

Title page

Self-reported stroke and myocardial infarction had adequate
sensitivity in a population-based prospective study:

JPHC (Japan Public Health Center)-based Prospective Study

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ABSTRACT

Objective We sought to clarify the validity of self-reported stroke and myocardial infarction among Japanese population, since information on the validity, particularly on the sensitivity, of self-reported cardiovascular disease is limited and may differ among countries.

Study design and setting Using the 10-year follow-up questionnaire and a stroke and myocardial infarction registry in the JPHC Study cohort (n =91,186), we calculated sensitivity and positive predictive values of self-reported stroke and myocardial infarction incidence over 10 years.

Results Sensitivity of self-reported incident stroke was 73% and that for myocardial infarction was 82%. Positive predictive values were 57% for stroke and 43% for myocardial infarction. The supplemental inclusion of self-reported angina pectoris increased the sensitivity of myocardial infarction to 89%, but attenuated the positive predictive value to 18%. Sensitivity of self-reported stroke was highest for subarachnoid hemorrhage (88%), but did not differ greatly among other stroke subtypes, affected sites or size.

Conclusion Self-reported stroke and myocardial infarction seem sensitive enough to use for exclusion of stroke and myocardial infarction at baseline in Japanese cohort studies. However, self-report has too many false positives to be used as the only criterion for incident stroke and myocardial infarction. (193 words)

Key words: sensitivity, predictive value, validity, self report, registration, cardiovascular disease

Short title: Validity of self-report stroke and MI

Word count: 3,835

What is new?**Key finding**

- Self reports detected $\approx 70\%$ of incident stroke and 80-90% of myocardial infarction among Japanese population.

What this adds to what was known

- Information on sensitivity of self-reported stroke and myocardial infarction has been scant among non-Western countries.

- This study showed that self reports of stroke and myocardial infarction among Japanese population were sensitive enough but were generally lower than Western reports.

What is the implication, what should change now

- The usage of questionnaires to exclude individuals with history of stroke and MI at baseline in non-Western cohort studies seems to be justified.

- The use of self-reported diagnoses is not sufficient to accurately classify incident stroke or MI events.

INTRODUCTION

Self-reported information on cardiovascular disease (CVD), such as stroke or myocardial infarction (MI), has been often used in cohort studies to exclude individuals with prevalent CVD or to capture incident cardiovascular disease events. Although several Western studies have reported the accuracy of self-reports, reports of the sensitivity of self-reported CVD has been limited in Japan, where the case mix of incident CVD is quite different from Western countries, with high incidence of stroke, especially hemorrhagic and lacunar stroke, but low incidence of myocardial infarction or large-artery occlusive stroke [1,2]. Furthermore, the saturation level of computed tomography (CT) and/or magnetic resonance imaging (MRI) in Japanese hospitals is the highest in the world [3], which may permit Japanese physicians to easily detect small cerebral infarctions. The severity and fatality of MI in Japan is considered to be lower than that in Western countries [4-6]. These ecological differences, ie, higher proportion and detectability of mild stroke and lower proportion of severe MI, may lower the sensitivity of self-reported stroke and MI compared with Western countries. However, data on this issue among non-Western countries have been scant.

We thus examined the accuracy of self-reported stroke and MI in a cohort of middle-aged Japanese. The Japan Public Health Center-based prospective Study on cancer and cardiovascular diseases (JPHC Study) [7] is a nationwide community-based prospective study of approximately 100,000 Japanese participants with systematic surveillance of cancer, stroke, and MI. Previously, the sensitivity of self-reported cancer in this cohort was reported [8]. The aim of this study was to clarify the accuracy of self-reported incident stroke and MI over 10 years in the general Japanese population. We especially focused on the sensitivity of self-reported stroke and MI as the primary aim of this study, because not many studies have reported sensitivity of these diseases [9-15].

METHODS

Study Population

Details of the JPHC Study protocol were described elsewhere [7]. Briefly, the JPHC Study included two local community cohorts based on Public Health Center (PHC) areas in Japan; Cohort I (started in 1990, four PHC areas: Ninohe PHC area, northeastern Japan; Yokote PHC area, northeastern Japan; Saku PHC area, central Japan; and Ishikawa (currently Chubu) PHC area, southwestern isolated island), and Cohort II (started in 1993, five PHC areas: Kasama (currently Mito) PHC area, mid-eastern Japan; Kashiwazaki (currently Nagaoka) PHC area, central Japan; Tosa-Yamada (currently Chuo-Higashi) PHC area, western Japan; Kamigoto PHC area, western isolated islands; and Miyako PHC area, southwestern isolated island). We recruited study participants living in the cohort communities at baseline who met the following age criteria; born from 1930 through 1949 for the January 1st, 1990 baseline (ages 40-59) for Cohort I; and born from 1923 through 1952 for the January 1st, 1993 baseline (ages 40-69) for Cohort II. Overall, 116,672 subjects (57,579 men and 59,093 women) were eligible for follow-up.

Self-reported stroke and MI

Ten years after the baseline survey, a follow-up questionnaire was distributed or mailed to all participants, except for those who had died or had been lost to follow-up. This was in 2000 for subjects in Cohort I and in 2003 for those in Cohort II (n=109,147 questionnaires distributed or mailed). The questionnaire asked for self-reports of first diagnosed stroke, MI and angina pectoris, and period of diagnosis (before 1990, 1990-1994 and 1995 or later for Cohort I, and before 1993, 1993-1997 and 1998 or later for Cohort II, Appendix). A total of 91,186 subjects (42,574 men and 48,612 women) responded to the 10-year follow-up questionnaire (response rate =84%). We excluded subjects who had already been diagnosed

stroke or MI before 1990 for Cohort I and before 1993 for Cohort II based on the 10-year follow-up questionnaire and/or the stroke and MI registry mentioned below. As a result, 89,914 subjects (41,790 men and 48,142 women) were eligible for the stroke analysis and 90,102 subjects (41,979 men and 48,123 women) for the MI analysis (Figure). The JPHC Study was approved by the institutional review board of the National Cancer Center, Tokyo, Japan.

Registry for stroke and MI

A total of 78 hospitals formed the register of events within the sampling areas of the JPHC cohort. All were major hospitals with the capability of treating patients with acute coronary heart disease, stroke or cancer events. In the present study, 97% of registered strokes and 92% of registered MIs were treated at these 78 hospitals. Clinical information was extracted from medical records onto cohort-specific registration forms. Physicians in the hospitals, PHCs or investigators, blinded to the patients' lifestyle data, reviewed the medical records of cohort participants at each hospital.

MI was confirmed in the medical records according to the criteria of the Monitoring Trends and Determinants of Cardiovascular Disease (MONICA) project [16], which requires typical chest pain and evidence from electrocardiogram and/or cardiac enzymes. For cases with typical chest pain but not confirmed by electrocardiograms or cardiac enzymes, a possible MI diagnosis was made and these were included in MI cases. Stroke was confirmed according to the criteria of the National Survey of Stroke [17], which requires the presence of focal neurological deficits of sudden or rapid onset lasting at least 24 hours or until death. Strokes were classified according to subtypes (ie intraparenchymal hemorrhage, subarachnoid hemorrhage, or cerebral (thrombotic or embolic) infarction). Further classifications were performed for intraparenchymal hemorrhage according to affected sites (subcortical,

putamen/internal capsule/basal ganglia, thalamus, cerebellum, brain stem, or multiple foci) and size ($<2\text{cm}$ or $\geq 2\text{cm}$), and for cerebral infarction according to sites (cortical/subcortical, perforator, overlapping cortical and perforator, thalamus, cerebellum, brain stem, multiple foci, or no apparent lesions) and size ($<1.5\text{cm}$ or $\geq 1.5\text{cm}$). Almost all registered hospitals were equipped with CT and/or MRI scans. Imaging was available for 98% of registered stroke events in this study.

There were a few missing reports from hospitals or cases treated at outside of registered hospitals. To complete the surveillance for nonfatal stroke and MI, we contacted any participants who reported the occurrence of coronary or stroke events in the 10-year follow-up questionnaire, but who were not registered in the stroke or MI registry, by letter or telephone, and sought permission to review relevant medical records. Of 653 individuals reporting unregistered stroke, 582 (89%) were contacted and 245 provided information consistent with suspected strokes. Of these 245 individuals, 213 (87%) provided written informed consent for their records to be reviewed by physicians. Among these participants, we confirmed strokes in 165 individuals and these cases were therefore included in the registry. Of 288 individuals reporting unregistered MI, 252 (88%) were contacted and 119 provided information consistent with suspected MIs. Of these 119 individuals, 102 (86%) provided written informed consent for their medical records to be reviewed by physicians. Among these participants, we confirmed MIs in 51 individuals, who were thus included in the registry. Similarly, cases identified by the 5-year follow-up questionnaire and confirmed by hospital records were also included in the registry. As a result, we identified 225 strokes and 93 MIs altogether. Of these, 172 first-ever strokes and 71 first-ever MIs were included in the present analyses.

For analysis, acute first-ever stroke and MI events were included if they occurred between the JPHC baseline and the month the 10-year follow-up questionnaire was

completed. Therefore, recurrent events, fatal events during the follow-up, or events without a corresponding 10-year questionnaire were not included in the analyses. Stroke and MI registrations were independently managed, that is, persons who had both stroke and MI during the follow-up were registered to both stroke and MI registries.

Statistical analyses

We calculated 10-year sensitivity and positive predictive values of events self-reported on the 10-year questionnaire. We regarded the stroke and MI registry plus the additional validated events as the gold standard. Sensitivity of self-reported stroke was calculated by the number of true-positive cases divided by the number of total registered strokes, and positive predictive value was by the number of true-positive stroke divided by the number of total self-reported strokes (18). Similar calculations were performed for MI. We also tested MI using both self-reported MI and angina pectoris, since MI was often perceived as angina pectoris by the participants. We did not focus on specificity and negative predictive values, because these two were close to 100% with the large number of non-cases (99% for specificity of stroke, and 100% for negative predictive values of stroke and MI, and specificity of MI). Sensitivities and positive predictive values stratified by sex and age groups (aged <65 or ≥65 at 10-year questionnaire), and sensitivities stratified by incident date (within 5 years or 6-10 years of the 10-year questionnaire) were calculated. Stratifications for stroke subtypes, affected site and size were also performed. As a supplementary analysis, we calculated the sensitivities excluding additionally validated events (ie, cases detected only by the questionnaire).

RESULTS

During the 10-year follow-up, 2,760 first-ever strokes and 591 first-ever MIs were registered.

Of these, 767 strokes (28%) and 151 MIs (26%) were fatal during follow-up, and 546 non-fatal strokes (20%) and 98 non-fatal MIs (17%) did not respond the 10-year follow-up questionnaire. These cases were excluded from the analyses. Thus, 1,447 strokes and 342 MIs with 10-year follow-up questionnaires were included in the analysis.

Table 1 presents the sensitivity and positive predictive values for stroke and MI. For stroke, the sensitivity of self-report was 73% whereas the positive predictive value was 57%. The respective values for MI were 82% and 43%. When we included self-reported angina pectoris with MI, the sensitivity increased up to 89%, but the positive predictive value decreased from 43% to 18%. Women showed lower positive predictive values for MI than men, probably reflecting the low incidence rate of MI among women. Sensitivities and positive predictive values were generally lower among elderly than younger participants for both stroke and MI. The sensitivity estimates were similar for cases incident within 5 years compared with those 6-10 years previously.

As shown in Table 2, the sensitivity of reported stroke was 88% for subarachnoid hemorrhage, which was higher than for intraparenchymal hemorrhage (74%) or cerebral infarction (69%). Among intraparenchymal hemorrhages, the sensitivity was higher for sites at the thalamus (79%), putamen/internal capsule/basal ganglia (75%) or cerebellum (74%) than other sites, and for hematoma of ≥ 2 cm (78%) than smaller hematoma. For ischemic stroke, the sensitivity was higher for the cortical and perforator sites (77%) and thalamus (75%) than other sites, but did not differ greatly by size.

Since 172 strokes and 71 MIs in the registry were initially detected by questionnaire, we calculated sensitivities excluding these cases from the analyses. The results, however, did not differ greatly: The sensitivities (95% confidence intervals) were 69 (66-71) % for stroke and 77 (73-82) % for MI (data not shown).

DISCUSSION

Sensitivities of self-reported stroke and MI were 73% and 82%, respectively, in the present study. That estimate for MI improved after including self-reported angina pectoris (89%), but at a large increase in false positives. Sensitivity was higher for subarachnoid hemorrhage than other subtypes of stroke.

The sensitivities in the present study were somewhat lower than those reported from the majority of previous Western studies, in particular for stroke. For example, a study from Olmsted County [9] reported a sensitivity of 78% for self-reported stroke and 90% for MI; the Newcastle Family Health Service Authority [10] reported 95% for stroke; British Regional Heart Survey [11] reported 89% for stroke and 94% for MI, although some studies [12,13] showed lower sensitivities for stroke (33%) or MI (52-74%). Other studies estimated sensitivities indirectly using a subsample of study participants: the Tromsø Study [14] estimated 70-85% sensitivity for stroke; and a study from Finland [15] estimated 100% for MI. We assume several reasons for generally lower sensitivity among Japanese. First, a high incidence of stroke, especially of mild strokes such as lacunar infarctions, typically located in the perforator area, may cause lower sensitivity of self-reported stroke. Since saturation levels of CT and/or MRI in Japan have been the highest in the world [5], Japanese physicians may detect lacunar infarction more. Although reported by physicians, patients with minor clinical symptoms may be more likely to forget or ignore the stroke diagnosis, because typical symptoms of lacunar infarction of perforator area, such as hemiparesis or dysarthria, are sometimes reversible or negligible if they are mild. These situations might have led to false-negative responses to the self-administrated questionnaire of stroke. Second, cognitive decline in stroke patients, which was considered as a cortical dysfunction, might also have led to underreporting. We did not observe much difference in sensitivity between perforator and cortical/subcortical infarctions, but the sensitivities of subcortical hemorrhage and embolic

stroke which could lead cognitive dysfunction, were slightly lower. Also, the sensitivities of stroke and MI were approximately 10% lower among elderly (aged ≥ 65) than younger persons. Third, the severity of coronary heart disease is generally considered to be low among Japanese compared with Western population [4-6]. This may have lowered the sensitivity of self-reported MI. Furthermore, Japanese physicians, when patients' symptoms are not severe, sometimes tell them that they had a 'stroke-like disease' or a 'near MI', which also leads the patients to underreport their stroke or MI. Fifth, differences in the methods, purposes and validation systems among studies may affect the sensitivity. Recall periods may also affect sensitivity. Previous studies with high sensitivity had longer recall periods (13.8 years for British Regional Heart Study [11] and lifetime for Olmsted [9], Newcastle [10] and Tromsø [14] studies) than that of the present study. However, the sensitivity of self-reported stroke or MI in JPHC Study was not greatly inferior to that of Western studies. In addition, sensitivity did not differ between short-term (≤ 5 years) and long term (6-10 years) recalls, suggesting that self-reports may detect history of old stroke and MI fairly sensitively. Taken together with the high specificity and negative predictive value (99 to 100 %), we believe that the exclusion of self-reported history of stroke and MI at baseline is suitable in Japanese cohort studies as well as Western studies.

The positive predictive value was not high in the present study, which may reflect the misclassification of transient ischemic attack with stroke, and of angina pectoris with MI. Therefore, the sole use of self-reported events to identify "incident" stroke or MI events is not appropriate for Japanese. Additional information on stroke or MI incidence, such as hospital records and death certificates should be systematically collected and carefully examined to rule out false-positive events.

The JPHC Study involved PHCs to systematically obtain hospital records and death certificates. This may have enhanced the accuracy of the JPHC stroke and MI registry. Not

many studies have reported the sensitivity of self-reported stroke or MI [9-15], probably due to the difficulty of systematic CVD surveillance and of identifying false-negative cases. A large sample size and high response rate are also advantages of the present study.

Furthermore, to our knowledge, the present study is the first to examine the sensitivity of self-reports of stroke or MI in a population-based prospective study in a non-Western country.

The present study has several limitations. First, our questionnaire asked the presence of disease history, but we did not provide a choice of “no history” (see Appendix). Therefore, we could not distinguish missing from “no history” responses. However, this may not greatly affect the results due to the large proportion of non-cases. Second, we could not include fatal cases during follow-up (26-28% of the registry) or non-responders to the questionnaire (17-20%), which may have affected the sensitivity. Furthermore, the registry was not completely independent of the questionnaire, because 12% of strokes and 21% of MI cases were identified by the questionnaire and were included in the registry. This could overestimate the sensitivity. When we recalculated the sensitivity using cases detected only by the registry, however, the sensitivities did not substantially decline for either stroke or MI. Third, although the JPHC Study is a large-scale nationally representative sample of the general population, we excluded subjects from Tokyo and Osaka (first and second largest cities in Japan) because of incomplete registration in these cities. Thus, it is uncertain whether our result is generalizable to metropolitan areas of Japan.

In conclusion, self-reports detected approximately 70% of incident strokes and 80-90% of MIs in this Japanese sample. Taken together with high specificity and negative predictive value, our findings seem to justify the usage of questionnaires to exclude individuals with history of stroke and MI at baseline in cohort studies. However, the use of self-reported diagnoses is not sufficient to accurately classify incident stroke or MI events. Our findings may be extrapolated to the other non-Western countries with similar epidemic of

incident cardiovascular diseases.

Figure legend

Flow chart of study participant selection. JPHC Study.

FUNDING

Grants-in-Aid for Cancer Research and for the Third-Term Comprehensive Ten-year Strategy for Cancer Control from the Ministry of Health, Labor and Welfare of Japan.

ACKNOWLEDGMENTS

The authors thank Mizue Fujii, Tomoko Seki, Keiko Nemoto, and Dr ChoyLye Chei, University of Tsukuba, for technical assistances, and all staff members in each study area and those in the central office for their painstaking efforts to conduct the baseline survey and follow-up. The authors also appreciate Prof Aaron R Folsom, University of Minnesota, for valuable comments.

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