ABSTRACT

The Japan Collaborative Cohort Study for Evaluation of Cancer Risk (JACC Study) was established in the late 1980s to evaluate the risk impact of lifestyle factors and levels of serum components on human health. During the 20-year follow-up period, the results of the study have been published in almost 200 original articles in peer-reviewed English-language journals. However, continued follow-up of the study subjects became difficult because of the retirements of principal researchers, city mergers throughout Japan in the year 2000, and reduced funding. Thus, we decided to terminate the JACC Study follow-up at the end of 2009. As a final point of interest, we reviewed the population registry information of survivors. A total of 207 (0.19%) subjects were ineligible, leaving 110,585 eligible participants (46,395 men and 64,190 women). Moreover, errors in coding date of birth and sex were found in 356 (0.32%) and 59 (0.05%) cases, respectively, during routine follow-up and final review. Although such errors were unexpected, their impact is believed to be negligible because of the small numbers relative to the large total study population. Here, we describe the final cohort profile at the end of the JACC Study along with selected characteristics of the participants and their status at the final follow-up. Although follow-up of the JACC Study participants is finished, we will continue to analyze and publish study results.

Key words: JACC Study; cohort study; Japan; follow-up

INTRODUCTION

To evaluate the risk impact of lifestyle factors and levels of serum components on human health, in the late 1980s we established a large-scale cohort study, the Japan Collaborative Cohort Study for Evaluation of Cancer Risk (JACC Study). During a follow-up period of approximately 20 years, data on deaths from major causes such as stomach cancer, lung cancer, and cardiovascular diseases enabled examination of risk factors. We subsequently published results regarding associations between lifestyle factors and health status in almost 200 original research articles in peer-reviewed English-language journals. Additionally, we are currently developing a website to increase public awareness.1

The enthusiasm of researchers is always important in promoting a cohort study, but enthusiasm is not enough since such work takes many years to bear fruit. A substantial budget is also required. The JACC Study was started after receiving a promise of funds for 10 years; however, after the initial 10 years had passed, it became necessary to apply for small public grants to maintain and follow cohort participants. In addition, administrative mergers of cities, towns, and villages throughout Japan in the year 2000 sometimes caused further difficulties in following subjects in the study area, due to changes in partnerships between local governmental offices and researchers. Moreover, with the retirement of key researchers, it was not always easy to transfer their work to their successors. As a result of these challenges, we decided to...
terminate follow-up of participants in the JACC Study at the end of 2009.

As a final point of interest, we used population registers in the study area to review the list of survivors. Some subjects were found to be no longer living in the study area, although the overall number of such participants was small. Moreover, a small number of errors in the coding of date of birth and sex were identified during follow-up data collection. Here we describe the final cohort profile obtained upon completion of the JACC Study. Data on cancer incidence have not yet been compiled because of the time lag of the cancer registry system. This process is expected to continue until 2013, at which point incidence information until 2009 will be made available.

METHODS

Study subjects
Details of the study design and concept have been described elsewhere.2–4 Briefly, the JACC Study was a multicenter collaborative study in which 24 institutions voluntarily participated. Recruitment of study subjects living in 45 areas was managed by individual investigators whose responsibility was to construct the cohort in that area. Data were collected from 1988 through 1990. However, although most baseline surveys were performed during this 3-year period, some subjects were recruited before and after this period because of the need for a preliminary study in 3 areas and later collaboration in 1 area. Individual informed consent before participation in the study was obtained in 36 of the 45 study areas (written consent in 35 areas and oral consent in 1 area); in the remaining 9 areas, group consent from the area leader was obtained. Participant eligibility was verified by individual investigators, who confirmed that (1) the participant was living within the study area and (2) was aged 40 to 79 years at baseline. In addition, date of birth and sex were further verified using official documents and/or a completed self-administered questionnaire.

Follow-up
As follow-up information, dates and causes of death were annually or biannually confirmed, with the permission of the Director-General of the Prime Minister’s Office (Ministry of Public Management, Home Affairs, Post and Telecommunications) and/or the Ministry of Health, Labor and Welfare, Japan. The date of move-out of cohort members from the study area was also annually or biannually verified by the investigator in cooperation with key members of the local governmental office. In 24 of the 45 areas, data on cancer incidence such as date of diagnosis and primary site were also collected through population-based cancer registers or by reviewing the records of local major hospitals. In most areas, follow-up was completed at the end of 2009; however, it was stopped at the end of 1999 in 4 areas, at the end of 2003 in another 4 areas, and at the end of 2008 in 2 areas.

Final data setup: correction of birth date and sex information, identification of decedents and subjects who had moved, and deletion of ineligible participants

To confirm if study participants had survived and were living in the study area at the end of follow-up, we conducted a systematic review of population registers of cohort members in 17 areas followed until 2009. In the remaining 18 areas followed until 2009, annual or biannual follow-up surveys were routinely performed using population registers; thus, no further reviews were conducted. If data from participants presumed to survive were found to be missing at the end of 2009, attempts were made to obtain information on their mortality status or current location, and relevant information was added to the follow-up data. A few participants were found to have never lived in the study area and were thus excluded from the baseline data.

This review process revealed some errors in coding of date of birth and sex. Moreover, during the merge of follow-up data with baseline identifiable data (name, date of birth, and sex), further errors in date of birth and sex were found. All such errors were corrected.

RESULTS

Of 110,792 participants aged 40 to 79 years at baseline, 207 (0.19%) were found to have never lived in the study area. As a result, 110,585 participants (46,395 men and 64,190 women) were ultimately deemed eligible as subjects for the JACC Study, with 707,136 and 1,025,703 person-years of follow-up for men and women, respectively. Errors in the coding of date of birth and sex were found in 356 (0.32%) and 59 (0.05%) cases, respectively, during routine follow-up and final review. Table 1 shows the age and sex distribution of study participants. There were no subjects from the Shikoku region. As compared with the overall distribution of the Japanese population in 1989, our cohort participants were slightly older and included a higher percentage of women.

Table 2 shows the follow-up results, and Table 3 shows the major causes of death up to 2009. These values include the follow-up information (death or move-out from the study area) that was reported in 10 of 17 areas for 516 subjects (0.5%) through a systematic review of population registers of cohort members. Finally, 27,410 deaths (24.8%; 15,401 men, 12,009 women) and 6,402 move-outs (5.8%; 2,343 men, 4,059 women) were identified during the median 18.0-year follow-up. The first cause of death was cancer among men (37.6%) and circulatory disease among women (33.7%), and the second cause of death was circulatory disease (27.8%) and cancer (30.8%), respectively (Table 3). Among those who died of cancer, the first, second, and third leading causes of death were cancer of the lung (23.2%), stomach (18.4%), and liver (10.7%) among men and cancer of the stomach (15.4%), lung (11.2%), liver, and pancreas (9.2% for both)
among women. When cancers of the colon and rectum were grouped together, that category was the second leading cause of death (12.7%) among women.

**DISCUSSION**

This final profile of the JACC Study Group describes the number of participants and their follow-up status. During the median 18-year follow-up, we found errors in the coding of date of birth and sex data as well as incorrectly registered cases. Accordingly, we would advise future researchers planning a field study to thoroughly check participant eligibility and basic information such as date of birth and sex; this can be performed at least twice, by using a population register and a self-questionnaire.

Although follow-up information was annually or biannually confirmed, 516 subjects who had died or moved out of the study area were not identified during routine follow-up. The

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**Table 1. Age distribution of cohort members at baseline by region**

| Age at baseline | Total | % |
|-----------------|-------|---|
| 40–44 | 45–49 | 50–54 | 55–59 | 60–64 | 65–69 | 70–74 | 75–79 |
| Men | | | | | | | | |
| Japan general population 1989 (×1000) | | | | | | | | |
| JACC Study participants | | | | | | | | |
| % | | | | | | | | |
| Hokkaido | | | | | | | | |
| Tohoku | | | | | | | | |
| Kanto | | | | | | | | |
| Chubu | | | | | | | | |
| Chugoku | | | | | | | | |
| Kyushu | | | | | | | | |
| Women | | | | | | | | |
| Japan general population 1989 (×1000) | | | | | | | | |
| JACC Study participants | | | | | | | | |
| % | | | | | | | | |
| Hokkaido | | | | | | | | |
| Tohoku | | | | | | | | |
| Kanto | | | | | | | | |
| Chubu | | | | | | | | |
| Chugoku | | | | | | | | |
| Kyushu | | | | | | | | |

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**Table 2. Follow-up status until 2009 by sex and age**

| Age at baseline | Total | % | Person-years | Mortality rate (per 1000 person-years) |
|-----------------|-------|---|--------------|---------------------------------------|
| 40–44 | 45–49 | 50–54 | 55–59 | 60–64 | 65–69 | 70–74 | 75–79 |
| Men | | | | | | | | |
| No. at baseline | 5991 | 5794 | 6309 | 7690 | 8415 | 5516 | 4021 | 2825 | 2141 | 1770 | 27668 |
| No. of deaths | 394 | 658 | 1113 | 2000 | 3252 | 3056 | 2782 | 2146 | 15401 |
| % | 6.6 | 11.4 | 17.6 | 26.0 | 38.6 | 55.4 | 69.2 | 80.7 | 33.2 |
| No. who left study area | 539 | 377 | 433 | 467 | 529 | 422 | 242 | 102 | 298 |
| % | 9.0 | 6.5 | 4.8 | 3.9 | 3.5 | 4.4 | 4.5 | 5.1 |
| Person-years | 107048 | 102338 | 108465 | 124421 | 123896 | 74267 | 43689 | 23012 | 707136 |
| Mortality rate (per 1000 person-years) | 3.7 | 4.4 | 4.8 | 5.5 | 6.9 | 8.7 | 7.8 | 6.3 |
| Women | | | | | | | | |
| No. at baseline | 7536 | 7912 | 9088 | 10792 | 11102 | 8589 | 5548 | 3623 | 64190 |
| No. of deaths | 242 | 368 | 637 | 1218 | 1982 | 2544 | 2632 | 2386 | 12609 |
| % | 3.2 | 4.7 | 7.0 | 11.3 | 17.9 | 29.6 | 47.4 | 65.9 | 18.7 |
| No. who left study area | 605 | 488 | 479 | 522 | 606 | 592 | 483 | 264 | 4059 |
| % | 8.0 | 6.2 | 5.3 | 6.8 | 6.9 | 7.8 | 7.8 | 7.8 | 6.3 |
| Person-years | 134927 | 139091 | 159465 | 182347 | 174721 | 125510 | 71076 | 38566 | 1025703 |
| Mortality rate (per 1000 person-years) | 1.8 | 2.6 | 4.0 | 6.7 | 11.3 | 20.3 | 37.0 | 61.9 | 11.7 |
Table 3. Mortality distribution according to cause of death during entire follow-up period

| Cause of death | Men | Women |
|----------------|-----|-------|
| | 40-44 | 45-49 | 50-54 | 55-59 | 60-64 | 65-69 | 70-74 | 75-79 | Total | % | %* |
| | 40-44 | 45-49 | 50-54 | 55-59 | 60-64 | 65-69 | 70-74 | 75-79 | Total | % | %* |
| All causes | 394 | 658 | 113 | 2000 | 3252 | 3056 | 2782 | 2146 | 15401 | 100.0 | |
| 40-49 | 242 | 368 | 637 | 1218 | 1982 | 2544 | 2632 | 2386 | 12009 | 100.0 | |
| C00-C09 | Certain infectious and parasitic diseases | 6 | 10 | 18 | 38 | 56 | 62 | 44 | 33 | 267 | 1.7 | |
| C10-C19 | Neoplasms | 160 | 312 | 542 | 927 | 1425 | 1073 | 972 | 561 | 5792 | 37.6 | 100.0 |
| C15 | Esophagus | 12 | 14 | 28 | 42 | 55 | 39 | 17 | 10 | 216 | 3.7 | |
| C16 | Stomach | 32 | 62 | 87 | 176 | 252 | 199 | 151 | 109 | 1068 | 18.4 | |
| C18 | Colon | 12 | 14 | 36 | 41 | 67 | 59 | 44 | 35 | 308 | 5.3 | |
| C19-C20 | Rectum | 8 | 17 | 26 | 52 | 39 | 30 | 27 | 22 | 221 | 3.8 | |
| C22 | Liver and intrahepatic bile ducts | 21 | 46 | 79 | 128 | 167 | 77 | 66 | 37 | 621 | 10.7 | |
| C23 | Gall bladder | 1 | 5 | 6 | 16 | 17 | 32 | 12 | 12 | 101 | 1.7 | |
| C24 | Other and unspecified parts of biliary tract | 5 | 11 | 34 | 41 | 42 | 28 | 16 | 18 | 186 | 3.2 | |
| C25 | Pancreas | 13 | 20 | 29 | 50 | 78 | 63 | 43 | 42 | 338 | 5.8 | |
| C33-C34 | Lung | 27 | 50 | 114 | 205 | 364 | 290 | 181 | 114 | 1345 | 23.2 | |
| C50 | Breast | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 2 | 0.0 | |
| C53 | Cervix uteri | 6 | 2 | 10 | 5 | 9 | 5 | 7 | 5 | 49 | 2.7 | |
| C54 | Corpus uteri | 2 | 2 | 7 | 7 | 9 | 3 | 4 | 2 | 36 | 1.0 | |
| C55 | Uterus, part unspecified | 2 | 3 | 1 | 3 | 13 | 9 | 8 | 7 | 46 | 1.2 | |
| C56 | Ovary | 13 | 8 | 15 | 16 | 22 | 10 | 9 | 5 | 98 | 5.8 | |
| C61 | Prostate | 2 | 4 | 20 | 21 | 68 | 49 | 59 | 279 | 4.8 | |
| C64 | Kidney | 0 | 4 | 7 | 12 | 14 | 9 | 12 | 4 | 62 | 1.1 | |
| C65-C67 | Urinary tract | 2 | 7 | 13 | 11 | 40 | 31 | 34 | 17 | 155 | 2.7 | |
| C68-C85 | Non-Hodgkin’s lymphoma | 0 | 8 | 17 | 29 | 44 | 20 | 15 | 15 | 148 | 2.6 | |
| C86-C89 | Multiple myeloma | 2 | 7 | 4 | 12 | 18 | 12 | 9 | 5 | 69 | 1.2 | |
| C92 | Myelodysplasia | 5 | 10 | 11 | 16 | 17 | 7 | 9 | 3 | 78 | 1.3 | |
| E00-E09 | Endocrine, nutritional and metabolic diseases | 8 | 10 | 17 | 29 | 38 | 35 | 27 | 28 | 192 | 1.2 | |
| E09-G09 | Diseases of the nervous system | 4 | 7 | 17 | 19 | 50 | 39 | 18 | 10 | 164 | 1.1 | |
| F00-F09 | Diseases of the circulatory system | 86 | 132 | 252 | 460 | 857 | 908 | 919 | 673 | 4287 | 27.8 | |
| I00-I25 | Ischemic heart disease | 34 | 45 | 69 | 124 | 204 | 781 | 147 | 1003 | 821 | 11.8 | |
| I46 | Atrial fibrillation and flutter | 0 | 0 | 4 | 10 | 19 | 25 | 24 | 15 | 97 | 1.0 | |
| I50 | Heart failure | 7 | 14 | 26 | 56 | 121 | 151 | 178 | 153 | 711 | 8.5 | |
| I60-I69 | Cerebrovascular disease | 30 | 44 | 113 | 194 | 362 | 389 | 408 | 285 | 1825 | 24.3 | |
| J00-J09 | Diseases of the respiratory system | 14 | 40 | 62 | 219 | 408 | 501 | 550 | 500 | 2294 | 14.9 | |
| J09-J18 | Influenza and pneumonia | 6 | 20 | 30 | 115 | 228 | 273 | 327 | 327 | 1326 | 2.2 | |
| J43 | Emphysema | 0 | 1 | 6 | 19 | 58 | 58 | 64 | 44 | 250 | 0.0 | |
| K00-K09 | Diseases of the digestive system | 28 | 35 | 53 | 78 | 82 | 109 | 80 | 46 | 511 | 3.3 | |
| K74 | Fibrosis and cirrhosis of liver | 16 | 16 | 27 | 34 | 20 | 13 | 19 | 6 | 151 | 1.8 | |
| L00-L09 | Diseases of the genitourinary system | 2 | 9 | 14 | 33 | 67 | 68 | 59 | 39 | 219 | 3.4 | |
| N17-N19 | Acute kidney failure and chronic kidney diseases | 2 | 7 | 12 | 22 | 50 | 52 | 52 | 53 | 250 | 1.2 | |
| R00-R99 | Symptoms, signs, and abnormal clinical and laboratory findings, not elsewhere classified | 4 | 4 | 6 | 7 | 26 | 52 | 99 | 109 | 307 | 2.0 | |
| R54 | Age-related physical debility | 0 | 0 | 0 | 4 | 19 | 37 | 87 | 99 | 246 | 0.0 | |
| S00-T88 | External causes | 78 | 86 | 113 | 150 | 170 | 150 | 126 | 93 | 966 | 6.3 | |
| Others | 4 | 13 | 19 | 40 | 73 | 59 | 60 | 34 | 302 | 2.0 | |

*Percentage of deaths per neoplasm.
use of population registers to verify that subjects are living in the study area is therefore necessary because it enables identification of deceased individuals and those who have moved out of the study area. Furthermore, 356 (0.32%) and 59 (0.05%) cases of incorrect coding of date of birth and sex, respectively, were found during routine follow-up and final review. Miscoding of data can occur by verification only once, and miscoding of date of birth and sex information may cause errors such as merging of the follow-up information of 1 participant with the baseline data of another participant. Thus, careful efforts such as independent double-entry are essential to reduce such miscoding.

The JACC Study is one of the largest cohort studies in Japan. Selected characteristics of study participants were similar to those of the Japanese general population, and thus, the JACC Study can be regarded as representative of the Japanese population, though it should be noted that no subjects were recruited from the Shikoku region. Almost 200 original articles on the risk factors for cancer, cardiovascular disease, and other diseases have been published using the results of the JACC Study. It was not an easy task to establish and maintain such a large collaborative cohort study with a limited budget; the voluntary efforts of the collaborators were essential. Although unexpected errors were found, we believe that the impact of these errors was negligible because the number of ineligible cases and amount of missing data were small relative to the large total study population.

Cohort studies need to continue over a long period if they are to yield fruitful results. Moreover, because all study participants must be followed up carefully and thoroughly, considerable funding is required. The JACC Study received systematic support for the first 10 years, at which point this funding ceased and maintenance and follow-up of cohort participants was accomplished by means of smaller grants. The retirements of principal researchers and city mergers throughout Japan made it difficult to continue follow-up. Thus, we decided to terminate the follow-up of participants in the JACC Study at the end of 2009. Our experience indicates that the development and maintenance of an appropriate long-term management system is essential when launching a cohort study and that adequate and steady support from funding bodies is also important.

We would like to express our sincere thanks to all participants and researchers related to the JACC Study, and to all the funding bodies that supported our study. Hereafter, we plan to use the final dataset and remaining sera to examine the risk impact of lifestyle factors and levels of serum components on human health.

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Conflicts of interest: None declared.

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