in men and women (Supplementary Fig. 2). The incidence rates of multiple falls were 7.9%, 22.7%, and 48.7% in men and 8.8%, 20.4%, and 43.1% in women among non-fallers, single fallers, and multiple fallers, respectively. The incidence rates of single falls were 5.9%, 9.1%, and 0.0% in men and 12.5%, 7.8%, and 8.6% in women among non-fallers, single fallers, and multiple fallers, respectively. The chi square test showed that the incidence of falls during the 3-year follow-up was significantly associated with previous falls at baseline in men and women ($p<0.0001$).

Fig. 2 shows the incidence rate of falls during the 3-year follow-up according to the presence of bone and joint diseases and cognitive impairment. The incidence rates of multiple falls were 16.6% and 9.2% in men and 14.8% and 9.7% in women in those with and without knee OA, respectively. The incidence rates of a single fall were 8.3% and 3.9% in men and 14.2% and 9.1% in women in those with and without knee OA, respectively. The chi square test showed that knee OA at baseline was significantly associated with the incidence rate of falls during the 3-year follow-up in men and women ($p<0.0001$). Regarding knee pain, the incidence rates of multiple falls were 18.8% and 10.7% in men and 18.7% and 10.2% in women in those with and without knee pain, respectively. The incidence rates of a single fall were 8.7% and 5.0% in men and 10.4% and 10.4% in women in those with and without knee OA, respectively. The chi square test showed that knee pain at baseline was significantly associated with the incidence of falls during the 3-year follow-up in men and women ($p<0.0001$). LS and lower back pain were not significantly associated with the incidence of falls in men ($p=0.52$ and 0.77, respectively) or in women ($p=0.45$ and 0.58, respectively). VFx at baseline was significantly associated with the incidence of falls in women (multiple falls 22.2% and 11.3%, single falls 14.4% and 11.4%, in those with and without VFx, respectively, $p=0.005$), but not in men ($p=0.06$). OP defined by L2–4 and femoral neck BMD was not associated with the incidence of falls in men and women. Cognitive impairment

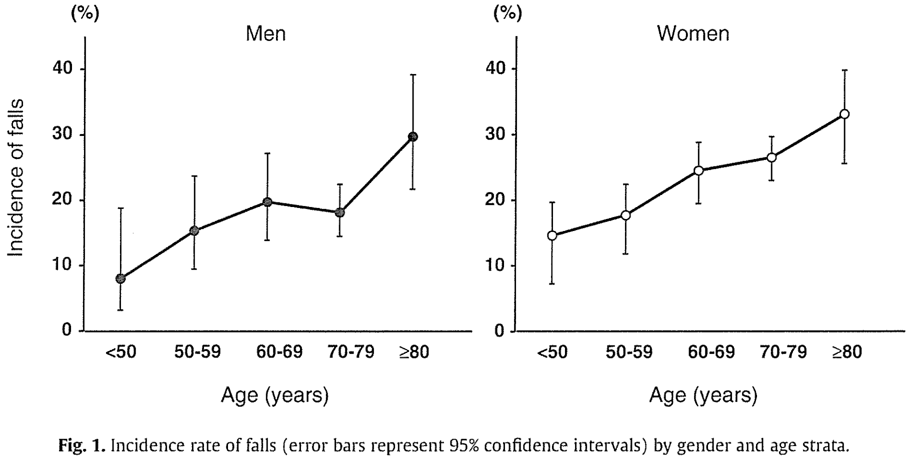


**Fig. 1.** Incidence rate of falls (error bars represent 95% confidence intervals) by gender and age strata.

**Table 3**
Comparison of characteristics among non-fallers, single fallers, and multiple fallers in men and women.

| | Men | | | | Women | | | |
|---|---|---|---|---|---|---|---|---|
| | Non-fallers | Single fallers | Multiple fallers | p value | Non-fallers | Single fallers | Multiple fallers | p value |
| Number of participants | 373 | 25 | 54 | | 680 | 105 | 111 | |
| Age (years) | 64.4 (11.7) | 67.2 (13.2) | 67.6 (10.1) | 0.10 | 62.4 (11.6) | 66.0 (12.6) | 66.7 (11.4) | <0.001 |
| BMI (kg/m$^2$) | 23.4 (3.1) | 24.6 (3.9) | 23.7 (3.3) | 0.16 | 22.8 (3.5) | 22.7 (3.1) | 23.8 (3.5) | 0.01 |
| Grip strength (kg) (median [IQR]) | 37.0 [32.0–43.0] | 37.0 [30.0–41.5] | 35.0 [28.8–40.0] | 0.08 | 24.0 [20.0–27.0] | 23.0 [19.5–27.0] | 22.0 [18.0–26.0] | 0.01 |
| 6-m walking time (s) (median [IQR]) | 4.5 [4.0–6.0] | 5.5 [4.6–7.3] | 6.2 [5.0–6.6] | <0.0001 | 5.0 [4.0–6.0] | 5.0 [4.0–6.5] | 5.5 [4.0–7.5] | <0.0001 |
| Chair stand time (s) (median [IQR]) | 8.0 [7.0-10.0]) | 11.0 [9.0-12.0] | 10.0 [8.0-13.0] | <0.0001 | 9.0 [7.0-11.0] | 9.0 [8.0-12.0] | 10.0 [8.0-12.25] | 0.0001 |
| LS BMD | 1.05 (0.20) | 1.05 (0.20) | 1.05 (0.15) | 0.99 | 0.89 (0.18) | 0.85 (0.16) | 0.86 (0.17) | 0.04 |
| Neck BMD | 0.75 (0.13) | 0.77 (0.12) | 0.75 (0.10) | 0.79 | 0.65 (0.13) | 0.61 (0.11) | 0.63 (0.11) | 0.003 |

Values are the means (standard deviation), except where indicated.
One-way analysis of variance was used to determine the differences in age, height, weight and BMI among non-fallers, single fallers, and multiple fallers.
Kruskal–Wallis test was used to determine the differences in grip strength, 6-m walking time and chair stand time among non-fallers, single fallers, and multiple fallers.
The chi square test was used to determine the differences in the prevalence of cognitive impairment among non-fallers, single fallers, and multiple fallers.
BMI: body mass index, LS: lumbar spondylosis, BMD: bone mineral density.

was associated with the incidence of falls in men (multiple falls 31.3% and 10.9%, single falls 18.8% and 5.1%, in those with and without cognitive impairment, respectively, $p=0.002$), but not in women ($p=0.19$).

In men, multinomial logistic regression analysis after adjusting for age and BMI showed that a longer 6-m walking time, longer chair stand time, and previous falls were risk factors for falls, but grip strength, bone and joint diseases, and cognitive impairment were not

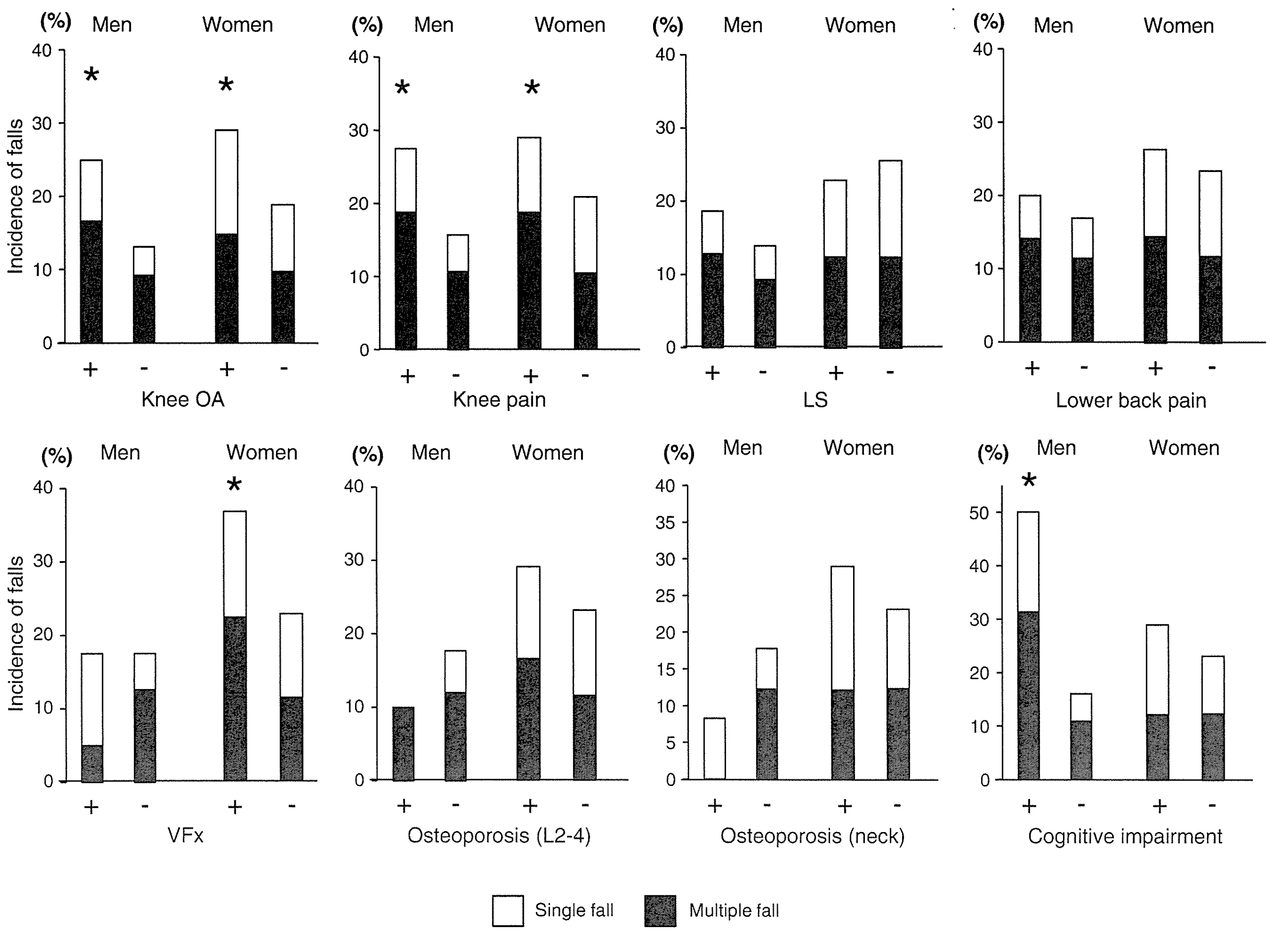


**Fig. 2.** Incidence of single and multiple falls by bone and joint diseases and cognitive impairment. *$p<0.05$ vs. participants without each disease or pain, respectively, according to the chi square test. OA, osteoarthritis; LS, lumbar spondylosis; VFx, vertebral fracture.

**Table 4**
Risk factors for single and multiple falls in men.

| | Crude OR (95% CI) | | Adjusted OR (95% CI) | |
|---|---|---|---|---|
| | Single falls | Multiple falls | Single falls | Multiple falls |
| Grip strength (5 kg increase) | 0.90 (0.71–1.14) | 0.84 (0.71–0.99) | 1.14 (1.01–1.29) | 0.88 (0.72–1.08) |
| 6-m walking time (1 s increase) | 1.12 (0.98–1.27) | 1.13 (1.03–1.26) | 1.11 (0.95–1.25) | 1.11 (1.01–1.23) |
| Chair stand time (1 s increase) | 1.17 (1.03–1.32) | 1.21 (1.11–1.33) | 1.15 (1.00–1.32) | 1.21 (1.09–1.33) |
| LS BMD (0.1 mg/cm$^2$ increase) | 1.00 (0.80–1.22) | 1.00 (0.86–1.16) | 0.92 (0.73–1.15) | 0.97 (0.83–1.13) |
| Neck BMD (0.1 mg/cm$^2$ increase) | 1.10 (0.81–1.47) | 0.98 (0.78–1.21) | 1.07 (0.73–1.51) | 1.01 (0.77–1.30) |
| Knee OA | 2.44 (1.09–5.56) | 2.08 (1.18–3.70) | 2.07 (0.84–5.21) | 1.77 (0.95–3.33) |
| Knee pain | 2.04 (0.72–5.09) | 2.05 (0.99–4.00) | 1.65 (0.57–4.21) | 1.78 (0.85–3.55) |
| VFx | 2.58 (0.82–6.85) | 0.40 (0.06–1.36) | 2.48 (0.75–7.04) | 0.32 (0.05–1.13) |
| Cognitive impairment | 6.19 (1.29–23.1) | 4.83 (1.41–15.1) | 13.48 (0.98–178.64) | 3.17 (0.44–21.99) |
| *Previous falls* | | | | |
| Single fall | – | – | – | 3.52 (1.07–9.97) |
| Multiple falls | 1.18 (0.25–4.61) | 9.54 (3.15–30.08) | – | 12.6 (5.80–27.97) |

Multinomial logistic regression analysis was used to calculate the crude odds ratio (OR) and 95% confidence interval (CI) compared with non-fallers.
Adjusted OR was calculated using multinomial logistic regression analysis after adjusting for age and body mass index (BMI).
OA: osteoarthritis, VFx: vertebral fracture, BMD: bone mineral density, LS: lumbar spondylosis.
Radiographic knee OA was defined as Kellgren Lawrence grade 3 or 4.

(Table 4). Previous falls were significantly associated with the incidence of multiple falls. In women, multinomial logistic regression analysis after adjusting for age and BMI showed that a longer 6-m walking time was a risk factor for multiple, but not single falls (Table 5). Chair stand time also tended to be associated with the incidence of single and multiple falls. Regarding bone and joint diseases, knee pain was a risk factor for single and multiple falls. VFx also tended to be associated with multiple falls, but radiographic knee OA was not associated with falls. Cognitive impairment was a risk factor for multiple falls, but not for single falls. A history of previous falls was a risk factor for multiple, but not single falls.

To determine the independent association of each physical performance parameter with the incidence of falls, multinomial logistic regression analysis was performed with age, BMI, 6-m walking time, and chair stand time as explanatory variables. We found that a longer chair stand time was an independent risk factor for multiple falls (OR 1.18, 95% CI 1.06–1.32), but a longer 6-m walking time was not (OR 1.05, 0.93–1.16). In women, a longer 6-m walking time tended to be associated with the incidence of multiple falls (OR 1.09, 95% CI 0.98–1.22), but a longer chair stand time was not (OR 1.01, 95% CI 0.94–1.07). After adjusting for previous falls, the independent association of a longer chair stand time with the incidence of falls remained in men (OR 1.15, 95% CI 1.02–1.30), and the independent association of a longer 6-m walking time with the incidence of falls remained in women (OR 1.12, 95% CI 1.00–1.25). In addition, knee pain and cognitive impairment in women were also significantly associated with falls, and VFx tended to be associated with falls with multinomial logistic regression analysis after adjusting for age and BMI. Thus, to determine the independent association of physical performance, bone and joint diseases, and cognitive impairment, multinomial logistic regression analysis was used with age, BMI, 6-m walking time, knee pain, VFx, and cognitive impairment as explanatory variables. We found that a longer 6-m walking time was an independent risk factor for multiple falls (OR 1.08, 95% CI 1.00–1.18), but the significant association of knee pain, VFx, and cognitive impairment with the incidence of falls disappeared (OR 1.47, 95% CI 0.91–2.35, OR 1.52, 95% CI 0.80–2.81, and OR 1.16, 95% CI 0.35–3.24, respectively).

## Discussion

The present study is the first longitudinal population-based cohort study to examine whether physical performance, bone and joint diseases, and cognitive impairment are risk factors for single and multiple falls in men and women. We found gender differences in risk factors for

**Table 5**
Risk factors for single and multiple falls in women.

| | Crude OR (95% CI) | | Adjusted OR (95% CI) | |
|---|---|---|---|---|
| | Single falls | Multiple falls | Single falls | Multiple falls |
| Grip strength (5 kg increase) | 0.84 (0.70–0.99) | 0.81 (0.68–0.95) | 0.94 (0.77–1.11) | 0.91 (0.75–1.08) |
| 6-m walking time (1 s increase) | 1.10 (1.01–1.19) | 1.16 (1.08–1.25) | 1.04 (0.94–1.14) | 1.11 (1.02–1.20) |
| Chair stand time (1 s increase) | 1.07 (1.02–1.12) | 1.07 (1.03–1.12) | 1.04 (0.99–1.10) | 1.04 (0.99–1.09) |
| LS BMD (0.1 mg/cm$^2$ increase) | 0.88 (0.78–1.00) | 0.90 (0.80–1.01) | 0.96 (0.83–1.11) | 0.92 (0.80–1.06) |
| Neck BMD (0.1 mg/cm$^2$ increase) | 0.75 (0.63–0.90) | 0.85 (0.72–1.01) | 0.79 (0.62–1.01) | 0.87 (0.69–1.10) |
| Knee OA | 1.79 (1.18–2.78) | 1.75 (1.16–2.63) | 1.52 (0.94–2.50) | 1.12 (0.79–1.82) |
| Knee pain | 1.83 (1.17–2.83) | 2.22 (1.44–3.37) | 1.62 (1.00–2.60) | 1.60 (1.00–2.54) |
| VFx | 1.54 (0.78–2.85) | 2.40 (1.35–4.12) | 1.15 (0.57–2.20) | 1.81 (0.98–3.24) |
| Cognitive impairment | 0.42 (0.02–2.12) | 2.12 (0.68–5.60) | 0.73 (0.19–2.61) | 4.95 (1.50–16.08) |
| *Previous falls* | | | | |
| Single fall | 0.55 (0.16–1.74) | 1.51 (0.33–5.41) | 0.70 (0.30–1.43) | 2.48 (1.40–4.28) |
| Multiple falls | 0.86 (0.39–1.81) | 8.55 (3.80–19.20) | 1.06 (0.35–2.62) | 6.93 (3.76–12.72) |

Multinomial logistic regression analysis was used to calculate the crude odds ratio (OR) and 95% confidence interval (CI) compared with non-fallers.
Adjusted OR was calculated using multinomial logistic regression analysis after adjusting for age and body mass index (BMI).
OA: osteoarthritis, VFx: vertebral fracture, BMD: bone mineral density, LS: lumbar spondylosis.
Radiographic knee OA was defined as Kellgren Lawrence grade 3 or 4.

falls. Regarding physical performance, a longer chair stand time was an independent risk factor for falls in men, whereas a longer 6-m walking time was an independent risk factor for falls in women. Knee pain, VFx, and cognitive impairment were associated with falls in women, but not in men.

The present study is a population-based longitudinal study to determine whether bone and joint diseases are risk factors for falls in Japanese men and women. After adjusting for age and BMI, knee pain was a risk factor for falls in women, but not in men. The sex differences regarding the association of knee pain with falls may be partly explained by the weaker quadriceps muscles in women, which is known to be an independent risk factor for falls [16]. Muscle strength is higher in men than in women in all decades [39], which may obscure the association of knee pain with falls. In addition, given the insignificant association of radiographic knee OA with falls, falls may occur due to symptoms such as pain rather than radiographic changes in the knee itself. Our study and other previous cross-sectional studies also suggested that knee pain is significantly associated with falls [11]. In other words, falls may be preventable when pain is relieved by medical care, even if patients have radiographic knee OA.

In the present study, LS and lower back pain were not associated with falls, whereas VFx was associated with falls. Lower BMD was not associated with falls in the present study, and thus, radiographic changes but not OP may be associated with falls. Studies of patients with VFx have reported increased kyphosis angles [16,17], which is an independent risk factor for injurious falls [40]. Previous studies [41,42] have demonstrated that people with kyphosis have greater balance abnormalities as assessed by computerized dynamic posturography. Specifically, they reported that women with OP-related kyphosis had greater mediolateral displacement and increased mediolateral velocity compared to controls [42]. In addition, lateral spontaneous sway amplitude has been reported to be the single best predictor of future risk of falls [43]. These observations may partly explain the association between VFx and falls.

In the present study, after adjusting for age and BMI, both a longer 6-m walking time and a longer chair stand time were associated with falls in men and women. A previous study also showed that slower walking speed is a risk factor for falls [44], although men and women were not separately analyzed in the study. To determine the independent association of the 6-m walking time and chair stand time, we further used multinomial logistic regression analysis with age, BMI, 6-m walking time, and chair stand time as explanatory factors, and found that in men, a longer chair stand time was an independent risk factor for multiple falls, but a longer 6-m walking time was not. In women, a longer 6-m walking time was associated with the incidence of multiple falls, whereas a longer chair stand time was not. This indicates that slower walking speed may more strongly affect the risk of falling in women than in men, whereas a longer chair stand time may more strongly affect the risk of falling in men than in women. The walking time and chair stand time can be easily and quickly measured in clinical and research settings without requiring monitoring devices or extensive training. The present study may indicate that walking time is a simple and quick option for measuring the risk of falling, particularly in women, and measuring the chair stand time is a simple and quick option for estimating the risk of falling, particularly in men.

The present study has several limitations. First, our participants lived in the community, and thus, our findings may not apply to elderly persons residing in institutions. Second, we did not include other anatomical locations of weight-bearing OA such as hip OA in the analysis, although this disorder also affects falls [45]. However, the prevalence of KL = 3 or 4 hip OA is 1.4% and 3.5% in Japanese men and women [46], respectively, which is lower than that of KL = 3 or 4 knee OA (12.2% and 21.0% in men and women, respectively) in the present study. Thus, it is possible that hip OA would not strongly affect the results of the present study. Third, non-responders were older, had lower physical performance and higher prevalence of knee pain, which were risk factors for falls. This means that the incidence of falls in the present study may have been underestimated. Fourth, the accuracy and reliability of recall of falls over the past 3 years was not assessed in the present study. Previous studies have shown that 13–32% of elderly subjects with confirmed falls did not recall falling over a 12-month period [47], even when excluding subjects with cognitive impairment. Therefore, the incidence of falls may be underestimated, particularly in older subjects and those with cognitive impairment. In addition, individuals are more likely to recall a fall that resulted in injury, which may have influenced the results of this study.

## Conclusion

The present longitudinal analysis using a large-scale population from the ROAD study revealed gender differences in risk factors for falls. A longer walking time was a risk factor for falls in women, whereas a longer chair stand time was a risk factor for falls in men. Knee pain and VFx were risk factors for falls in women, but not in men. Further studies, along with continued longitudinal surveys in the ROAD study, will help elucidate the background of bone and joint diseases and their relationship with falls.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.bone.2012.10.020.

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ORIGINAL ARTICLE

# Prevalence of Falls and the Association With Knee Osteoarthritis and Lumbar Spondylosis As Well As Knee and Lower Back Pain in Japanese Men and Women

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***Objective.*** **There is little information on falls by sex and age strata in Japan, and few factors associated with falls have been established. However, the association between bone and joint diseases and falls remains unclear. We examined prevalence of falls by sex and age strata, determined its association with radiographic osteoarthritis (OA) of the knee and lumbar spine, and determined knee and lower back pain after single and multiple falls.**

***Methods.*** **A questionnaire assessed the number of falls during 12 months preceding baseline. Knee and lumbar spine radiographs were read by Kellgren/Lawrence (K/L) grade; radiographic knee OA and lumbar spondylosis were defined as a K/L grade of 3 or 4. Knee and lower back pain were estimated by an interview.**

***Results.*** **A total of 587 men and 1,088 women (mean ± SD age 65.3 ± 12.0 years) were analyzed. During 1 year, 79 (13.5%) men and 207 (19.0%) women reported at least 1 fall. With increasing age, the prevalence of multiple falls was higher in women, but lower in elderly men age >60 years. In men, few factors were significantly associated with falls. In women, radiographic knee OA and lumbar spondylosis, as well as knee and lower back pain, were significantly associated with multiple falls without adjustment. Lower back pain and knee pain were independently associated with multiple falls in women after adjustment.**

***Conclusion.*** **Lower back pain and knee pain were significantly associated with multiple falls in women.**

## INTRODUCTION

Falls are one of the main causes of injury, disability, and death among the elderly (1,2). In Japan, according to the recent National Livelihood Survey of the Ministry of Health, Labour and Welfare, fall and fracture are ranked fifth among diseases that cause disabilities and subsequently require support with activities of daily living (3). However, there have been few population-based studies for prevalence of fall based on sex and age strata. Further, in terms of factors associated with falls, muscle strength, balance, vision, and functional capacities, there are traits that diminish with aging, and these factors have been suggested as predictive risk factors for falls and fractures (4). Cognitive impairment has also been established as a risk factor for falls (5), but the association of bone and joint diseases, especially osteoarthritis (OA), with falls remains unclear.

The representative sites of OA are the knee and lumbar spine. Knee OA and lumbar spondylosis (LS) are major public health issues since they cause chronic pain and disability (6–11). The prevalence of radiographic knee OA and LS is high in Japan (12,13), with 25,300,000 and 37,900,000 subjects ages ≥40 years estimated to experience radiographic knee OA and LS, respectively (14). The National Livelihood Survey ranked OA fourth among diseases that cause disabilities and subsequently require sup-

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## Significance & Innovations

- During 1 year, 13.5% of men and 19.0% of women reported at least 1 fall.
- With increasing age, prevalence of multiple falls was higher in women, but lower in elderly men age >60 years.
- Lower back pain and knee pain were independently associated with multiple falls in women.

port with activities of daily living (3), but there have been few studies of the association between falls and OA (15,16). In previous studies, knee OA was assessed only by interview and not by radiography. The principal clinical symptom of knee OA is pain (17), but its correlation with the radiographic severity of knee OA is not as strong as expected (12,18–20). In fact, in a study in Japan, ~20% of the subjects without knee OA had knee pain, and 30% of the subjects with severe knee OA had no knee pain (12). Therefore, knee OA diagnosed by interview could be limited by variable accuracy. In addition, men and women were not examined separately in these previous studies, although sex differences have been found in the prevalence of knee OA (12). Furthermore, knee OA is conventionally defined according to Kellgren/Lawrence (K/L) grade (21), and our previous study showed that the association of a K/L grade of 2 (knee OA with pain) was weak, but that a K/L grade of 3 or 4 (knee OA with pain) was strong (12); therefore, the association of knee OA with falls may be different between a K/L grade of 2 for knee OA and a K/L grade of 3 or 4 for knee OA. However, there are no population-based studies on the association of severity of knee OA with falls. With regard to LS, to the best of our knowledge, there have been no population-based studies regarding its association with falls.

Previous studies have shown that associations between individual risk factors and a single fall are few in number and weak compared to risk factors for multiple falls (16), indicating that single and multiple falls may have different backgrounds. Therefore, to determine factors associated with falls, single and multiple falls should be analyzed separately.

The objectives of this study were to clarify prevalence of single and multiple falls by sex and age strata in Japan using a large-scale, population-based cohort study known as Research on Osteoarthritis/osteoporosis Against Disability (ROAD). Further, we examined the associations of radiographic knee OA and LS, as well as knee and lower back pain, with single and multiple falls in Japanese men and women.

## PATIENTS AND METHODS

**Patients.** The ROAD study is a nationwide prospective study designed to establish epidemiologic indexes for evaluation of clinical evidence for the development of a disease-modifying treatment for bone and joint diseases (OA and osteoporosis are the representative bone and joint diseases, respectively). It consists of population-based cohorts in 3 communities in Japan. A detailed profile of the ROAD study has been described elsewhere (12–14,22); a brief summary is provided here. To date, we have completed the creation of a baseline database that includes clinical and genetic information for 3,040 subjects (1,061 men and 1,979 women) with a mean age of 70.6 years (range 23–95 years), who were recruited from resident registration listings in 3 communities: an urban region in Itabashi, Tokyo; a mountainous region in Hidakagawa, Wakayama; and a coastal region in Taiji, Wakayama.

Residents of these regions were recruited from the resident registration list of the relevant region. The participants in the urban region were recruited from a randomly selected cohort from the Itabashi-ward residents' registration database (22). The participation rate was 75.6%. The participants in mountainous and coastal regions were also recruited from the resident-registration lists, and the participation rates in these 2 areas were 56.7% and 31.7%, respectively. The inclusion criteria, apart from residence in the communities mentioned above, were the ability to 1) walk to the survey site, 2) report data, and 3) understand and sign an informed consent form. The baseline survey of the ROAD study was completed in 2006. All participants provided their written informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo and the Tokyo Metropolitan Institute of Gerontology.

**Falls assessment.** All subjects were interviewed with regard to falls and fractures by experienced interviewers and were asked the following questions: "Have you experienced falls during the 12 months preceding baseline, and if yes, how many falls did you experience?" and "Have you experienced any fractures when you fell?" According to a previous study on falls (23), a fall is defined as a sudden, unintentional change in position causing an individual to land at a lower level on an object, the floor, or the ground, other than as a consequence of a sudden onset of paralysis, epileptic seizure, or overwhelming external force.

**Pain assessment.** All subjects were also interviewed by experienced orthopedists (SM and HO) with regard to knee pain and lower back pain and were asked the following questions: "Have you experienced knee pain on most days in the past year, in addition to now?" and "Have you experienced lower back pain on most days in the past year, in addition to now?" Those who answered yes were defined as having pain.

**Radiographic assessment.** All participants underwent radiographic examination of both knees using anteroposterior and lateral views with weight-bearing and foot map positioning: radiographic examination of the anteroposterior and lateral views of the lumbar spine, including intervertebral levels L1/2 to L5/S, was also performed. Knee and lumbar spine radiographs were read without the knowledge of participant clinical status by a single, experienced orthopedist (SM) using the K/L radiographic atlas

(21) to determine the severity of K/L grading. Radiographs were scored as grade 0 through 4, with higher grades being associated with more severe OA. We defined knee OA and LS as a K/L grade of ≥3 in at least 1 knee and 1 intervertebral level, respectively. To evaluate the intraobserver variability of K/L grading, 100 randomly selected radiographs of the knee and the lumbar spine were scored by the same observer more than 1 month after the first reading. One hundred other radiographs were also scored by 2 experienced orthopedic surgeons (SM and HO) using the same atlas for interobserver variability. The intra- and interobserver variabilities evaluated were confirmed by kappa analysis to be sufficient for assessment (0.86 and 0.80 for knee OA, and 0.84 and 0.76 for LS, respectively).

**Covariates.** Anthropometric measurements included height, weight, and body mass index (BMI; $kg/m^2$). Grip strength was measured on bilateral sides using a TOEI LIGHT handgrip dynamometer, and the best measurement was used to characterize maximum muscle strength. To measure physical performance, the time taken to walk 6 meters at normal walking speed in a hallway was recorded. Subjects were told to walk from a marked starting line to a 6-meter mark as if they were walking down their hallway at home. Time was measured in seconds with a stopwatch and rounded to the nearest hundredth of a second. The average of 2 trials was recorded. These gait-speed trial measurements are considered highly reliable in community-dwelling elderly subjects (24–27).

The time taken for 5 consecutive chair rises without the use of hands was also recorded. Hands were folded in front of the chest with feet flat on the floor, following the protocol described by Guralnik et al (28) and used by other researchers (25,29,30). Time was measured in seconds with a stopwatch and rounded to the nearest hundredth of a second. Timing began with the command "go" and ended when the buttocks contacted the chair on the fifth landing. The reliability of this protocol is adequate (25,28,29). Cognition was also evaluated for all subjects using a Mini-Mental State Examination, and a cutoff score of <24 was used to select participants with cognitive impairment (31).

**Statistical analyses.** The differences in age, anthropometric measurements, and physical performance measurements between men and women were examined by Student's unpaired *t*-test, and among groups of nonfallers, single fallers, and multiple fallers using one-way analysis of variance (ANOVA). The prevalence of cognitive impairment, radiographic knee OA and LS, and knee and lower back pain was compared between men and women, and among nonfallers, single fallers, and multiple fallers by using the chi-square test. The prevalence of single and multiple falls was also compared between men and women, among subjects with no knee OA (K/L grade 0 or 1), with K/L grade 2 for knee OA and K/L grade 3 or 4 for knee OA, and among subjects with no LS (K/L grade 0 or 1), with K/L grade 2 for LS, and K/L grade 3 or 4 for LS by using the chi-square test. The association of knee pain and lower back pain with physical performance was determined by logistic regression analysis. Multinomial logistic regression analysis was also used to determine the association of anthropometric measurements, physical performance, cognitive impairment, radiographic knee OA and LS defined as K/L grade 3 or 4, and knee and lower back pain, with single and multiple falls compared with nonfalls. Further, to determine the independent association of radiographic knee OA and LS, and knee and lower back pain with single and multiple falls compared with nonfalls, we first used multinomial logistic regression analysis with age, BMI, cognitive impairment, radiographic knee OA and LS, and knee and lower back pain as independent variables. In addition to the above independent variables, we additionally adjusted for grip strength, 6-meter walking time, and chair stand time. Data analyses were performed using SAS software, version 9.0.

## RESULTS

Of the 1,690 subjects in the mountainous and seaside cohorts at baseline, 15 subjects provided incomplete fall questionnaires, leaving a total of 1,675 subjects (587 men, 1,088 women). Table 1 shows the age, anthropometric measurements, and physical performance of the participants in the present study. Regarding physical performance, grip strength, 6-meter walking time, and chair stand time were significantly better in men than in women. The prevalence of cognitive impairment was not significantly different between men and women. The prevalence of radiographic knee OA and knee pain was significantly higher in women than in men, while that of LS and lower back pain was not different between men and women.

During the 12 months preceding the baseline examination, 79 men (13.5%, 95% confidence interval [95% CI] 10.9–16.5%) and 207 women (19.0%, 95% CI 16.8–21.5%) reported at least 1 fall, and 48 men (8.2%, 95% CI 6.2–10.7%) and 80 women (7.4%, 95% CI 5.9–9.1%) reported multiple falls. Chi-square test showed that the prevalence of single and multiple falls were significantly different between men and women ($P < 0.0001$). Among 286 subjects with at least 1 fall, 6 subjects (2.1%) had a wrist fracture, 2 (0.7%) had a proximal humerus fracture, 1 (0.3%) had a vertebral fracture, and 12 (4.2%) had fractures at other sites. With increasing age, the prevalence of falls was lower in elderly men age >60 years; however, the prevalence of falls was higher in women with increasing age (Table 2). Moreover, with increasing age, the prevalence of multiple falls was also lower in elderly men age >60 years, but it was higher in women with increasing age (Table 2). The prevalence (95% CI) of a single fall (%) was similar among age strata in men and women (for men: 5.3% [1.8–14.4%], 6.8% [3.3–13.4%], 3.2% [1.4–7.3%], 5.5% [3.2–9.4%], and 7.4% [1.0–12.5%] in the age subgroups of <50 years, 50–59 years, 60–69 years, 70–79 years, and ≥80 years, respectively; for women: 11.9% [7.5–18.5%], 11.1% [7.5–16.1%], 12.0% [8.9–16.0%], 11.6% [8.6–15.6%], and 11.4% [6.7–18.9%] in the age subgroups of <50 years, 50–59 years, 60–69 years, 70–79 years, and ≥80 years, respectively).

Table 3 shows the age, anthropometric measurements,

**Table 1. Characteristics of participants***

| | Overall | Men | Women |
|---|---|---|---|
| Subjects, no. | 1,675 | 587 | 1,088 |
| Age, years | 65.3 ± 12.0 | 66.3 ± 11.7 | 64.7 ± 12.1† |
| Height, cm | 155.1 ± 9.3 | 163.4 ± 7.2 | 150.6 ± 6.9† |
| Weight, kg | 55.6 ± 10.8 | 62.3 ± 10.9 | 52.0 ± 8.9† |
| BMI, kg/m$^2$ | 23.0 ± 3.4 | 23.3 ± 3.2 | 22.9 ± 3.5† |
| Grip strength, kg | 27.4 ± 9.8 | 35.7 ± 9.3 | 22.9 ± 6.8† |
| 6-meter walking time, seconds | 5.5 ± 2.5 | 5.3 ± 2.2 | 5.6 ± 2.6† |
| Chair stand time, seconds | 10.1 ± 4.4 | 9.7 ± 3.6 | 10.4 ± 4.8† |
| Cognitive impairment, % | 4.5 | 5.2 | 4.2 |
| Radiographic knee OA, % | 20.3 | 15.0 | 23.0‡ |
| Radiographic lumbar spondylosis, % | 37.1 | 37.7 | 36.9 |
| Knee pain, % | 24.4 | 18.9 | 27.4‡ |
| Lower back pain, % | 20.1 | 21.7 | 21.2 |

* Values are the mean ± SD unless indicated otherwise. BMI = body mass index; OA = osteoarthritis.
† $P < 0.05$ vs. men by Student's unpaired $t$-test.
‡ $P < 0.05$ vs. men by chi-square test.

physical performance, and prevalence of cognitive impairment among nonfallers, single fallers, and multiple fallers. One-way ANOVA showed that there were no significant associations of age, anthropometric measurements, physical performance, and prevalence of cognitive impairment with falls in men, while age and BMI were higher in multiple fallers than in nonfallers in women. With regard to physical performance, grip strength was lower and 6-meter walking time and chair stand time were longer in multiple fallers than in nonfallers and single fallers in women. Further, prevalence of cognitive impairment was also different among nonfallers, single fallers, and multiple fallers in women. Further, to determine the association of anthropometric measurements, physical performance, and cognitive impairment with single and multiple falls, we also used multinomial logistic regression analysis and found that age (odds ratio [OR] 1.04, 95% CI 1.02–1.06), BMI (OR 1.10, 95% CI 1.03–1.17), grip strength (OR 0.92, 95% CI 0.89–0.96), 6-meter walking time (OR 1.10, 95% CI 1.02–1.17), chair stand time (OR 1.06, 95% CI 1.02–1.10), and cognitive impairment (OR 3.86, 95% CI 1.67–3.83) were significantly associated with multiple falls in women.

To determine the association of the severity of knee OA with falls, we classified subjects as those with no knee OA (K/L grade 0 or 1), with K/L grade 2 for knee OA, and with K/L grade 3 or 4 for knee OA. The prevalence of falls in subjects with no knee OA, K/L grade 2 for knee OA, and K/L grade 3 or 4 for knee OA was 11.8%, 17.1%, and 12.5%, and 17.7%, 17.6%, and 25.6% in men and women, respectively. There were no significant associations between falls and the severity of knee OA in men (chi-square test; $P = 0.27$), while prevalence of falls was higher in women with K/L grade 3 or 4 for knee OA than those with no knee OA and K/L grade 2 for knee OA ($P = 0.01$). Similar to knee OA, we classified subjects as those with no LS (K/L grade 0 or 1), those with K/L grade 2 for LS, and those with K/L grade 3 or 4 for LS. The prevalence of falls in subjects with no LS, K/L grade 2 for LS, and K/L grade 3 or 4 for LS was 16.3%, 11.3%, and 14.0%, and 17.0%, 20.5%, and 20.7% in men and women, respectively. There were no significant associations between falls and the severity of LS in men and women (chi-square test, $P = 0.38$ and 0.32, respectively). We next used the chi-square test to determine the association of single and multiple falls with knee OA and LS defined as K/L grade 3 or 4 (Table 4). A chi-square test showed that no significant factors were associated with falls in men, but radiographic knee OA, knee pain, and lower back pain were significantly associated with falls in women.

Multinomial logistic regression analysis also showed that radiographic knee OA, LS, and knee and lower back pain were significantly associated with multiple falls in women (Table 5). Because knee pain and lower back pain were also significantly associated with grip strength, 6-meter walking time, and chair stand time in men and women

**Table 2. Prevalence of falls by age strata in men and women***

| | Single fall | | Multiple falls | |
|---|---|---|---|---|
| Age, years | Men | Women | Men | Women |
| <50 | 15.8 (8.5–27.4) | 13.4 (8.7–20.2) | 10.5 (4.9–21.1) | 1.5 (0.4–5.3) |
| 50–59 | 10.7 (6.1–18.1) | 17.4 (12.8–23.1) | 3.9 (1.5–9.6) | 6.3 (3.7–10.4) |
| 60–69 | 16.7 (11.6–23.3) | 18.8 (14.9–23.4) | 13.5 (9.0–19.7) | 6.8 (4.5–10.1) |
| 70–79 | 12.4 (8.7–17.5) | 21.1 (16.9–25.9) | 6.9 (4.2–11.1) | 9.4 (6.7–13.1) |
| ≥80 | 11.1 (5.2–22.2) | 23.8 (16.7–32.8) | 3.7 (1.0–12.5) | 12.4 (7.4–20.0) |

* Values are the percentage (95% confidence interval).

**Table 3. Comparison of characteristics among nonfallers, single fallers, and multiple fallers in men and women***

| | Men | | | | Women | | | |
|---|---|---|---|---|---|---|---|---|
| | Nonfallers | Single fallers | Multiple fallers | *P* | Nonfallers | Single fallers | Multiple fallers | *P* |
| Subjects, no. | 508 | 31 | 48 | | 881 | 127 | 80 | |
| Age, years | 66.4 ± 11.7 | 67.6 ± 11.9 | 64.6 ± 11.3 | 0.50 | 64.4 ± 12.1 | 64.3 ± 12.2 | 69.1 ± 10.4 | 0.004 |
| Height, cm | 163.5 ± 7.4 | 162.3 ± 6.3 | 162.9 ± 5.9 | 0.56 | 150.9 ± 6.8 | 150.7 ± 7.7 | 148.5 ± 7.0 | 0.01 |
| Weight, kg | 62.6 ± 11.1 | 60.7 ± 10.4 | 60.3 ± 9.0 | 0.27 | 51.8 ± 8.8 | 53.3 ± 9.2 | 52.8 ± 8.9 | 0.15 |
| BMI, kg/m$^2$ | 23.3 ± 3.2 | 23.0 ± 3.1 | 22.7 ± 2.8 | 0.27 | 22.7 ± 3.4 | 23.4 ± 3.6 | 23.9 ± 3.7 | 0.002 |
| Grip strength, kg | 35.8 ± 9.3 | 34.0 ± 9.6 | 35.5 ± 9.1 | 0.57 | 23.3 ± 6.8 | 22.6 ± 6.5 | 19.9 ± 5.3 | < 0.001 |
| 6-meter walking time, seconds | 5.2 ± 2.2 | 5.8 ± 2.5 | 5.6 ± 2.3 | 0.21 | 5.5 ± 2.6 | 5.7 ± 2.6 | 6.3 ± 2.7 | 0.03 |
| Chair stand time, seconds | 9.6 ± 3.6 | 10.3 ± 3.8 | 10.2 ± 3.3 | 0.30 | 10.2 ± 4.8 | 10.5 ± 4.6 | 11.9 ± 5.1 | 0.01 |
| Cognitive impairment, % | 4.6 | 6.5 | 10.6 | 0.26 | 3.3 | 5.6 | 11.7 | 0.008 |

* Values are the mean ± SD unless indicated otherwise. One-way analysis of variance was used to determine the differences in age, height, weight, body mass index (BMI), grip strength, 6-meter walking time, normal step length, and chair stand time among nonfallers, single fallers, and multiple fallers. Chi-square test was used to determine the differences in prevalence of cognitive impairment among nonfallers, single fallers, and multiple fallers.

(logistic regression analysis; $P < 0.05$); to examine the independent association between radiographic knee OA, knee pain, radiographic LS, and lower back pain in women, we first used multinomial logistic regression analysis with age, BMI, cognitive impairment, radiographic knee OA, knee pain, radiographic LS, and lower back pain as independent variables (Table 5). In this analysis, only lower back pain was independently associated with multiple falls in women. In addition to the above independent variables, we also adjusted for grip strength, 6-meter walking time, and chair stand time, and found that the significant association of lower back pain with multiple falls disappeared, while knee pain was independently associated with multiple falls in women (Table 5).

## DISCUSSION

The present study is the first large-scale population-based cohort study of the prevalence of single and multiple falls and their association with radiographic knee OA and LS, as well as pain in Japanese men and women. We found that lower back pain and knee pain were independently associated with multiple falls in women.

There were distinct associations between age strata and single and multiple falls. We found that several factors were associated with multiple falls in women, but no factors were associated with a single fall in women. Previous studies have shown that associations between individual risk factors and a single fall are few in number and weak compared with risk factors for multiple falls (16). A single fall in a year could be accidental and occur due to individual as well as environmental factors, which may partly explain why there were no factors significantly associated with a single fall in our study. In contrast, several factors were associated with multiple falls in the present study, indicating that multiple falls may occur primarily due to individual factors.

In women, the prevalence of multiple falls was higher with increasing age, but in men, the prevalence of multiple falls was lower in subjects ages >60 years, although this could be a random error because of small prevalence, particularly in men. This may be partly explained by the

**Table 4. Comparison of radiographic knee OA and LS, as well as knee and lower back pain, among nonfallers, single fallers, and multiple fallers in men and women***

| | Men | | | | Women | | | |
|---|---|---|---|---|---|---|---|---|
| | Nonfallers | Single fallers | Multiple fallers | *P* | Nonfallers | Single fallers | Multiple fallers | *P* |
| Subjects, no. | 508 | 31 | 48 | | 881 | 127 | 80 | |
| Radiographic knee OA† | 77/507 (15.2) | 4/31 (12.9) | 7/47 (14.9) | 0.9417 | 186/875 (21.3) | 31/127 (24.4) | 33/79 (41.8) | 0.0002 |
| Knee pain‡ | 97/508 (19.1) | 3/31 (9.7) | 11/48 (22.9) | 0.3268 | 224/880 (25.5) | 37/127 (29.1) | 37/80 (46.3) | 0.0003 |
| Radiographic LS | 190/508 (37.4) | 12/31 (38.7) | 19/48 (39.6) | 0.9490 | 318/881 (36.1) | 45/127 (35.4) | 38/80 (47.5) | 0.1210 |
| Lower back pain§ | 99/508 (19.5) | 10/31 (32.3) | 9/48 (18.8) | 0.2203 | 177/880 (20.1) | 31/127 (24.4) | 28/80 (35.0) | 0.0062 |

* Values are the number/total number (percentage) unless otherwise indicated. The chi-square test was used to determine the differences in radiographic findings and pain among nonfallers, single fallers, and multiple fallers. Radiographic knee OA and LS were defined as Kellgren/Lawrence grade 3 or 4. OA = osteoarthritis; LS = lumbar spondylosis.
† Nine subjects with total knee arthroplasty were excluded.
‡ One subject with incomplete information regarding knee pain was excluded.
§ One subject with incomplete information regarding lower back pain was excluded.

**Table 5. Association of radiographic knee OA and LS, as well as knee and lower back pain, with single and multiple falls in women***

| | Crude OR (95% CI) | | Adjusted $OR_1$ (95% CI)† | | Adjusted $OR_2$ (95% CI)‡ | |
|---|---|---|---|---|---|---|
| | Single falls | Multiple falls | Single falls | Multiple falls | Single falls | Multiple falls |
| Radiographic knee OA | 1.20 (0.76–1.83) | 2.66 (1.64–4.26) | 1.07 (0.63–1.82) | 1.43 (0.78–2.61) | 1.04 (0.60–1.77) | 1.31 (0.70–2.43) |
| Knee pain | 1.20 (0.79–1.81) | 2.52 (1.58–4.02) | 1.00 (0.62–1.61) | 1.61 (0.92–2.79) | 0.99 (0.60–1.61) | 1.87 (1.06–3.28) |
| Radiographic LS | 0.97 (0.65–1.43) | 1.60 (1.01–2.54) | 0.87 (0.57–1.32) | 1.12 (0.68–1.85) | 0.88 (0.57–1.33) | 1.04 (0.61–1.74) |
| Lower back pain | 1.28 (0.82–1.96) | 2.14 (1.30–3.46) | 1.34 (0.84–2.08) | 1.72 (1.01–2.88) | 1.33 (0.84–2.08) | 1.58 (0.91–2.70) |

* Radiographic knee osteoarthritis (OA) and lumbar spondylosis (LS) were defined as Kellgren/Lawrence grade 3 or 4. Multinomial logistic regression analysis was used to calculate the odds ratio (OR) and 95% confidence interval (95% CI) compared with nonfallers. Eight subjects with total knee arthroplasty or incomplete information regarding pain were excluded.
† Adjusted $OR_1$ was calculated using multinomial logistic regression analysis with age, body mass index, cognitive impairment, radiographic knee OA, knee pain, radiographic LS, and lower back pain as independent variables.
‡ Adjusted $OR_2$ was calculated using multinomial logistic regression analysis with grip strength, 6-meter walking time, and chair stand time in addition to the above independent variables.

fact that elderly men generally retire from their occupations at approximately ages 60–70 years; therefore, their environment may change and men may become more sedentary as they age, leading to lower risks of falls. Women, however, must often continue to do household chores even after age 60 years, and their environment may therefore change to a smaller extent than that of men, but their health or muscle strength continues to decline (32), leading to the higher risk of falls.

Our study is the first population-based study to examine the association between knee OA and LS diagnosed by radiography and falls in Japanese men and women. Radiographic knee OA and LS were significantly associated with multiple falls in women, but not in men, although no significant association of radiographic knee OA or LS with falls may be due to the small number of falls in men. The sex differences identified in the association between radiographic knee OA and falls may be partly explained by the weaker quadriceps muscles and increased postural sway associated with knee OA (33,34), both of which are known to be independent risk factors for falls (16,35). In men, muscle strength was higher than that in women in all decades (32), which may obscure the association between radiographic knee OA and falls. LS was also significantly associated with falls in this study, but the OR was lower than that for knee OA. Therefore, falls may be more strongly associated with problems of the lower extremities rather than the trunk.

After adjustment for age, BMI, and cognitive impairment, lower back pain was independently associated with multiple falls, and after adjustment for age, BMI, grip strength, cognitive impairment, 6-meter walking time, and chair stand time, knee pain was independently associated with multiple falls. Given that the significant association of radiographic knee OA and LS with multiple falls disappeared after adjustment, multiple falls may occur due to symptoms such as pain caused by radiographic knee OA or LS rather than radiographic changes in the knee or lumbar spine itself. A previous study also suggested that subjects with knee pain had an increased risk of falls (15). In other words, falls may be preventable when pain is relieved by medical care, even if subjects have radiographic knee OA or LS.

The present study has several limitations. First, this is a large-scale population-based study with a cross-sectional analysis of baseline data. Therefore, causal relationships could not be determined. The ROAD study is a longitudinal survey; therefore, further progress may help elucidate any causal relationships. Second, our subjects lived in the community, and therefore our findings may not apply to elderly persons residing in institutions. Third, we did not include other weight-bearing OA diseases, such as hip OA, in the analysis, although this disorder also affects falls (36). However, the prevalence of K/L grade 3 or 4 for hip OA is 1.4% and 3.5% in Japanese men and women (37), respectively, which is smaller than that of K/L grade 3 or 4 for knee OA in the present study. Therefore, it is possible that hip OA would not strongly affect the results of the present study. Fourth, the prevalence of fall was comparably small, particularly in men. Therefore, our results regarding the prevalence may include random error, but the present study is the first large-scale, population-based cohort study of the prevalence of falls in Japanese men and women.

In conclusion, the present cross-sectional analysis using a large-scale population from the ROAD study revealed the prevalence and factors associated with falls in men and women. In women, lower back pain and knee pain were significantly associated with multiple falls. Further studies, along with continued longitudinal surveys in the ROAD study, will help elucidate the background of knee OA and LS, and their relationship with falls.

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## AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Muraki had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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KNEE ARTHROPLASTY

# Fall incidence and risk factors in patients after total knee arthroplasty

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**Abstract**
*Purpose* To prospectively investigate the relationship between physical function and falls among elderly patients who underwent total knee arthroplasty (TKA) and to determine the incidence of falls as well as their risk factors.
*Methods* A total of 108 patients (17 male, 91 female) over 60 years of age who underwent TKA were enrolled and who were living independently in community. 75 patients fulfilled our inclusion criteria and 74 (8 male, 66 female) of them agreed to participate. Baseline assessment (physical examination, physical performance tests, and self-administered questionnaire) were conducted between 6 and 12 months after the last arthroplasty and the follow-up assessment was performed 6 months after the baseline assessment. Monthly pre-stamped postcards were sent to assess the incidence of falls.
*Results* Of the 74 patients enrolled, 70 (94.6%) completed a 6-month prospective observation. 23 of 70 patients (32.9%) fell during the observational period. Postoperative range of knee flexion, ranges of knee flexion and extension and ankle plantar flexion were significantly lower in fallers than in non-fallers ($P = 0.016, P = 0.037, P = 0.014$, respectively). In the multivariate analysis, postoperative range of knee flexion (OR 0.277, 95%CI 0.088–0.869, $P = 0.028$) and ankle plantar flexion (OR 0.594, 95%CI 0.374–0.945, $P = 0.028$) were determined to be significant risk factors.
*Conclusion* Elderly people who underwent TKA are considered more likely to fall compared with healthy elderly people. For patients with limited knee flexion and ankle plantar flexion, improvement of ROM by exercise therapy and patient education regarding the prevention of falls and fractures are considered necessary.

**Keywords** Total knee arthroplasty · Falls · Physical function · Range of motion

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## Introduction

Falls in the elderly have become a social problem. In particular, fragility fractures caused by falls in the elderly reduce their daily activity [1] and may lead to conditions requiring nursing care. Prevention of falls is therefore extremely important in allowing elderly people to continue to live independently.

Among the intrinsic risk factors for falls are deformed or painful joints. Age-related deformities of the knees, feet, or spine impair skeletal alignment and balance, thereby increasing the frequency of falls. Osteoarthritis (OA) in particular causes deformities of the knee joints and pain during walking, and has been reported to increase the risk of falls and fractures [2].

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The standard approach to the treatment of deformity and pain in the knee joint is total knee arthroplasty (TKA). TKA is a surgical intervention that eliminates pain and deformity and improves patients' quality of life (QOL). It results in stable outcomes [3] and was performed on approximately 680,000 patients in the USA in 2009 [4]. However, studies have demonstrated persistent deterioration in proprioception of the knee [5] and balance impairment [6] after TKA, and that among the elderly who underwent TKA, quadriceps torque was weaker and walking speed was lower compared with healthy counterparts [7, 8]. These findings suggest that physical functioning in the elderly declines after TKA. Moreover, supracondylar fractures of the femur were shown to occur in 0.3 to 2.5% of patients who underwent TKA [9–11], and delayed union or malunion have been reported after the surgical treatment of these fractures [12, 13]. Fractures around knee joints after TKA are thus a serious problem that impairs patients' activities of daily living (ADL) and QOL.

There are few surveys on falls and fractures after TKA. In 2009, Swinkels et al. [14] used a self-administered questionnaire to conduct a prospective study of the incidence of falls in 99 patients who underwent TKA, and showed that a preoperative history of falls and Geriatric Depression Scale (GDS) scores predicted postoperative occurrence of falls. In addition, Levinger et al. [15] identified impairment of lower limb proprioception and weakened knee extension strength as risk factors for falls during the early post-TKA period (within 4 months). However, there is not yet sufficient evidence on whether physical function after surgery is related to falls among the elderly after TKA.

Falls often occur due to impaired physical function and therefore, assessment of motor function [16] is essential when evaluating elderly patients with respect to their risk of falls for preventive purposes. Other risk factors for falls include changes in lower thoracic slope and knee joint angle [16], weakened lower limb muscles [17], kyphosis [18], and deformity of the foot [19]. Many elderly people who undergo TKA suffered from OA or rheumatoid arthritis (RA) before the surgery and therefore tend to exhibit the impairments mentioned above. For this reason, it is important to evaluate the physical functioning [20] of elderly patients who underwent TKA and clarify the risk factors for falls so as to minimize the postoperative incidence of falls and fractures and maintain QOL and ADL.

The present study was conducted to prospectively investigate the relationship between physical function and falls among elderly patients who underwent TKA and to determine the incidence of falls as well as their risk factors.

## Patients and methods

### Patients

Subjects included 108 patients (17 male, 91 female) over 60 years of age who underwent TKA at the Hakuai Hospital between January 2008 and December 2010, and who were living independently in community. Both bilateral and unilateral TKA patients were included. Their mean age was 75.8 ± 6.1 and their operations took place between 6 and 11 months before the enrollment. Patients were ineligible if they had cognitive impairment, mental disease, cerebrovascular disease, or Parkinson's disease. Seven patients were excluded as they did not meet the inclusion criteria. Another four were excluded due to the need for additional surgery and two due to hospital for fracture treatment. An additional 20 patients were excluded because they did not visit our hospital for follow-up. Thus, 75 patients fulfilled the inclusion criteria and 74 (8 male, 66 female) of them agreed to participate. The investigators provided written and verbal explanations of the study and obtained written consent from the subjects. The mean patient age was 75.7 ± 5.8 years old (range 60–88).

All surgeries were performed with a standard medial parapatellar approach by three orthopedists. The implants used were Scorpio (Stryker, USA) for 70 knees and LCS (DePuy, USA) for 4 knees. Early joint motion and weight bearing were encouraged during hospitalization and patients underwent rehabilitation for about 4 weeks according to the relevant clinical pathway. Postdischarge follow-up was planned for 1, 3, 6 months, and a year after surgery. Table 1 shows patients' preoperative characteristics and surgical information.

We assessed range of motion (ROM) of the knee (flexion, extension, range of flexion and extension) during the preoperative period and conducted the baseline assessment (physical examination, physical performance tests, and self-administered questionnaire) between 6 and 12 months after the last arthroplasty. Follow-up assessment was performed 6 months after the baseline assessment.

### Fall assessment

A fall was defined as the subject unintentionally coming to rest on the floor or some lower level and not because of a major intrinsic event. In order to assess the incidence of falls we sent out monthly pre-stamped postcards. The postcard included the following questions: (a) Did you fall during the this month? (b) If you fell, did you fall once, twice, or more than three times? (c) If you fell, did you experience any fractures or injuries? Written reminders were sent if patients did not return their monthly postcard. Patients who completed the postcard incorrectly were contacted by telephone.

**Table 1** Preoperative characteristics and surgical information ($n = 74$)

| | |
|---|---|
| OA grade[a] and deformity type | |
| Grade 2 | 3 |
| Grade 3 | 41 |
| Grade 4 | 23 |
| Valgus type | 3 |
| RA | 4 |
| Diagnosis OA:RA | 70:4 |
| Femoral tibial angle (degrees) | 186.3 ± 6.8 (167–201) |
| Range of motion of the knee (degrees) | |
| Flexion | 118.3 ± 13.0 (80–145) |
| Extension | −7.9 ± 6.6 (−30 to 0) |
| Range of knee flexion and extension | 110.9 ± 17.0 (65–135) |
| TKA type (PS:CR) | 65:9 |
| Tibial insert (cm) | 11.1 ± 1.4 (10–15) |

Data are presented as mean ± SD (range)

*OA* osteoarthritis, *RA* rheumatoid arthritis, *PS* posterior-stabilized, *CR* cruciate-retaining

[a] Kellgren and Lawrence grade (1–4)

## Physical examinations

Preoperative and postoperative (baseline period) ROM of the knee (flexion, extension) and ankle (plantar flexion, dorsal flexion) were measured using a goniometer. All measurements were made with the patients sitting on the chair. All assessments were performed on the side that had been operated on, while for patients who had undergone bilateral TKA, we evaluated the side operated on last.

Anterior–posterior drawer test and varus–valgus stress test were performed to assess the instability of the knee on the TKA-affected side. With the patient lying supine, the examiner sat on the examination table in front of the involved knee and grasped the tibia just below the joint line of the knee. We quantify instability using a 4-point ordinal scale (0: rigid, 1: normal, 2: slightly instable, 3: more than moderately instable).

Muscle strength during knee extension on the TKA-affected side was recorded with a hand-held dynamometry (MUSCULATOR GT-10, OG Giken, Okayama, Japan).Each subject was seated in a chair with the hips flexed 90° and the relevant knee flexed to 75°[21]. The hand-held dynamometry was placed in front of facies anterior cruris and the examiner met the resistance of a 5-s maximal isometric knee extension. The measured value was divided by the subject's body weight (Nm/kg).

Hallux valgus was assessed using the Manchester scale [22]. We defined the hallux valgus on a scale from 1 (no deformity) to 4 (severe deformity).

To assess limitations of ankle mobility we used a modified Niki's method [23, 24]. This method evaluates limitation of mobility in the talocalcaneal joint (inversion and eversion). We defined "limitation" as the restriction of either inversion or eversion, and as with the other examinations, assessed it on the TKA-affected side or the side last operated on (in patients who had undergone bilateral TKA).

Kyphosis was assessed by Milne's method [25]. A 60-cm flexicurve was placed on the patient's back, with one end on the seventh cervical spine and closely applied to the midline of the back. Patients were then asked to stand as erect as possible. The level of the lumbosacral joint was marked on the flexicurve with a grease pencil, and the instrument was then laid on a piece of paper and the spinal curve was copied by running a pencil along the flexicurve. The index of kyphosis was represented by the height of the thoracic curve divided by spinal length. Kyphosis was defined as present if the index was greater than 15% [26].

## Physical performance test

### *One-leg standing test*

The one-leg standing test was performed on the leg on the TKA-affected side, and consisted of measuring the length of time a patient was able to stand on one leg. We asked patients to stand on one leg for as long as possible with arms resting by their sides. Patients who underwent bilateral TKA were assessed on the last-operated side.

### *10-m gait test*

Patients were asked to walk 14 m at normal speed, with measurements taken only during the middle 10 m (i.e., between the 2- and 12-m points). The first and last 2 m were used to eliminate periods of acceleration and deceleration. We used a modified version of Tiedemann's method [27]. The time and steps required to walk 10 m at normal speed were assessed, and we used these to calculate gait speed (m/s) and step length (m).

## Self-administered questionnaire

### *Japanese Knee Osteoarthritis Measure (JKOM)*

Pain, limitation in mobility related to daily activity, and restriction of participation in social life and health perception were assessed with the JKOM. This measure has sufficient reliability and validity for studying clinical outcomes in Japanese people with knee OA. It consists of a visual analogue scale (VAS) and 25 questions (score range 25–125, with 125 being worst). It has shown good correlation with the Western Ontario and McMaster Universities index (WOMAC) and the Medical Outcome 36-Items Short Form (SF-36) [28].