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ORIGINAL ARTICLE: SOCIAL RESEARCH, PLANNING AND PRACTICE

Incidence of certified need of care in the long-term care insurance system and its risk factors in the elderly of Japanese population-based cohorts: The ROAD study

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Aim: To examine the incidence of certified need of care in the national long-term care insurance (LTCI) system, and to determine its risk factors in the elderly of Japanese population-based cohorts of the Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study.

Methods: Of the 3040 participants in the baseline examination of the ROAD study, we enrolled 1773 (699 men, 1074 women) aged 65 years or older who were not certified as in need of care level elderly at baseline. Participants were followed for incident certification of need of care in the LTCI system. Associated factors in the baseline examination with occurrence were determined by multivariate Cox proportional hazards regression analysis. Muscle dysfunction was defined in accordance with the European Working Group on Sarcopenia in Older People algorithm for screening sarcopenia.

Results: A total of 54 men and 115 women were certified as in need of care level elderly during the average 4.0-year follow up. The incidence was 2.0 and 2.5 per 100 person-years in men and women, respectively. Identified risk factors were region, age, body mass index <18.5 or ≥27.5 kg/m^2, grip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction.

Conclusions: Both underweight and obesity, as well as low muscle strength and physical ability, are risk factors for certification of need of care. Considering muscle dysfunction is a risk factor for occurrence, screened individuals are recommended to receive early intervention programs regardless of muscle volume. **Geriatr Gerontol Int 2014; 14: 695–701.**

Keywords: activities of daily living, certification of need of care (*youkaigo-nintei*), disability, long-term care insurance system, prospective cohort study.

Introduction

Japan is a super-aged society experiencing an unprecedented aging of the population. The proportion of the population aged 65 years or older was 23% in 2010, and is expected to reach 30.1% in 2024 and 39% in 2051.[1] This leads to an increasing proportion of disabled elderly requiring support or long-term care, imposing enormous economic and social burdens on the country. The Japanese Government started the national long-term care insurance (LTCI) system in 2000 based on the Long-Term Care Insurance Act.[2] The aim was to certify need of care level elderly, and to provide suitable care services according to the level of care required (seven levels, including requiring support [levels 1 and 2] and requiring long-term care [levels 1–5]). The total number of certified in need of care level elderly was reported to be 5 million in 2011.[2]

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Certification of need of care in the national LTCI system is an important outcome in Japan, not only because of its massive social and economic burdens, but also because it is urgently required to reduce its risk and decrease the number of disabled elderly requiring care in their activities of daily living (ADL). For establishment of an evidence-based prevention strategy, it is critically important to accumulate epidemiological evidence including the incidence of certified need of care and identification of risk factors. However, there have been no studies to clarify the incidence of certified need of care in the LTCI system or its risk factors using large-scale, population-based cohorts.

In 2005, we started a large-scale, population-based cohort study entitled the Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study with a total of 3040 participants, which aims to elucidate the environmental and genetic backgrounds of musculoskeletal diseases.[3,4] The present study investigated the incidence of certified need of care in the national LTCI system, and determined its risk factors using a database from the ROAD study.

Methods

Participants

The present analysis was based on data collected from cohorts established in 2005 for the ROAD study. Details of the cohorts have been reported elsewhere.[3,4] Briefly, we created a baseline database from 2005–2007, which included clinical and genetic information on 3040 residents of Japan (1061 men, 1979 women). Participants were recruited from resident registration listings in three communities, namely, an urban region in Itabashi, Tokyo, and rural regions in Hidakagawa and Taiji, Wakayama. Participants in the urban region in Itabashi were recruited from those of a cohort study,[5] in which participants were randomly drawn from the register database of Itabashi ward residents, with a response rate of 75.6% in the group aged >60 years. Participants in the rural regions in Hidakagawa and Taiji were recruited from resident registration lists, with response rates of 68.4% and 29.3%, respectively, in the groups aged >60 years. Inclusion criteria were the ability to: (i) walk to the survey site; (ii) report data; and (iii) understand and sign an informed consent form. For the present study, we enrolled 1773 participants (699 men, 1074 women; mean age 75.4 years) aged 65 years or older who were not certified as need of care level elderly in the national LTCI system at baseline. All participants provided written informed consent, and the study was carried out with approval from the ethics committees of the University of Tokyo and the Tokyo Metropolitan Institute of Gerontology.

Baseline procedures

Participants completed an interviewer-administered questionnaire containing 400 items that included lifestyle information, such as smoking habits, alcohol consumption and physical activity. At baseline, anthropometric measurements, including height and weight, were taken, and body mass index (BMI; weight [kg]/height^2 [m^2]) was estimated based on the measured height and weight. Underweight was defined as BMI <18.5 and obesity as BMI ≥27.5, according to the 2004 consensus statement from the WHO regarding appropriate BMI for Asian populations.[6] Grip strength was measured on bilateral sides using a handgrip dynamometer (TOEI LIGHT, Saitama, Japan); the higher measurement was recorded. Isometric peak knee extension torque was measured at a knee flexion angle of 90° using a dynamometer (GT-30; OG GIKEN, Okayama, Japan) twice in participants from the urban regional cohort (Itabashi, Tokyo); the higher measurement was recorded. The time taken to walk 6 m at usual walking speed in a hallway was recorded, and usual gait speed was calculated. Skeletal muscle dysfunction was defined as usual gait speed ≤0.8 m/s or grip strength <30 kg in men and <20 kg in women, according to the algorithm for screening sarcopenia recommended by the European Working Group on Sarcopenia in Older People (EWGSOP).[7,8] The time taken for five consecutive chair rises without the use of hands was recorded in the rural regional cohorts (Hidakagawa and Taiji, Wakayama). Hands were folded in front of the chest with feet flat on the floor. Timing began with the command "Go", and ended when the buttocks contacted the chair on the fifth landing.

Certification of need of care in the LTCI system

The nationally uniform criteria for long-term care need certification was established objectively by the Japanese Government, and certification of need of care level elderly is determined based on evaluation results by the Certification Committee for Long-term Care Need in municipalities in accordance with basic guidelines formulated by the Government. The process of eligibility for certification of need of care in the LTCI system was described in detail by Chen *et al.*[9] An elderly person who requires help with ADL or the caregiver contacts the municipal Government to request official certification of care needs. After the application, a trained official visits the home to assess the current physical status of the elderly person, including the presence or absence of muscle weakness or joint contracture of limbs, and difficulties in sitting-up, standing-up, maintaining sitting or standing position, transferring from one place to another, standing on one leg, walking, bathing, dressing, and other ADL. Mental status, including dementia, is also assessed. These data are analyzed to calculate a

Table 1 Baseline characteristics of population at risk for certified need of care in the long-term care insurance system

	Entire cohort		Urban cohort		Rural cohort	
	Men	Women	Men	Women	Men	Women
No. participants	699	1,074	333	486	366	588
Age (years)	75.6 (5.1)	75.2 (5.3)	77.5 (3.7)	77.3 (3.8)	73.8 (5.5)†	73.5 (5.8)†
Height (cm)	160.9 (6.0)	147.9 (6.0)*	161.0 (5.8)	148.2 (5.4)*	160.8 (6.2)	147.7 (6.5)*
Weight (kg)	59.4 (9.1)	50.0 (8.3)*	59.4 (8.2)	49.8 (7.8)*	59.4 (9.9)	50.1 (8.8)*
BMI (kg/m^2)	22.9 (2.9)	22.8 (3.4)	22.9 (2.7)	22.7 (3.3)	22.9 (3.1)	22.9 (3.5)
BMI <18.5 (%)	6.2	8.0	6.1	7.9	6.3	8.0
BMI ≥27.5 (%)	5.7	9.3**	3.9	8.5**	7.4	9.9
Grip strength (kg)	30.4 (6.8)	19.4 (4.9)*	28.6 (6.1)	18.2 (4.1)*	31.9 (7.0)†	20.3 (5.2)*†
Knee extension torque (kgm)	–	–	79.6 (27.2)	54.8 (17.0)*	–	–
Usual gait speed (m/s)	1.17 (0.31)	1.10 (0.33)*	1.27 (0.24)	1.22 (0.24)*	1.08 (0.34)†	1.00 (0.36)*†
Chair stand time (s)	–	–	–	–	10.8 (3.7)	12.2 (5.4)*
Muscle dysfunction (%)§	48.7	56.0**	52.6	60.0**	45.2	52.6**‡
Smoking (%)	21.0	3.2**	19.2	3.0**	22.6	3.4**
Alcohol consumption (%)	61.2	23.0**	61.0	28.8**	61.3	18.4**‡

Except where indicated otherwise, values are mean (SD). *$P < 0.05$ versus men in the corresponding group of the same cohort by unpaired Student's t-test. **$P < 0.05$ versus men in the corresponding group of the same cohort by χ^2-test. †$P < 0.05$ versus urban cohort in the corresponding group of the same sex by unpaired Student's t-test. ‡$P < 0.05$ versus urban cohort in the corresponding group of the same sex by χ^2-test. §Muscle dysfunction was defined as usual gait speed ≤0.8 m/s or grip strength <30 kg in men and <20 kg in women. BMI, body mass index; LTCI, long-term care insurance system.

standardized score for determination of the level of care needs (certified support, levels 1–2; or long-term care, levels 1–5). In addition, the primary physician of the applicant assesses physical and mental status, including information on diseases causing ADL disability and the extent of disabilities caused by them. Finally, the Certification Committee for Long-term Care Need reviews the data and determines the certification and its level.

Follow up and definition of incident certified need of care

After the baseline ROAD survey, participants who were not certified as need of care level elderly at baseline were followed for incident certification of need of care in the LTCI system. Incident certified need of care was defined as the incident certified 7 level, including requiring support (levels 1–2) and requiring long-term care (levels 1–5). Information on the presence or absence of certification of need of care and its date of occurrence were collected by the resident registration listings in three communities every year up to 2010, and were used for analyses in the present study.

Statistical analysis

All statistical analyses were carried out using STATA statistical software (STATA, College Station, TX, USA). Differences in the values of the parameters between two groups were tested for significance using the non-paired Student's t-test and χ^2-test. Factors associated with occurrence of certified need of care were determined using Cox proportional hazards regression analysis; hazard ratios (HR) and 95% confidence intervals (CI) were determined after adjusting for region, age, sex, and BMI.

Results

Of the 1773 participants who were not certified as in need of care level elderly at baseline, information on certification of need of care could be obtained in 1760 (99.3%) during the average 4.0-year follow up. A total of 54 men and 115 women were certified as in need of care level elderly in the national LTCI system; whereas, 1591 remained uncertified during the follow-up period. A total of 126 participants died, and eight moved away.

Table 1 shows the baseline characteristics of the population at risk for occurrence of certified need of care in the LTCI system. Although BMI was not significantly different between men and women in the entire, urban or rural cohorts, prevalence of obesity (BMI ≥27.5) was significantly higher in women than in men in the entire and urban cohorts. The prevalence of underweight was higher in women than in men in the entire,

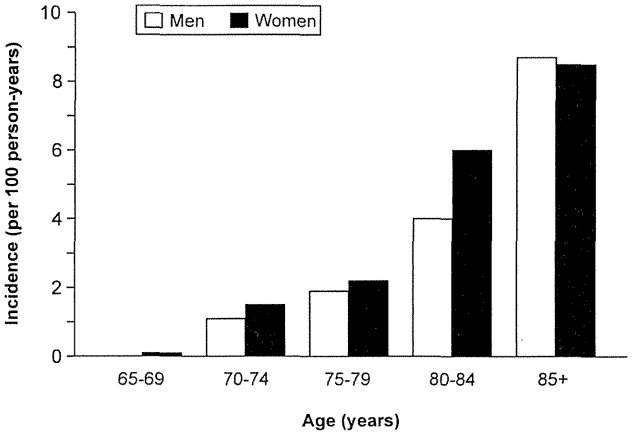

Figure 1 Incidence of certified need of care in the long-term care insurance system in men and women in each age stratum.

urban and rural cohorts; however, there was no significant difference. The prevalence of skeletal muscle dysfunction, determined by gait speed and grip strength, was significantly higher in women than in men in the entire, urban and rural cohorts.

Figure 1 shows sex- and age-distributions of the incidence of certified need of care in the LTCI system. Incidence was 2.3/100 person-years in the overall population of the entire cohort, and 2.0/100 person-years in men and 2.5/100 person-years in women. The incidence was very low in the age-stratum of 65–69 years, whereas, it tended to be markedly higher in the age-strata of 80 years and older in both sexes.

We then determined the risk factors for occurrence of certified need of care in the LTCI system. First, analysis was carried out using region, age, sex and BMI as explanatory variables in the Cox proportional hazards regression model (upper part of Table 2). Rural region and age were found to be risk factors for occurrence of certified need of care in the overall population. Sex and BMI were not significantly different. To further investigate the association between BMI and occurrence, we categorized BMI into three groups. Both underweight (BMI <18.5) and obesity (BMI ≥27.5) were found to be risk factors for occurrence of certified need of care, showing a U-shaped association. As for muscle strength and physical performance, handgrip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction were found to be significantly associated with occurrence of certified need of care (lower part of Table 2). We carried out the same analyses in men and women separately (Table 2), and found results similar to those of the overall population.

Discussion

The present study investigated the incidence of certified need of care in the national LTCI system, and

Table 2 Hazard ratios and 95% confidence intervals for occurrence of certified need of care in the long-term care insurance system

	Overall population		Men		Women	
	Crude HR (95% CI)	Adjusted HR (95% CI)	Crude HR (95% CI)	Adjusted HR (95% CI)	Crude HR (95% CI)	Adjusted HR (95% CI)
Region (rural *vs* urban)	1.15 (0.83–1.59)	1.61 (1.17–2.24)[b]	1.13 (0.65–1.96)	1.64 (0.94–2.86)[g]	1.15 (0.77–1.72)	1.59 (1.07–2.38)[g]
Age (+1 year)	1.17 (1.13–1.20)	1.17 (1.14–1.21)[c]	1.19 (1.12–1.26)	1.19 (1.13–1.26)[h]	1.16 (1.12–1.20)	1.16 (1.12–1.21)[h]
Sex (women *vs* men)	1.25 (0.90–1.74)	1.24 (0.89–1.73)[d]	–	–	–	–
BMI (+1 kg/m^2)	0.98 (0.93–1.03)	1.01 (0.96–1.06)[c]	0.93 (0.84–1.02)	0.96 (0.88–1.06)[i]	1.00 (0.94–1.06)	1.02 (0.97–1.08)[i]
≥18.5 or <27.5	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)	1 (Reference)
BMI <18.5	2.10 (1.31–3.38)	1.77 (1.10–2.84)[e]	2.43 (1.09–5.40)	1.69 (0.75–3.82)[i]	1.93 (1.07–3.48)	1.79 (0.99–3.22)[i]
BMI ≥27.5	1.82 (1.13–2.93)	2.12 (1.32–3.43)[e]	1.39 (0.50–3.87)	1.91 (0.68–5.38)[i]	1.92 (1.12–3.29)	2.18 (1.27–3.75)[i]
Grip strength (+1 kg)	0.93 (0.91–0.95)	0.94 (0.91–0.97)[f]	0.91 (0.87–0.95)	0.94 (0.89–0.99)[j]	0.89 (0.85–0.92)	0.94 (0.89–0.98)[j]
Knee extension torque (+1 kgm)	0.97 (0.96–0.99)	0.97 (0.96–0.99)[f]	0.97 (0.95–0.99)	0.97 (0.95–0.99)[j]	0.97 (0.95–0.99)	0.97 (0.95–1.00)[j]
Usual gait speed (+0.1 m/s)	0.80 (0.77–0.85)	0.84 (0.79–0.90)[f]	0.81 (0.74–0.88)	0.83 (0.74–0.92)[j]	0.80 (0.76–0.85)	0.85 (0.78–0.92)[j]
Chair stand time (+1 s)	1.09 (1.07–1.12)	1.06 (1.03–1.10)[f]	1.18 (1.10–1.27)	1.11 (1.03–1.21)[j]	1.09 (1.06–1.11)	1.06 (1.02–1.09)[j]
Muscle dysfunction (yes *vs* no)[a]	2.91 (2.02–4.19)	1.71 (1.16–2.52)[f]	2.60 (1.45–4.68)	1.68 (0.91–3.09)[j]	3.07 (1.92–4.92)	1.72 (1.04–2.85)[j]
Smoking (yes *vs* no)	0.98 (0.58–1.68)	1.39 (0.79–2.43)[f]	1.18 (0.62–2.26)	1.54 (0.79–3.01)[j]	0.95 (0.30–2.99)	1.09 (0.35–3.47)[j]
Alcohol consumption (yes *vs* no)	0.71 (0.50–0.99)	0.83 (0.58–1.21)[f]	0.78 (0.45–1.35)	0.93 (0.53–1.61)[j]	0.70 (0.42–1.16)	0.76 (0.46–1.27)[j]

[a]Muscle dysfunction was defined as usual gait speed ≤0.8 m/s or grip strength <30 kg in men and <20 kg in women. [b]Adjusted for age, sex and body mass index (BMI). [c]Adjusted for region, sex and BMI. [d]Adjusted for region, age and BMI. [e]Adjusted for region, age and sex. [f]Adjusted for region, age, sex and BMI. [g]Adjusted for age and BMI. [h]Adjusted for region and BMI. [i]Adjusted for region and age. [j]Adjusted for region, age and BMI. Urban region and men were used as references. CI, confidence interval; HR, hazard ratio.

determined its risk factors using Japanese population-based cohorts. Identified risk factors were region, age, underweight, obesity, handgrip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction (determined by the EWGSOP algorithm for screening sarcopenia).

In the present study, we could not obtain information on causes of certified need of care in the LTCI system. Therefore, we could not analyze the direct association of each causing condition with such factors as anthropometric and physical performance measurements. The Government of Japan reported that the top five leading causes of certified need of care were cerebral stroke, dementia, asthenia as a result of older age, joint disease and fall-related fracture, comprising 71.6% of all causes in 2010.[10] Based on these data, most of the causes of incident certification in the present study are inferred to be among the top five leading conditions.

Both low and high BMI were found to be risk factors for occurrence of certified need of care, showing an overall U-shaped association. This U-shaped association is similar to that between BMI and risk of death.[11,12] The association between risk of death from cardiovascular disease and other causes, and BMI was reported to be U-shaped in East Asians,[11] whereas the risk of all-cause mortality versus BMI was also found to have a U-shaped association in Western European and North American populations.[12] High BMI is an established risk factor for chronic diseases, including hypertension, dyslipidemia and diabetes mellitus, which increase the risk of cerebral stroke.[13] High BMI is also a major risk factor for knee osteoarthritis,[14–17] which can cause ADL disability in the elderly.[18] In contrast, low BMI is an established risk factor for osteoporosis and related fracture.[19] It also might relate to asthenia, a condition of loss or lack of bodily strength as a result of chronic wasting disease. Underweight as a result of malnutrition or sarcopenia is suggested to be included in this category.

Other identified risk factors were handgrip strength, knee extension torque, usual gait speed, chair stand time and muscle dysfunction (determined by the EWGSOP algorithm for screening sarcopenia). Previous studies have reported that low muscle strength and physical performance were predictors of subsequent ADL disability in the elderly.[20–23] The results of the present study are consistent with these previous reports. As many of the performance tests used in the present study are easy to carry out and evaluate, they can be utilized for screening elderly persons at high risk of certified need of care in the LTCI system. Those who were classified as having muscle dysfunction in the present study were at high risk of sarcopenia as well as certified need of care, regardless of muscle volume. Therefore, elderly persons screened by the EWGSOP algorithm are recommended to receive early intervention programs for prevention of ADL disability and subsequent deterioration leading to certified need of care.

The Japanese Orthopedic Association proposed the concept of "locomotive syndrome" in 2007 for the promotion of preventive health care of locomotive organs.[24–26] Locomotive syndrome refers to conditions under which the elderly have been receiving support or long-term care, or high-risk conditions under which they might soon require support or long-term care, that are caused by musculoskeletal disorders.[24–26] Functional declines in locomotive organs, including muscle strength, walking speed and balancing ability, usually progress slowly and gradually. As such, it might be difficult for people to recognize this decline in their daily life. Therefore, it is of particular importance to raise awareness of the growing risk caused by these disorders, and to take action to improve and maintain the health of locomotive organs. Population approaches, including promotion of the concept of locomotive syndrome to both younger and older generations, are important, in addition to high-risk approaches, including identifying those at risk for certified need of care and practicing intervention programs to reduce the risk of certified need of care.

There were some limitations in the present study. As we could not obtain information on causing conditions, we could not determine the risk factors for occurrence of certified need of care with respect to each causing condition. Additional studies are necessary to identify those direct associations. In the present study, the rural region was at higher risk of incident certified need of care compared with the urban region. The reasons for this could include differences in available public and private transportation or delivery services regarding meals and commodities for the elderly. In addition to these, the threshold between certified and non-certified elderly might be different among municipalities, which could lead to regional differences. Although the Certification Committee for Long-term Care Need in each municipality determines certification in accordance with guidelines formulated by the Government, the Committee also has to consider assessment by the applicant's primary physician and objective evaluation results regarding physical and mental status, which could affect the threshold of certification. Another limitation was health bias. Participants at baseline in the present study were those who could walk to the survey site, and could understand and sign an informed consent form. As those who could not were not included in the analyses, the study participants do not truly represent the general population due to health bias. Therefore, incidence of certified need of care was most likely underestimated, which should be taken into consideration when generalizing the results of the present study.

In conclusion, the present study revealed the incidence of certified need of care in the national LTCI

system, and determined its risk factors using Japanese population-based cohorts. Both underweight and obesity were found to be risk factors for certified need of care, suggesting that maintenance of intermediate BMI is important for prevention. Low muscle strength and physical ability were also shown to be risk factors for certified need of care. Physical performance measures identified as predictors can be used as screening tools to identify high-risk individuals. Considering muscle dysfunction, screened by the EWGSOP algorithm, was a risk factor for occurrence, screened individuals are recommended to receive early intervention programs regardless of muscle volume. Further studies are necessary to develop intervention programs and to test their effectiveness, along with accumulation of epidemiological evidence, to prevent certified need of care and reduce the social and economic burdens associated with this condition.

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Disclosure statement

The authors declare no conflict of interest.

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ORIGINAL ARTICLE

A 5–22-year follow-up study of stemmed alumina ceramic total elbow arthroplasties with cement fixation for patients with rheumatoid arthritis

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Abstract

Background We determined mid to long-term results of total elbow arthroplasty (TEA) by use of unlinked elbow prostheses with solid alumina ceramic trochleae, and ceramic ulnar stems (stemmed Kyocera type I; SKC-I) for patients with rheumatoid arthritis.

Patients and methods Fifty-four elbows of 39 patients were available for detailed clinical and radiographic review after a follow-up period of at least 5 years. The mean follow-up period was 12.6 years (range 5–22 years). Clinical condition before and after surgery was assessed by use of a modified version of the Mayo Elbow Performance Score (MEPS; 0–100 points) and a Japan Orthopaedic Association Elbow score (JOA score; 0–100 points). The radiographs were reviewed and loosening was defined as a progressive radiolucent line >1 mm wide that was completely circumferential around the prosthesis. Clinical records of post-operative events affecting the elbows were used for survival analysis of the prostheses using the Kaplan–Meier method.

Results The average modified MEPS and JOA scores improved significantly from 39.7 ± 14.3 to 44.7 ± 9.4, respectively, pre-operatively, to 89.7 ± 15.4 and 83.1 ± 12.8, respectively, post-operatively ($P < 0.0001$). The functional assessment score also improved from 4.9 ± 2.8 to 8.5 ± 3.3 points ($P < 0.0001$). With loosening or implant revision defined as end points, the likelihood of survival of the prosthesis for up to 20 years was 92.6 % (95 % confidence interval (CI), 85.6–100.0) or 86.3 % (95 % CI 75.0–97.6), respectively.

Conclusion Satisfactory clinical results were obtained after TEA using SKC-I prostheses, which provided excellent pain relief and functional range of motion. The results of our study reveal the high reliability over a long period of the cemented SKC-I prosthesis with an alumina ceramic component.

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Introduction

The elbow joint is affected in 25–53 % of patients with rheumatoid arthritis (RA) [1]. The mainstay of surgical treatment for RA elbows includes open or arthroscopic synovectomy for early-stage disease, and interposition and total elbow arthroplasty (TEA) for progressive and late-stage disease. TEA is primarily indicated for damaged RA elbows with painful stiffness, painful instability, and ankylosis. The clinical outcomes of TEA for the reconstruction of RA elbows were disappointing in the late 1970s, but modifications and improvements of elbow prostheses during the ensuing three decades has made TEA a reliable procedure with results that rival those of hip and

knee arthroplasties [2, 3]. The most successful prostheses identified by long-term follow-up studies have an unlinked (non-constrained) or linked (semi-constrained) design. The former includes Capitellocondylar [4], Souter–Strathclyde [5, 6], and Kudo elbows [7, 8]; the latter includes Coonrad-Morrey [9] and GSB III prostheses [10]. The unlinked design relies on the presence of sufficient bone stock to seat the prosthesis and the ligaments and capsular structures to provide stability of the elbow, whereas the linked design relies on mechanical linkage. Theoretically, the potential for instability or dislocation after a TEA is greater with the unlinked prosthesis, whereas loosening and wear are the major concerns associated with linked prostheses [2].

In 1979, on the basis of a measurement study involving Japanese cadaveric elbows, we developed an unlinked surface replacement prosthesis using polycrystalline alumina ceramic as a solid trochlea on high-density polyethylene (Kyocera type I; KC-I) and used this clinically [11]. The initial design of the KC-I prosthesis did not include the intra-medullary stem, and the results of a 3-year follow-up of prostheses implanted without bone cement in 21 RA elbows were disappointing, with loosening and subsidence of the humeral component caused by inadequate fixation [11]. In 1986, the first model change was made to an unlinked stemmed type (Stemmed Kyocera type I; SKC-I), and this was used in 15 RA elbows [15]. The initial 8 elbows were implanted without cement fixation and early tilt or subsidence of the humeral component was noted; consequently we decided to use cement fixation in all cases from late 1987, resulting in stable clinical outcomes. This retrospective case series reports mid to long-term results from cemented alumina ceramic TEA using an SKC-I prosthesis for reconstruction of RA elbows.

Patients and methods

In this retrospective study we reviewed clinical and radiographic outcomes of TEA using SKC-I unlinked elbow prostheses (Fig. 1). This study was approved by the Ethics Committee of our institute. The SKC-I prosthesis consists of a humeral component (polycrystalline alumina ceramic trochlea with a sapphire stem) and an ulnar component (high-density polyethylene; HDP) to which a plate is connected with a ceramic stem. The length of the stem was 6 cm for the humeral component and 2.5 cm for the ulnar component. The humeral articular surface was designed with 8° of valgus angulation and 23° of anterior flexion to the stem. The stem of the ulnar component was designed with 7° of valgus angulation to the ulnar articular surface. There was no size variation, but right and left discrimination was present. We used the SKC-I solely for RA elbows with painful flexion contracture of less than

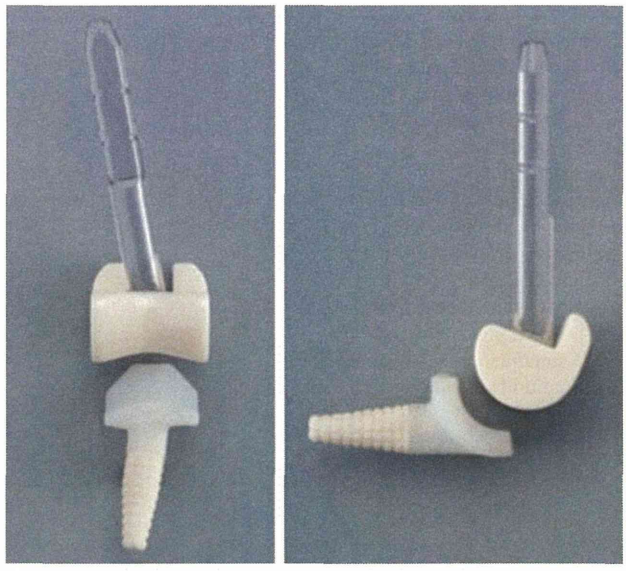

Fig. 1 Photograph of a stemmed Kyocera type I prosthesis (a prosthesis for the left elbow is shown). The humeral component consists of a solid ceramic trochlea and sapphire stem, and the ulnar component consists of a high-density polyethylene and ceramic stem. On the anterior/posterior plane, maximum curvature difference is 0.75 mm (range 0–0.75 mm) at the center of trochlea, and 1.25 mm (range 0.62–1.25 mm) at the lateral edge of trochlea. On the lateral/medial plane, maximum curvature difference is 1 mm (range 0–1 mm)

100° or painful instability causing extreme limitation of daily function. Joint destruction should be advanced beyond Larsen's grade IV [12] on radiographs. If either half of the humeral condyle or olecranon was absent with severe lateral or medial instability, a linked elbow prosthesis was indicated (Fig. 2).

We enrolled 83 patients (105 elbows) who underwent primary TEA with SKC-I prostheses using cement fixation between December 1987 and February 1999. All patients met the American Rheumatism Association 1987 revised criteria for RA. One surgeon (H.I.) implanted all of the prostheses. Fourteen patients (14 elbows) were lost to follow-up. Of the remaining 91 elbows in 69 patients, 37 elbows in 32 patients for whom follow-up was <5 years were excluded from survival analysis. Because two patients who underwent bilateral TEA were recorded in both the <5 years and the >5 years follow-up groups, data for 54 elbows in 39 patients were used for the 5-year minimum detailed clinical and radiographic reviews. All elbows were classified as Larsen's grade IV or V. Thirty-seven women and 2 men were enrolled; the patients' ages ranged from 43 to 72 years of age (average 59.0 years) at the time of surgery, with 28 right and 26 left elbow replacements. The average follow-up period was 150.6 months (range 61–269 months). Twelve patients (18 elbows) died; their pre-operative data and records at the final follow-up visit were used for analysis (Table 1). All patient data were