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IV. 研究成果の刊行物・別刷

ORIGINAL ARTICLE

Prevalence of knee osteoarthritis, lumbar spondylosis, and osteoporosis in Japanese men and women: the research on osteoarthritis/osteoporosis against disability study

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Abstract Musculoskeletal diseases, especially osteoarthritis (OA) and osteoporosis (OP), impair activities of daily life (ADL) and quality of life (QOL) in the elderly. Although preventive strategies for these diseases are urgently required in an aging society, epidemiological data on these diseases are scant. To clarify the prevalence of knee osteoarthritis (KOA), lumbar spondylosis (LS), and osteoporosis (OP) in Japan, and estimate the number of people with these diseases, we started a large-scale

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population-based cohort study entitled research on osteoarthritis/osteoporosis against disability (ROAD) in 2005. This study involved the collection of clinical information from three cohorts composed of participants located in urban, mountainous, and coastal areas. KOA and LS were radiographically defined as a grade of ≥ 2 by the Kellgren-Lawrence scale; OP was defined by the criteria of the Japanese Society for Bone and Mineral Research. The 3,040 participants in total were divided into six groups based on their age: ≤ 39 , 40-49, 50-59, 60-69, 70-79, and \geq 80 years. The prevalence of KOA in the age groups <39, 40-49, 50-59, 60-69, 70-79, and ≥ 80 years 0, 9.1, 24.3, 35.2, 48.2, and 51.6%, respectively, in men, and the prevalence in women of the same age groups was 3.2, 11.4, 30.3, 57.1, 71.9, and 80.7%, respectively. With respect to the age groups, the prevalence of LS was 14.3, 45.5, 72.9, 74.6, 85.3, and 90.1% in men, and 9.7, 28.6, 41.7, 55.4, 75.1, and 78.2% in women, respectively. Data of the prevalence of OP at the lumbar spine and femoral neck were also obtained. The estimated number of patients with KOA, LS, and L2-L4 and femoral neck OP in Japan was approximately 25, 38, 6.4, and 11 million, respectively. In summary, we estimated the prevalence of OA and OP, and the number of people affected with these diseases in Japan. The ROAD study will elucidate epidemiological evidence concerning determinants of bone and joint disease.

Keywords Epidemiology · Prevalence · Establishment of population-based cohort · Osteoarthritis · Osteoporosis

Introduction

Osteoarthritis (OA) and osteoporosis (OP) are major public health problems in the elderly that affect their

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activities of daily life (ADL) and quality of life (QOL), leading to increased morbidity and mortality. The number of patients with OA increases with the age of the population. According to the recent National Livelihood Survey of the Ministry of Health, Labour and Welfare in Japan, OA is ranked fourth, and falls and osteoporotic fractures are ranked fifth, among the diseases causing disabilities that subsequently require support for activities related to daily living [1]. The authors of the present study as well as other authors have reported increased mortality following osteoporotic fractures at the hip and other sites [2, 3].

Because of the increasing proportion of the aging population in Japan, there is an urgent need for a comprehensive and evidence-based prevention strategy for musculoskeletal diseases, including OA and OP. However, few prospective longitudinal studies have been undertaken, and little information is available regarding the prevalence and incidence of OA and lumbar spondylosis (LS), as well as pain and disability, in the Japanese population [4–7]. Only the estimated number of patients with knee osteoarthritis (KOA) and LS is not known.

More population-based prospective studies have been performed for OP than for OA [8–12]. Japanese guidelines for the prevention and treatment of OP, on the basis of evidence obtained from studies conducted with Japanese subjects, were published in 2006 [13]; however, many epidemiological indices of OP still remain to be clarified. For instance, there is insufficient evidence regarding the risks relating to the incidence of OP, osteoporotic vertebral fractures, and bone loss. Further, data on the number of patients with OP were last reported in 1999 [14], thus necessitating an analysis based on the current prevalence of OP. It is difficult to design rational clinical and public health approaches for the diagnosis, evaluation, and prevention of OA and OP without such epidemiological data.

The research on osteoarthritis/osteoporosis against disability (ROAD) study is a prospective cohort study that aims to elucidate the environmental and genetic background for bone and joint diseases, especially OA and OP; it is designed to examine the extent to which risk factors for these diseases are related to clinical features, laboratory and radiographic findings, bone mass and bone geometry, lifestyle, nutritional factors, anthropometric and neuromuscular measures, and fall propensity, as well as to determine how these diseases affect ADL and QOL in Japanese men and women.

Here, the prevalence of KOA, LS, and OP is clarified, and the number of patients with these diseases in Japan is estimated by analyzing the baseline data of the ROAD study.

Participants and methods

Study population

A complete baseline database was established that included the clinical and genomic information of 3,040 inhabitants (1,061 men and 1,979 women) with a mean age of 70.3 [standard deviation (SD), 11.0] years, 71.0 (SD, 10.7) years in men and 69.9 (SD, 11.2) years in women. These subjects were recruited from listings of resident registrations in three communities with different characteristics: an urban region in Itabashi, Tokyo; a mountainous region in Hidakagawa, Wakayama; and a coastal region in Taiji, Wakayama (Fig. 1).

Itabashi Ward, an urban community located in the eastern Tokyo (area, 32 km²) has a population of 529,400, and the proportion of aged people in this region, defined as the number of residents who were 65 years old or older (\geq 65) divided by the total population, is 19.1%. The percentage of the population having jobs in primary industries (agriculture, forestry, fishing, or mining), secondary industries (manufacturing and construction), and in tertiary industries (service industries) is 0.1, 25, and 75%, respectively [15]. Hidakagawa Town, a rural mountainous community located in the center of Wakayama (area, 330 km²), has a population of 11,300 and 30.5% of the inhabitants are \geq 65 years old. The percentages of workers with jobs in the primary, secondary, and tertiary industries are 29, 24 and 47%, respectively [15]. Taiji Town, a rural coastal community located south of Wakayama (area, 6 km²), has a population of 3,500, with 34.9% of inhabitants ≥65 years old; the percentages of workers with jobs in primary, secondary, and tertiary industries are 13, 18, and 69%, respectively [15].

Residents of these three urban, mountainous, and coastal regions were recruited from the resident-registration lists of the relevant regions. Participants in the urban region, aged \geq 60 years, were recruited from among those of a randomly selected cohort study from the previously established Itabashi Ward resident registration database [16]. The

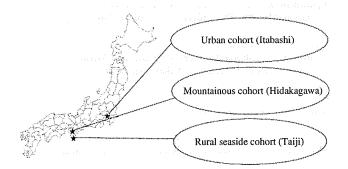


Fig. 1 Location of the three cohorts with different characteristics in Japan



response rate was 75.6%. Participants in the mountainous and coastal regions, aged \geq 40 years, were recruited from listings of resident registration. However, those inhabitants aged <60 years in the urban area and <40 years in the mountainous and coastal areas who were interested in participating in the study were invited to be examined.

In addition to residence in the communities as outlined above, the inclusion criteria were as follows: the patient had to (1) be able to walk to the clinic at which the survey was performed, (2) provide self-reported data, and (3) understand and sign an informed consent form. No other exclusion criteria were used.

Participants were enrolled and the initial baseline examinations were completed over a 1.5-year period from October 2005 through March 2007. All participants provided written informed consent. The study was conducted with the approval of the ethics committees of the University of Tokyo (nos. 1264 and 1326) and the Tokyo Metropolitan Institute of Gerontology (no. 5). Careful consideration was given to ensure a safe experience for participants during their examinations and any other study procedures.

Radiographic assessment

Plain radiographs of the lumbar spine in the anteroposterior and lateral views and bilateral knees in the anteroposterior view with weight-bearing and foot map positioning were obtained. The severity of radiographic OA was determined according to Kellgren-Lawrence (KL) grading as follows [17]: KL0, normal; KL1, slight osteophytes; KL2, definite osteophytes; KL3, joint or intervertebral space narrowing with large osteophytes; KL4, bone sclerosis, joint or intervertebral space narrowing, and large osteophytes. In the ROAD study, participants were classified into KL3 if they had joint or intervertebral space narrowing without large osteophytes. Radiographs at each site, i.e., the knees, hips, and vertebrae, were examined by a single, experienced orthopaedic surgeon (S.M.), who was masked regarding participants' clinical status. If at least one knee joint was graded as KL2 or higher, the participant was diagnosed with radiographic KOA. Similarly, if at least one intervertebral level of the lumbar spine was graded as KL2 or higher, the participant was diagnosed with radiographic LS.

Bone mineral density measurement

In the mountainous and coastal areas, bone mineral density (BMD) was measured at the lumbar spine (L2–L4) and the proximal femur using dual-energy X-ray absorptiometry (DXA) (Hologic Discovery; Hologic, Waltham, MA, USA) at baseline.

To control quality, 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 ± 0.016 g/cm² ($\pm 1.5\%$) during all examinations. In addition, the same physician (N.Y.) examined all participants to prevent observer variability. Intraobserver variability using the Lunar DPX in vitro and in vivo had been measured by the same physician (N.Y.) for another study [18]. Coefficient of variance (CV) for L2–L4 in vitro was 0.35%, and CVs for L2–L4, the proximal femur, Ward's triangle, and the trochanter examined in vivo in five male volunteers were 0.61–0.90, 1.02–2.57, 1.97–5.45, and 1.77–4.17%, respectively.

OP was defined as a BMD of less than 70% of peak bone mass according to the criteria of the Japanese Society for Bone and Mineral Research [19]. OP was defined by BMD $< 0.708 \text{ g/cm}^2$ at the lumbar spine in the case of both men and women, and by BMD $< 0.604 \text{ g/cm}^2$ at the femoral neck for men and $< 0.551 \text{ g/cm}^2$ for women, respectively.

Statistical analysis

All statistical analyses were performed using STATA statistical software (STATA, College Station, TX, USA). Differences in proportion were compared by the chi-square test. Differences of continuous values were tested for significance using analysis of variance (ANOVA) for comparisons among multiple groups and Scheffe's least significant difference (LSD) test for pairs of groups. Significant items were selected, and multiple regression and logistic regression analyses were performed by adjusting suitable variables.

Results

Table 1 shows selected characteristics of the participants in the three regions including age, height, weight, body mass index (BMI), and BMD. The percentage of participants >60 years of age was 99.8, 84.3, and 54.7% in the urban, mountainous, and seacoast regions, respectively. Two-thirds of the 3,040 participants were women, and the mean age of female participants was 1 year less than that of the male participants.

Regarding the gender differences in the anthropometric measurements, height and weight were significantly lower in women than in men, but no significant difference in BMI was noted between the genders. All values of BMD at L2–L4, femoral neck, and total hip were significantly higher in men than in women (P < 0.001).

Table 1 Age-sex distribution and mean values (standard deviation) of selected characteristics of the participants

Age strata (years)	Men				Women			
	Total	Urban	Mountainous	Seacoast	Total	Urban	Mountainous	Seacoast
-39	14	0	2	12	31	0	7	24
40-49	44	0	7	37	105	0	17	88
50-59	107	0	36	71	211	2	67	142
60-69	168	11	93	64	385	60	183	142
70–79	535	315	150	70	913	594	196	123
80-	193	139	31	23	334	229	75	30
Total	1,061	465	319	277	1,979	885	545	549
Age (years)	71.0 (10.7)	77.2 (4.3)	69.5 (9.1)	62.6 (13.2)	69.9 (11.2)	76.3 (5.0)	68.6 (10.4)	60.8 (12.5)
Height (cm)	162.5 (6.7)	161.3 (5.9)	161.4 (6.9)	165.8 (6.8)	149.8 (6.5)	148.5 (5.6)	148.2 (6.7)	153.2 (6.2)
Weight (kg)	61.3 (10.0)	60.0 (8.5)	60.0 (10.2)	64.8 (11.0)	51.5 (8,6)	50.8 (8.3)	50.5 (8.6)	53.5 (8.8)
BMI (kg/m ²)	23.1 (3.0)	23.0 (2.8)	23.0 (3.0)	23.5 (3.4)	22.9 (3.5)	23.0 (3.4)	23.0 (3.4)	22.8 (3.6)
BMD (g/cm ²)								
L2-L4	1.05 (0.20)	-	1.04 (0.20)	1.06 (0.21)	0.87 (0.18)	-	0.83 (0.18)	0.91 (0.18)
Femoral neck	0.74 (0.13)		0.73 (0.13)	0.76 (0.13)	0.63 (0.12)		0.60 (0.12)	0.66 (0.13)
Total hip	0.88 (0.14)	- 1.1 st	0.87 (0.14)	0.90 (0.14)	0.74 (0.14)	_	0.72 (0.13)	0.76 (0.14)

BMI body mass index, BMD bone mineral density

Table 2 shows the age-sex distribution for prevalence of radiographic KOA and LS determined by a KL grade ≥2, classified by region. In the overall population, prevalence of radiographic KOA and LS was 54.6% (42.0% in men and 61.5% in women) and 70.2% (80.6% in men and 64.6% in women), respectively, indicating that the prevalence of LS was higher than that of KOA in the overall population, as well as in the respective genders. When the prevalence was compared among the age strata, radiographic KOA and LS tended to be higher with age in both genders (Table 2). Prevalence of radiographic KOA was 0% in men and 3.2% in women in the <40-year age group and 42.6% in men and 62.4% in women in the \geq 40-year age group, and the differences were significant (P < 0.001). According to gender, the prevalence was significantly higher in women than in men in the overall population (P < 0.001). OA in both knees was observed in 43.1% (31.5% in men and 49.4% in women) of all participants. The overall prevalence of radiographic LS across all ages was 80.6% in men and 64.6% in women, which was considerably higher than that of KOA. In contrast to radiographic KOA, the prevalence of this condition was significantly higher in men than in women (P < 0.001). Similar to KOA, the prevalence of LS was lower in the <40-year age group than in the ≥40-year age group, with significant differences in both genders (P < 0.001). Among all the participants, 42.3% (37.1% in men and 45.1% in women) had both KOA and LS.

The prevalence of KOA and LS classified by region is also shown in Table 2. Regarding the regional differences,

the prevalence of KOA was the highest in the mountainous area, followed by the urban area and the seacoast area in both men and women. By contrast, the prevalence of LS was the highest in the urban area, followed by the mountainous area and the seacoast area.

Logistic regression analysis was performed to determine the effect of region, gender, age, and body build on the prevalence of OA in participants ≥60 years of age, using the presence of KOA as an objective variable, and region (seacoast: 0, mountainous: 1), gender (men: 0, women: 1), age, and BMI as explanatory factors. The analysis revealed that the risk for KOA was significantly higher in the mountainous area [odds ratio (OR), 2.7; 95% confidence interval (CI), 2.1-3.6, P < 0.001], in women (OR, 3.4; 95% CI, 2.79–4.06; P < 0.001), in advanced age (+1 year: OR, 1.09; 95% CI, 1.07–1.11, P < 0.001), and in larger body build (+1 BMI: OR, 1.16; 95% CI, 1.13-1.20; P < 0.001). By contrast, the risk of LS was reduced in the mountainous area (OR, 0.63; 95% CI, 0.48-0.83; P < 0.01) and in women (OR, 0.47; 95% CI, 0.38–0.58; P < 0.001). Advanced age and higher BMI were associated with the presence of LS as well as KOA (+1 year: OR, 1.08; 95% CI, 1.06–1.10; P < 0.001; +1 BMI: OR, 1.09; 95% CI, 1.05–1.12; P < 0.001, respectively).

Table 3 shows the mean values of BMD among residents of mountainous and coastal regions in the ROAD study. Although the mean BMD values of the lumbar spine were no different between men and women in the age group of <40 years, those of the femoral neck and proximal total hip in the same age group were significantly



Table 2 Prevalence (%) of knee osteoarthritis and lumbar spondylosis classified by age, gender, and region

Age strata (years)	Knee osteoarthritis				Lumbar spondylosis			
	Total	Urban	Mountainous	Seacoast	Total	Urban	Mountainous	Seacoast
Men								
-39	0.0	_	0.0	0.0	14.3	_	0.0	16.7
4049	9.1		42.9	2.7	45.5	-	28.6	48.7
50-59	24.3	_	55.6	8.5	72.9	_	75.0	71.8
60-69	35.2	37.5	44.1	21.9	74.6	75.0	69.9	81.3
70–79	48.2	41.3	63.5	45.7	85.3	83.8	85.3	91.4
80–	51.6	45.6	74.2	56.5	90.1	89.9	90.3	91.3
Total	42.0	42.5	57.1	23.8	80.6	85.5	78.4	75.1
Women								
-39	3.2		0.0	4.2	9.7	_	0.0	12.5
40-49	11.4	_	29.4	8.0	28.6	_	29.4	28.4
50-59	30.3	50.0	46.3	22.5	41.7	100.0	29.9	46.5
60-69	57.1	49.1	68.3	45.8	55.4	64.3	50.3	58.5
7079	71.9	69.3	83.2	66.1	75.1	76.1	70.4	32.0
80-	80.7	77.3	91.9	76.9	78.2	79.6	69.3	90.0
Total	61.5***	70.0***	72.1***	37.8***	64.6***	76.3***	56.3***	54.6***

^{***} Significantly different (P < 0.001) from prevalence in men of the same region

higher in men than in women (P < 0.001). When the BMD values were compared among age strata, the prevalence of OP tended to be higher with age in both genders; however, the tendency was much greater in women than in men. Multiple regression analysis was performed to determine the effect of region, gender, age, and body build on BMD in the overall population of the mountainous and seacoast areas, using each value of BMD at lumbar spine, femoral neck, and total hip as an objective variable, and region (seacoast: 0, mountainous: 1), gender (men: 0, women: 1), age, and BMI as explanatory factors. The analysis revealed there was no regional difference in the BMD values at L2-L4, femoral neck, and total hip, whereas there were significant differences in gender (beta at L2-L4, femoral neck, and total hip, -0.41, -0.41, and -0.47, respectively, all P < 0.001), age (beta at L2-L4, femoral neck, and total hip, -0.28, -0.43, and -0.42, respectively, all P < 0.001), and BMI (beta at L2-L4, femoral neck, and total hip, 0.29, 0.33, and 0.37, respectively, all P < 0.001).

Table 4 reveals the prevalence of OP at the lumbar spine, the femoral neck, and the total hip among residents of mountainous and coastal regions in the ROAD study. The prevalence of OP in women was six, two, and three-fold higher, respectively, than in men, with a significant difference (P < 0.001). Although the prevalence of OP at the lumbar spine was higher for persons in the seacoast area than in the mountainous area, the prevalence at the femoral neck and total hip were higher in the mountainous area than in the seacoast area. In women, the prevalence of

OP at the lumbar spine, femoral neck, and total hip were all higher in the mountainous area than in the seacoast area.

Logistic regression analysis was performed to determine the effect of region, gender, age, and body build on the prevalence of OP, using the presence of OP at L2-L4 as an objective variable, and region (seacoast: 0, mountainous: 1), gender (men: 0, women: 1), age, and BMI as explanatory factors. The analysis revealed that the risk for OP at L2-L4 was significantly higher in women (OR, 10.2; 95% CI, 6.07–17.1; P < 0.001), in advanced age (+1 year: OR, 1.10; 95% CI, 1.08–1.12; P < 0.001), whereas it was significantly lower in larger body build (+1 BMI: OR, 0.74; 95% CI, 0.69–0.79; P < 0.001). There was no significant difference in the prevalence of OP at L2-L4 between the mountainous and seacoast area. A similar tendency was shown in the prevalence of OP at the femoral neck and total hip (femoral neck: women versus men, OR, 3.82; 95% CI, 2.77-5.27; P < 0.001; +1 year: OR, 1.11; 95% CI, 1.09– 1.13; P < 0.001; +1 BMI: OR, 0.75; 95% CI, 0.72–0.79; P < 0.001; total hip: women versus men, OR, 4.39; 95% CI, 2.88–6.70; P < 0.001; +1 year: OR, 1.11; 95% CI, 1.09-1.14; P < 0.001; +1 BMI: OR, 0.70; 95% CI, 0.65-0.75; P < 0.001).

Discussion

Little epidemiological information is available for musculoskeletal diseases such as OA and OP in Japan. The

