

Daiko Study of the Japan Multi-Institutional Collaborative Cohort Study: a progress report

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Background:

The Japan Multi-Institutional Collaborative Cohort Study (J-MICC Study) is a long term cohort study aiming to investigate interactions between genotypes and life style, mainly in regard to cancer. Since 2005, the base-line surveys have been conducted by the ten affiliated universities/institutes throughout Japan. Deaths and cancer occurrences will be followed up until 2025. Nagoya University, one of the affiliated team, has two survey fields; Nagoya and Shizuoka. In the former, called Daiko Study, the base-line survey has been conducted at the Daiko Medical Center of Nagoya University since June 2008, expecting 5,000 participants. This paper reports the outline of the Daiko Study, its progress, and interim analysis of anti-*Helicobacter pylori* (*H. pylori*) antibody prevalence among the participants.

Methods:

Subjects are registered residents of Nagoya city aged 35 to 69 years, who have not participated in the other fields of the J-MICC Study. Participants were recruited mainly through leaflets distributed to mailboxes citywide, personal communications and regional information such as posters put up at public or commercial facilities. This study was also introduced by a news paper and a TV program.

The J-MICC Study protocol requires that participants provide blood plasma, serum and buffy-coat and complete a questionnaire on their lifestyle, disease history, family history, and reproductive history for women. For the participants, blood tests (total cholesterol, HDL cholesterol, triglyceride, creatinine, uric acid, AST, ALT, and γ -GTP), urinalysis (proteinuria, glycosuria, and so on), urine test of anti-*H. pylori* antibody (RAPIRUN *H. pylori* antibody detection kit, Otsuka Pharmaceutical Co., Ltd), blood pressure, body measurements (height, weight, and abdominal circumference) are provided, whose results are also used for the research purposes.

The informed consent form to certify the agreement of the above checkup and follow-up is requested for all participants before the enrollment subsequent to the 20-minute group explanation using a video and individual confirmation of the consent contents.

Results and discussion:

By the end of July 2009, after a total of 1,329,600 leaflets had been distributed throughout the city of Nagoya, 3,054 participants had been recruited, whose mean age \pm S.D. were 52.8 ± 10.2 years. The recruited

Table: Participants by age group and their anti-*H. Pylori* antibody positive rate in urine

Age (years)	35 to 39	40 to 49	50 to 59	60 to 69	Total	Mantel-Haenszel Chi-squared test for trend
Total	418 [20.1%]	828 [24.5%]	810 [38.3%]	998 [49.8%]	3,054 [35.8%]	$p < 0.001$
Male	100 [24.0%]	188 [23.9%]	230 [38.3%]	319 [54.2%]	837 [39.4%]	$p < 0.001$
Female	318 [18.9%]	640 [24.7%]	580 [38.3%]	679 [47.7%]	2,217 [34.5%]	$p < 0.001$

residents were 0.23 % of the posted leaflets. A survey for the participants between 8 November 2008 and 2 June 2009 (n=1,824) demonstrated that 64.9 % (n=1,183) had obtained the information directly through posted leaflets and 25.9 % (n=472) through the hearsay of the participants or propagation of the staff.

Interim analysis on anti-*H. pylori* antibody showed that 35.8% of 3,054 participants were positive (Table). The positive rate significantly increased with age ($p<0.001$). When the age distribution was adjusted, the difference in the rate between males and females was not significant (Mantel-Haenszel test: $p=0.14$). The rate seemed lower than in other reports in Japan. Since *H. pylori* infection depends on sanitary conditions in childhood, the improvement of the conditions might be earlier in Nagoya than in other areas of Japan.

Conclusion:

Daiko Study with more than 3,000 participants as of the end of July 2009, is on going to enroll the expected 5,000 residents until spring of 2010. The interim analysis on anti-*H. pylori* antibody demonstrated the present infection prevalence in Nagoya.