

REVIEW OF DEATH CERTIFICATE DIAGNOSIS OF CORONARY HEART DISEASE AND HEART FAILURE IN JAPAN

Isao SAITO*

Vital statistics for coronary heart disease (CHD) were dramatically influenced by the tenth revision of the International Classification of Diseases (ICD-10) in 1995. To better understand the accuracy of death certificate diagnosis of CHD and heart failure, validation studies in Japan were reviewed. Positive predictive values and sensitivity, calculated as validation measures, varied widely between studies, differing with regard to autopsy rates, amount of information on medical records, and period investigated. However, heart failure, which has been frequently assigned on death certificates in Japan, was validated in some studies. Half of these were evaluated to be sudden deaths, including coronary deaths. Because autopsy-based studies on sudden deaths indicated that 30-50% of these were accounted for by CHD deaths, deaths assigned to heart failure should be taken into consideration in order to determine the actual number of CHD deaths in Japan. Focusing on changes in vital statistics after the 1995 ICD revision, the Oita Cardiac Death Surveys (OCDS) allowed interpretation of its effects on CHD and heart failure. Much of the increase in CHD deaths on vital statistics reflects more false positive cases, particularly for out-of-hospital deaths. Considering the Japanese features of vital statistics for CHD, further epidemiological validation studies are needed in order to confirm the accuracy of CHD death certificate diagnoses and to monitor actual CHD trends in Japan.

Key words : coronary disease; vital statistics; sudden death; validation; review

I. Introduction

Although official vital statistics on coronary heart disease (CHD) provide useful information on trends and patterns of CHD throughout the whole country and in regional communities, they are not considered to be sufficiently reliable for epidemiological purposes^{1,2)}. This is because vital statistics reflect varying diagnostic preferences, coding processes, and autopsy rates among communities³⁻⁶⁾.

Heart failure is a very commonly assigned as an underlying cause of death in Japan. However, an autopsy study provided evidence that this is not appropriate⁷⁾ because Japanese physicians assign heart failure to acute deaths lacking symptoms and signs or to deaths occurring during the end stages of cancer or stroke. The over assignment of deaths to heart failure in Japan can thus be considered due to individual diagnostic practices⁸⁾, leading to concerns about trends in CHD vital statistics in Japan⁹⁾.

In 1994, before the 1995 implementation of the 10th International Classification of Diseases (ICD-10), the Ministry of Health and Welfare of

Japan instructed physicians to avoid using heart failure nonspecifically in completing death certificates and to carefully record not only the apparent immediate cause of death and also the probable underlying cause. As a result, mortality assigned to underlying CHD increased markedly by 36% between 1993 and 1995, while the heart failure mortality rate decreased by 70%, as shown in Figure 1^{10,11)}.

In order to validate CHD diagnosis on death certificates, Dr Ozawa and his colleagues, including myself conducted the Oita Cardiac Death Survey (OCDS) for data on individuals who died in Oita due to heart and other CHD-related diseases during 1987-88¹²⁾, 1992-93¹³⁾, and 1997-98¹⁴⁾. In this report, while focusing on our OCDS results, we review validation studies on vital statistics for CHD and heart failure in Japan and address the features of the vital statistics for CHD before and after the ICD revision. Additionally, recent mortality and incidence trends in CHD are discussed.

II. Validation studies on fatal coronary heart disease in Japan

The validity of diagnosis on death certificates generally refers to the degree to which the physician's diagnosis was based on medical findings in ac-

* Department of Public Health, Nara Medical University, 840 Shijo-cho, Kashihara, Nara 634-8521, Japan
E-mail: saitoi@naramed-u.ac.jp

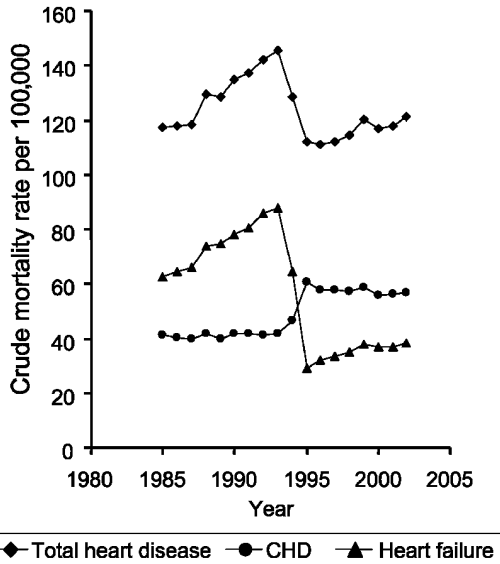


Figure 1. Vital statistics on crude mortality rates for total heart disease, coronary heart disease (CHD), and heart disease from 1985 to 2002.

Note: Although death certificates were revised in 1995, the Ministry of Health and Welfare of Japan introduced new guidelines to physicians in 1994. Some effect on CHD and heart failure vital statistics was thus observed already in 1994.

Source: Vital statistics of Japan (1985–2002).

cordance with the gold standard World Health Organization (WHO) Monitoring Trends and Determinants in Cardiovascular Disease (MONICA) project criteria¹⁵). These criteria include diagnostic components for chest pain, enzymes, electrocardiogram, autopsy, and previous CHD history. In this report, true fatal CHD is defined as ‘definite fatal AMI’ or ‘possible fatal AMI or CHD death’ based on the MONICA criteria.

A summary of validation studies on fatal CHD in Japan is shown in Table 1. In order to confirm the accuracy of death certificates, we have calculated the positive predictive value (PPV) and sensitivity (SN) as validation measures using standard formulae^{16,17}). The PPV indicates the percentage of individuals assigned an underlying cause of CHD on the death certificate and who met the fatal CHD criteria after validation. SN gives the percentage of validated CHD deaths with CHD as the underlying cause on the death certificate.

The Ni-Hon-San study¹⁸) validated diagnosis on death certificates based on autopsy findings as the gold standard. The Japanese cohort in the collaborative study included 327 deaths (age at death, 45–64

years) that were autopsied between 1965 and 1970 (autopsy rate, 33%). The CHD diagnosis had a PPV of 50% and an SN of 60%. Similarly, the Hisayama study¹⁹) documented the accuracy of cause of death on vital statistics in residents who died at age 20 years or over between 1961 and 1983. Validation was performed based only on autopsy findings, which had been performed on most individuals in the study (autopsy rate, 79%). The PPV and SN for diagnosis of fatal CHD were found to be 46% and 40%, respectively. In the Suita study²⁰), 409 deaths classified as due to heart disease, stroke or other causes were investigated in a large population and were reclassified based on the MONICA criteria. In particular, they reviewed police records, including postmortem records, to obtain detailed information on items such as the presence of witnesses. The PPV and SN in this study were 68.9% and 72.3%. They validated 67 stroke deaths in order to investigate whether CHD death was included; however, there was no fatal CHD among cases designated as stroke. The Toyama study²¹) was designed to validate fatal CHD, heart failure and stroke as underlying causes of death. Information for the validation was similar to the Oita study, and the PPV was calculated as 56.5%.

In Oita city, validation studies were performed three times; 1987–1988, 1992–93, and 1997–98. The first was carried out for heart disease deaths and the other two for other causes related to CHD. Because few autopsies were performed (autopsy rate, <3%), information on the medical records and interviews with physicians were primarily used for validation. Oita PPV and SN values varied ranged from 50.3 to 77.8% and 75.5 to 91.2%, respectively. The ICD-10 revision in 1995 greatly influenced CHD diagnosis on death certificates, as seen in Figure 1. The 1997–98 OCDS data after the revision showed a PPV of 50.3% and an SN of 86.5%. The effects of the revision on vital statistics will be discussed in section IV.

III. Effect of heart failure as an underlying cause of death on CHD vital statistics

Before ICD-9 was revised to ICD-10, heart failure (ICD-9: 428) as an underlying cause of death accounted for two thirds of total heart disease (Figure 1). The diagnosis of heart failure on death certificates was thus very common in Japan. Because the number of deaths due to heart failure was increasing, some argued that numerous CHD deaths were thereby hidden, leading to an underestimation of this cause in Japan²²). In addition, a postmortem study indicated a large difference in the frequency of

Table 1. Summary of validation studies on mortality due to coronary heart disease on death certificates in Japan.

Reference	Population (size)	Year	Number of subjects (age)	Underlying cause of death investigated	Information for validation	Accuracy of CHD diagnosis on vital statistics
Worth RM, et al 1975	Hiroshima-Nagasaki (9329)*	1965-70	327 men (45-64)	All causes	Autopsy findings	PPV: 50% (9/18) SN: 60% (9/15)
Hasuo Y. et al 1989	Hisayama (7,000)	1961-83	846 (≥20)			PPV: 46% (21/46) SN: 40% (21/52)
Baba S. et al 1994	Suita (347,000)	1984-86	409 (20-74)	Heart disease Stroke Others [§]	Medical records Autopsy findings Police records Interview with physicians	PPV: 68.9% (73/106) SN: 72.3% (73/101)
Yamashita T. et al 1997	Oita (238,000) [†]	1987-88	271 (25-74)	Heart disease	Medical records Autopsy findings Interview with physicians	PPV: 54.2% (52/96) SN: 91.2% (52/57)
Naruse Y. et al 1997	Toyama (209,000)	1988-90	317 (15-74)	CHD Heart failure Stroke		PPV: 56.5% (48/85) SN: †NA
Saito I. et al 1997	Oita (253,000) [†]	1992-93	382 (25-74)	Heart disease Others [§]	Interview with physicians	PPV: 77.8% (77/99) SN: 75.5% (77/102)
Saito I. et al 2001	Oita (273,000) [†]	1997-98	342 (25-74)			PPV: 50.3% (83/165) SN: 86.5% (83/96)

* Number of Japanese participants in the Ni-Hon-San study, [†] Ages 25-74 years, [§] Diabetes mellitus (ICD-9: 250; ICD-10: E10-E14), hypertensive disease (401-405; I10-I15), diseases of arteries, arterioles, and capillaries (440-448; I70-I79), and ill-defined and unknown causes (797-799; R54, R95-R99).

‡ NA, not available for calculation, PPV, positive predictive value; SN, sensitivity

heart failure diagnosis between clinical practitioners and postmortem physicians in Japan⁷⁾.

Validation studies in Japan also examined the diagnosis of heart failure and classified such cases into validated fatal CHD, other causes, sudden death and insufficient data, as represented in Figure 2. Validated fatal CHD accounted for 2.4-18.9% of heart failure deaths. Furthermore, 27.1-49.6% cases were classified as sudden death, which included deaths within 24 hours of onset of acute symptoms without reports of "typical" or "atypical" chest pain, as defined by the MONICA criteria, and without clear signs suggesting another cause.

Indeed, approximately half of deaths due to heart failure were validated as CHD or sudden deaths. Therefore, the main difficulty in counting true fatal CHD occurrences in the population lies in deciding how to estimate fatal CHD hidden among sudden deaths, because epidemiological data based on autopsies indicate that CHD contributes to most sudden deaths occurring within 1 hour of onset²³⁻²⁵⁾.

Based on autopsy findings, the Hisayama study²⁶⁾ between 1961 and 1983 demonstrated the 24.4% and 51.5% of unexpected sudden deaths within 24 hours were due to CHD and stroke, respectively. These percentages changed with time, and the proportion of CHD increased by 33% from 1972 to

1983. A postmortem study indicated that 65.9% of 1,230 sudden deaths examined between 1982 and 1986 in Osaka were caused by cardiac diseases and that 50.7% were due to CHD²⁷⁾. Similarly, 18,189 sudden deaths were investigated in a Tokyo postmortem study from 1989 to 1993, and 45.3% and 44.2% with and without past histories of disease, respectively, were confirmed as CHD deaths based on autopsy results²⁸⁾. In a population study from 1989 to 1999 in Saku, it was found that there were 217 sudden deaths within 24 hours, and 35.4% of 55 autopsied cases were diagnosed as CHD²⁹⁾.

Autopsy-based findings imply that 30-50% of unexpected deaths within 24 hours from onset of symptoms are due to CHD, so that, when we assess the actual number of fatal CHD in a community, it is important to take these into consideration.

IV. Effects of the 1995 ICD-10 revision on CHD vital statistics

ICD changes are known to impact on national vital statistics and the 1995 implementation of ICD-10 in Japan had a particularly large effect on both CHD and heart failure data. In this section, we discuss why CHD mortality rates from vital statistics greatly increased in Japan, and present validation

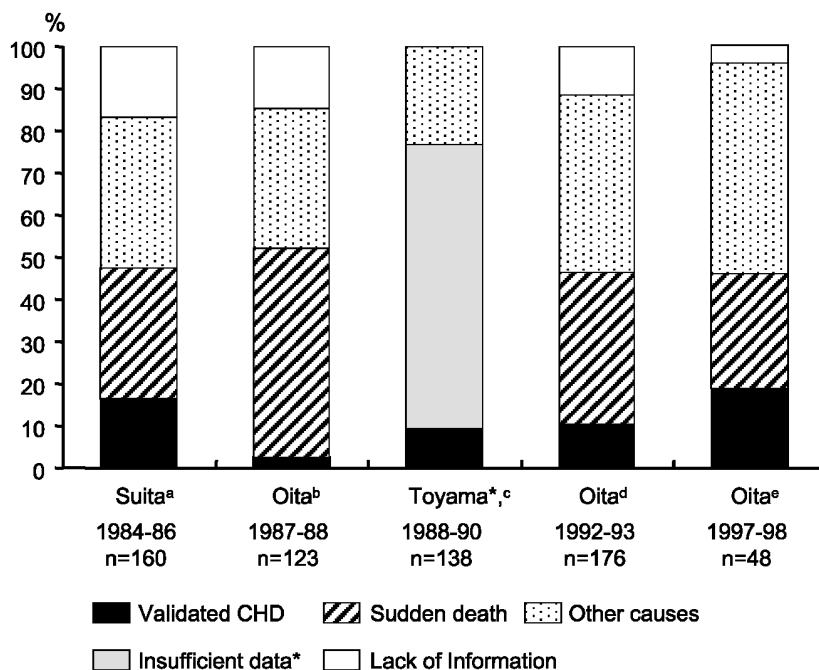


Figure 2. Proportion of validated classification of certified heart failure in validation studies in Japan.

*The Toyama study did not classify sudden death, so the gray region represents insufficient data, possibly including sudden deaths.

Source: ^aBaba S. et al 1994, ^bYamashita T. et al 1997, ^cNaruse Y. et al 1997, ^dSaito I. et al 1997, ^eSaito I. et al 2001.

measures based on OCDS data.

The 1997-98 OCDS¹⁴⁾ validated deaths based on the ICD-10 and the generated SN, PPV, specificity, and negative predictive values, as calculated for CHD death certificate diagnosis, were 86.5%, 50.3%, 64.7%, and 92.0%, respectively (Table 2). The PPV varied significantly with age and place of death and the ratio of false positive cases to true positive cases for fatal CHD was highest among those who died at a younger age or out of hospital.

When compared with the 1992-93 data from ICD-9³⁰⁾, the SN for an underlying cause of CHD on death certificates was increased, while the PPV and specificity dropped due to an increase in false positive fatal CHD cases. Stratified by place of death, in-hospital sensitivity, PPV, and specificity values in 1992-93 were 79.0%, 80.0% and 87.9%, while out-of-hospital values were 81.3%, 68.4%, and 90.3%, respectively. These data imply that false positive cases increased, particularly in out-of-hospital deaths, and much of the shift was related to sudden deaths being mostly coded as CHD in ICD-10 versus heart failure in ICD-9.

We do not believe that these substantial mortality shifts were caused by nosologists assigning differ-

ent codes or underlying causes based on the new ICD-10 rules. When the Ministry of Health reclassified 1994 deaths coded by ICD-9 using ICD-10 rules, heart failure decreased by only 1.6% and AMI decreased by 8.9%³¹⁾. Rather, we found that the main cause of this change in CHD vital statistics was the way physicians classified sudden deaths, the majority of which were out-of-hospital³²⁾. Due to low autopsy rates, unexpected deaths were, generally classified as heart failure on death certificates in ICD-9, as reported elsewhere^{20,33)}. Furthermore, upon validation, the ICD-9 heart failure classification was found to include many in-hospital deaths from causes other than heart disease. These data suggest that physicians misused heart failure as a cause of death in ICD-9. In contrast, after national instruction on ICD-10, physicians assigned CHD on certificates of deaths that were sudden or lacking clear signs suggestive of other causes.

Taking these facts into consideration, the OCDS showed the PPV and specificity to be lower in ICD-10. The findings clearly suggest that false positive fatal CHD cases increased and that physicians might be using an underlying cause of CHD nonspecifically on death certificates in ICD-10.

Table 2. Sensitivity, positive predictive value, specificity, and negative predictive value for CHD death certificate diagnosis in the 1997–98 OCDS.

Factors	Category	TP	FP	FN	TN	Sensitivity	Positive predictive value	Specificity	Negative predictive value
		n				%			
Total		83	82	13	150	86.5(77.6–92.3)	50.3(42.5–58.1)	64.7(58.1–70.7)	92.0(86.5–95.5)
Sex	Male	60	54	11	97	84.5(73.5–91.6)	52.6(43.1–62.0)	64.2(56.0–71.8)	89.8(82.1–94.6)
	Female	23	28	2	53	92.0(72.5–98.6)	45.1(31.4–59.5)	65.4(54.0–75.4)	96.4(86.4–99.4)
	<i>P</i> value					>0.2	0.20	>0.2	>0.2
Age at death	25–54 years	6	24	1	37	85.7(42.0–99.2)	20.0(8.4–39.1)	60.7(47.3–72.7)	97.4(84.6–99.9)
	55–64	24	25	7	43	77.4(58.5–89.7)	49.0(34.6–63.5)	63.2(50.6–74.4)	86.0(72.6–93.7)
	65–74	53	33	5	70	91.4(80.3–96.8)	61.6(50.5–71.7)	68.0(57.9–76.6)	93.3(84.5–97.5)
	<i>P</i> value					0.19	0.001	>0.2	>0.2
Place of death	In-hospital	68	43	9	111	88.3(78.5–94.2)	61.3(51.5–70.2)	72.1(64.2–78.9)	92.5(85.8–96.3)
	Out-of-hospital	15	39	4	39	78.9(53.9–93.0)	27.8(16.9–41.9)	50.0(38.6–61.4)	90.7(76.9–97.0)
	<i>P</i> value					>0.2	0.001	0.001	>0.2

TP: true positive, FP: false positive, FN: false negative, TN: true negative
95% confidence interval ()

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Finally, the number of heart failures is gradually increasing from the 1995 level on vital statistics, particularly for in-hospital deaths. We should therefore continue to follow this curious phenomenon, which is probably caused by diagnostic practices that have become very common.

V. Incidence, mortality, and their trends in CHD in Japan

As described in previous sections, vital statistics for CHD have been affected by diagnostic practices and ICD revisions in Japan. Moreover, given the information on unexpected sudden deaths, it is very difficult to visualize the actual trend in fatal CHD using only vital statistics. Nonetheless, questions regarding actual fatal CHD trends often arise in the field of public health and preventive medicine.

Since epidemiological studies on fatal CHD trends with large populations in Japan are rare, there are limited data to clearly identify any trend. The OCDS conducted 3 validation studies and showed validated fatal CHD trends from 1987 to 1998³²⁾ (Figure 3). When classifying sudden deaths within 24 hours of onset as CHD deaths, validated CHD mortality rates in men and women did not increase during this period. Rather, total or out-of-hospital CHD deaths in men tended to decrease.

CHD mortality trends by place of death provide valuable insight when looking at preventive effects in a population^{34,35)}. Though the US definition of in-hospital and out-of-hospital deaths differs from the Japanese definition for DOA (dead on arrival)

cases, it is commonly considered that out-of-hospital CHD trends which have been clearly declining in the US population^{34,35)} reflect primary prevention effects.

In the 1990s, incidence rates for CHD in Japan were considered based on various social factors using a community-based registration system^{29,36,37)}. Although it is impossible to directly compare event rates, because of variation in the registration system and subject conditions, such as history of CHD or age range investigated, each study consistently emphasized the low Japanese CHD incidence when compared with those in Europe and the US.

In order to confirm actual differences in CHD mortality rates between Japan and the US, a comparison study of validated fatal CHD cases was performed using data from the OCDS and the Atherosclerosis Risk in Communities (ARIC) study³³⁾. Four-fold differences in fatal CHD were observed, even if authors included the number of CHD deaths reported as sudden deaths. Particularly large differences were seen between out-of-hospital fatal CHD in Japan and the US.

Secular CHD incidence trends in the community were also described in long-term follow-up studies^{38–41)}. Kitamura et al. demonstrated the CHD incidence rates for Osaka men aged 40–59 years to have increased from 1963–70 to 1987–94, but they have remained almost level over the last two decades⁴⁰⁾. Unchanged secular trends in incidence and mortality rates for CHD were seen in the Hisayama study from 1961–73 to 1988–2000⁴¹⁾. On subgroup analysis by age, elderly people aged 80 and

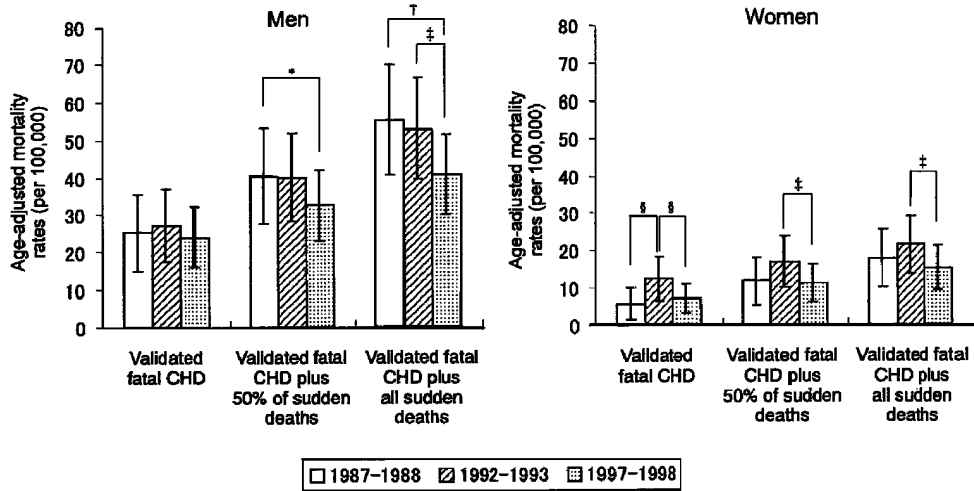


Figure 3. Trends in age-adjusted mortality rates due to validated fatal CHD, validated fatal CHD plus 50% of sudden deaths, and validated fatal CHD plus all sudden deaths from 1987 to 1998 among people aged 25-74 years in Oita City, Japan. Validated fatal CHD comprised 'Definite fatal AMI' and 'Possible fatal AMI or CHD death.' * P for trend = 0.09 and † P for trend = 0.03; ‡ P < 0.1, § P < 0.05 for difference.

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over showed a trend for increased CHD incidence. Although there were small numbers of cardiovascular events in such cohort studies for analysis, secular changes in CHD risk factors, such as blood pressure and total cholesterol levels, were very useful in interpreting the trends observed in the general population.

VI. Conclusion

Numerous validation studies of CHD death certificate diagnosis have been reported in Europe and the US^{16,17,42-44}). In an overview of seven validation studies in Japan, autopsy rates, the amount of information for validation, and the ICD version were found to influence to some extent the validation measures over time. Based on OCDS findings, ICD-10 death certificate diagnosis of CHD was characterized by a high SN and a low PPV, indicating an increase in the frequency of CHD diagnosis for people who died suddenly without information on symptoms or medical evidence. Epidemiological validation studies are needed to confirm the accuracy of CHD death certificate diagnoses in order to monitor actual CHD trends for public health purposes. Continuing population-based validation studies will play an important role in solving the controversial issue of whether CHD mortality trends in Japan are indeed increasing.

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