Original Article

Excess mortality among patients on dialysis: Comparison with the general population in Korea

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ABSTRACT

Background: Although patients with end-stage renal disease (ESRD) experience excess mortality compared with the general population, the standardized mortality ratio (SMR) for Korean patients on dialysis has not yet been investigated. In this study, we evaluated the SMR among all Korean ESRD patients on maintenance dialysis in 2009 and 2010, and compared it according to age categories, sex, and dialysis modality.

Methods: We used data from all patients on maintenance dialysis between January 1, 2009 and December 31, 2010 in Korea using the database of the Korean Health Insurance Review and Assessment Service, and the SMR was determined by calculating of the ratio between the number of actual deaths and expected deaths.

Results: A total of 45,568 patients in 2009 and 48,170 patients in 2010 were included in the analysis. The overall age- and sex-adjusted SMR was 10.3 [95% confidence interval (CI), 10.0–10.6] in 2009 and 10.9 (95% CI, 10.7–11.2) in 2010. The SMR for females was much higher than for males. The SMR gradually decreased with increasing age groups. The overall SMR for maintenance hemodialysis patients was lower than that of peritoneal dialysis patients.

Conclusion: The SMR among Korean ESRD patients is likely to be higher than in other countries. Further evaluation is needed to attempt to improve the outcomes.

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Introduction

Dialysis therapy has been considered a standard option for patients with end-stage renal disease (ESRD) unless kidney transplantation is possible. Since the process of separating solutes in vitro using semipermeable membranes was invented and the word “dialysis” was coined [1], great advances have
been made in this technology. In Korea, the first report of 14 ESRD patients was published in 1967, and it described the short-term results of dialysis treatment [2]. The prevalence of ESRD patients is increasing rapidly due to the expansion of the elderly population and an increase in the incidence of diabetes, and in 2010, 46,818 patients were known to be on maintenance hemodialysis (HD) or peritoneal dialysis (PD) [3]. In addition, there were 4,560,457,000 cases of HD, and 373,958,629,000 Korean Won were claimed for the reimbursement of HD in 2010 [4].

In order to collect nationwide data on dialysis therapy, the Korean Society of Nephrology (KSN) launched an official registry program in 1985, and in the annual report of mortality data, the overall 5-year survival rate of male patients undergoing dialysis was 65.3% and that of female patients was 68.0% [3]. The registry, however, includes only approximately two-thirds of the patients undergoing dialysis in Korea because not all the dialysis centers participated in enrollment for the registry [5]. The mortality rate for the whole ESRD population therefore needs to be determined.

When designing an epidemiological study, the issue of confounding needs to be considered as well as interaction. Age and sex have always been treated as important confounding risk factors in clinical studies. The methods of “standardization” are an effective way to deal with major confounding factors whereby a standard population is chosen. By comparing the specificity of a study population to that of a standard population, the effect of the particular distribution of the confounding variable, such as age and sex, in the study population is negated [6].

In the present study, we investigated mortality rates among all Korean ESRD patients on maintenance dialysis in 2009 and 2010. In addition, we compared mortality rates between dialysis patients and the whole general population by calculating the standardized mortality ratio (SMR) according to age categories, sex, and dialysis modality.

### Methods

#### Data source and study population

All data used in the present study were obtained from the Korean Health Insurance Review and Assessment Service (HIRA) database. In Korea, all citizens are obliged to join the National Health Security System as a mandatory social insurance program. In 2007, 96% of citizens were covered by the National Health Insurance Scheme, which is financed by contributions from those insured and government subsidies, and the remaining 4% of citizens were covered by a separate program called Medical Aid, which is a public assistance program that provides minimum livelihood assistance to low-income households [7]. Under these programs, all claims for dialysis-associated medical services submitted by health care providers are reviewed by the HIRA [7,8]. Using the HIRA database, we were able to identify every ESRD patient among the entire South Korean population and analyze the data for all ESRD patients on dialysis therapy.

For the analysis of the mortality rate among dialysis patients, we initially identified all patients on maintenance dialysis between January 1, 2009 and December 31, 2010 in Korea. Patients who were younger than 20 years or who survived fewer than 90 days from the date of dialysis initiation were excluded.

Patients who had started HD were identified by the occurrence of a new claim for the payment code of HD: O7020 or O7021; patients who had started PD were identified by the simultaneous occurrence of new claims for the payment code of PD: O7061, O7062, O7071, or O7072, and for the drug code of PD solutions specified in the National Health Insurance Claims Database. The death of a dialysis patient in 2009 and 2010, respectively, was defined as a case in which the discharge form in the claims data was classified as death or there were no records of a hospital visit over 180 days, regardless of the type of care center. The crude mortality rate was a measure of the number of deaths divided by that of a population per year. The number and mortality rate of the entire population in 2009 and 2010 were obtained from Statistics Korea [9].

### Statistical analysis

All statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC, USA). To compute indirect standardization by a typical method, we implemented two-stage processes in the following manner. First, in order to obtain the expected number of deaths in dialysis patients, we multiplied the mortality rate of the national population as a standard population by the prevalence of dialysis patients. By default, 10-year-old age-sex-specific death rates in the standard population were applied to the dialysis patients with the same unit as a study population. Second, the SMR was determined by calculating the ratio between the number of observed deaths ($e$) and expected deaths ($E$). Let $e$ be the number of events in the $i$th age group of a study population. The events are deaths in this study. Let $p_i$ be the size of the $i$th age group of the study population and the superscript $o$ denote the whole population. Here, $\rho_{i}^{(o)} = e_{i}^{(o)}/p_{i}^{(o)}$, is the event rate in the $i$th age group for the whole population. The formula of the SMR can be represented as follows [10,11]:

$$E = \sum \rho_{i}^{(o)} p_i = \sum \left( \frac{e_{i}^{(o)}}{p_{i}^{(o)}} \right) p_i$$

$$\text{SMR} = \frac{\text{Observed deaths}}{\text{Expected deaths}} = \frac{e}{E}$$

The 95% confidence interval (CI) of the SMR was calculated using the method presented by Vandenbroucke [12], and its formula is defined as follows:

$$\text{Lower CI of SMR} = \frac{\left( \sqrt{\text{Observed deaths}} - 1 \right)^2}{\text{Expected deaths}}$$

$$\text{Upper CI of SMR} = \frac{\left( \sqrt{\text{Observed deaths} + 1} + 1 \right)^2}{\text{Expected deaths}}$$

### Results

#### Baseline characteristics

In total, 45,568 patients in 2009 and 48,170 patients in 2010 who received dialysis due to ESRD were included in this study (Table 1). The mean age of prevalent patients on maintenance dialysis was 57.8 ± 13.3 years in 2009 and 58.4 ± 13.4 years in
Table 1. Standardized mortality ratios among prevalent dialysis patients in 2009 and 2010.

| Year | Sex | Age group (y) | Whole population | Dialysis patients |
|------|-----|---------------|------------------|-------------------|
|      |     |               | N                |                  |
|      |     |               | Observed deaths (%)* | Mortality rate (/100,000) |
|      |     |               |                  |                  |
|      | Male | 20–29         | 3,711,498        | 2,462 (0.1)       | 66.3            |
|      |     | 30–39         | 4,205,242        | 4,945 (0.1)       | 117.6           |
|      |     | 40–49         | 4,311,802        | 13,058 (0.3)      | 302.8           |
|      |     | 50–59         | 3,165,112        | 20,383 (0.6)      | 643.8           |
|      |     | 60–69         | 1,874,749        | 28,047 (1.5)      | 1,466.0         |
|      |     | 70–79         | 1,025,013        | 37,862 (3.7)      | 3,693.8         |
|      |     | ≥ 80          | 262,882          | 28,764 (10.9)     | 10,941.8        |
|      | Female | 20–29       | 34,352,230       | 1,589 (0.0)       | 46.3            |
|      |     | 30–39         | 4,006,927        | 2,813 (0.1)       | 70.2            |
|      |     | 40–49         | 4,159,745        | 4,912 (0.1)       | 118.1           |
|      |     | 50–59         | 3,169,833        | 6,999 (0.2)       | 220.8           |
|      |     | 60–69         | 2,094,210        | 12,086 (0.6)      | 577.1           |
|      |     | 70–79         | 1,489,171        | 28,666 (1.9)      | 1,925.0         |
|      |     | ≥ 80          | 623,820          | 50,590 (8.1)      | 8,109.7         |
|      | Total |             | 37,536,274       | 243,176 (0.6)     | 647.8           |

| Year | Sex | Age group (y) | N          | Prevalence (PMP) | Observed deaths (%)* | Expected deaths | Mortality rate (/100,000) | SMR (95% CI) |
|------|-----|---------------|------------|------------------|----------------------|---------------|--------------------------|--------------|
|      | Male | 20–29         | 633        | 170.6            | 66 (10.4)            | 0.4           | 10,426.5                  | 157.2 (120.9–200.9) |
|      |     | 30–39         | 1,939      | 461.1            | 185 (9.5)            | 2.3           | 9,541.0                   | 81.1 (69.6–94.0)    |
|      |     | 40–49         | 4,312      | 1,000.0          | 450 (10.4)           | 13.1          | 10,436.0                  | 34.5 (31.3–37.9)    |
|      |     | 50–59         | 6,675      | 2,108.3          | 656 (9.8)            | 43.0          | 9,827.7                   | 15.3 (14.1–16.5)    |
|      |     | 60–69         | 7,281      | 3,883.7          | 933 (12.8)           | 108.9         | 12,814.2                  | 8.6 (8.0–9.1)       |
|      |     | 70–79         | 4,114      | 4,013.6          | 695 (16.9)           | 152.0         | 16,893.5                  | 4.6 (4.2–4.9)       |
|      |     | ≥ 80          | 747        | 2,879.6          | 154 (20.6)           | 81.7          | 20,615.8                  | 1.9 (1.6–2.2)       |
|      | Female | 20–29       | 412        | 119.9            | 50 (12.1)            | 0.2           | 12,135.9                  | 262.4 (193.4–347.8) |
|      |     | 30–39         | 1,394      | 347.9            | 127 (9.1)            | 1.0           | 9,110.5                   | 129.8 (107.8–154.9) |
|      |     | 40–49         | 3,257      | 783.0            | 351 (10.8)           | 3.8           | 10,766.8                  | 91.3 (81.8–101.5)   |
|      |     | 50–59         | 4,937      | 1,557.5          | 535 (10.8)           | 10.9          | 10,836.5                  | 49.1 (44.9–53.3)    |
|      |     | 60–69         | 5,437      | 2,596.2          | 807 (14.8)           | 31.4          | 14,842.7                  | 25.7 (23.9–27.6)    |
|      |     | 70–79         | 3,691      | 2,478.6          | 754 (20.4)           | 71.0          | 20,428.1                  | 10.6 (9.9–11.4)     |
|      |     | ≥ 80          | 739        | 1,184.6          | 196 (26.5)           | 59.9          | 26,522.3                  | 3.3 (2.8–3.8)       |
|      | Total |             | 19,867     | 1,046.8          | 2,820 (14.2)         | 178.3         | 14,194.4                  | 15.8 (15.2–16.4)    |

* The proportion of observed death (%) is the percentage of the number of observed deaths divided by the population.
CI, confidence interval; PMP, per million population; SMR, standardized mortality ratio.
The number of males was 25,701 (56.4%) in 2009 and 27,398 (56.9%) in 2010. The patients were divided into seven age categories: 20–29 years, 30–39 years, 40–49 years, 50–59 years, 60–69 years, 70–79 years, and ≥ 80 years. In 2009 the number of patients included in each group were 1,045 (2.3%), 3,333 (7.3%), 7,569 (16.6%), 11,612 (25.5%), 12,718 (27.9%), 7,805 (17.1%), and 1,486 (3.3%), respectively. In 2010 the number of patients included in each group were 1,045 (2.2%), 3,348 (7.0%), 7,595 (15.8%), 12,226 (25.4%), 13,240 (27.5%), 8,909 (18.5%), and 1,807 (3.7%), respectively.

The prevalence of patients on dialysis therapy was 1,214.0 per million population (PMP) and 1,267.8 PMP in 2009 and 2010, respectively (Table 1). The prevalence of male patients was higher than that of female patients (1,385.0 PMP vs. 1,046.8 PMP in 2009; 1,460.0 PMP vs. 1,081.7 PMP in 2010). The prevalence among patients < 50 years of age was much lower compared with those aged ≥ 50 years. The peak prevalence in males was in patients aged 70–79 years (4,013.6 PMP and 4,377.4 PMP in 2009 and 2010, respectively), whereas the prevalence among female patients aged 70–79 years was similar to among those aged 60–69 years in both years (Fig. 1).

The total numbers of HD and PD patients in 2009 were 36,285 (79.6%) and 9,283 (20.4%), respectively; whereas those of HD and PD patients in 2010 were 38,750 (80.4%) and 9,420 (19.6%), respectively. When we calculated the crude mortality rates for 1 year, the overall prevalence in this study was 1,214.0 PMP in 2009 and 2010 died (Table 1). The mortality rate for females was higher than that for males in 2009 [2,820 (14.2%) vs. 3,139 (12.2%)], whereas the mortality rate for females in 2010 was similar to that for males [3,039 (14.6%) vs. 4,007 (14.6%)]. Among HD patients, 4,842 patients (13.3%) and 5,600 patients (14.5%) died in 2009 and 2010, respectively, whereas the number of deaths among PD patients was 1,117 (12.0%) and 1,446 (15.4%), respectively (Table 2).

The overall age- and sex-adjusted SMR for all dialysis patients was 10.3 (95% CI, 10.0–10.6) in 2009 and 10.9 (95% CI, 10.7–11.2) in 2010 (Table 1). Because the mortality rate in the overall population in Korea was lower in females than in males, the SMR for females was much higher than that of males: 15.8 (95% CI, 15.2–16.4) vs. 7.8 (95% CI, 7.5–8.1) in 2009 and 15.4 (95% CI, 14.8–16.0) vs. 9.0 (95% CI, 8.7–9.3) in 2010. In 2009, the SMR for males gradually decreased from 157.2 (95% CI, 120.9–200.9) among patients between 20 years and 29 years of age to 1.9 (95% CI, 1.6–2.2) among patients aged ≥ 80 years, and the SMR for females also decreased from 262.4 (95% CI, 193.4–347.8) among patients aged 20–29 years to 3.3 (95% CI, 2.8–3.8) among patients aged ≥ 80 years. A similar decrease in SMR with increasing age was observed in 2010.

The overall SMRs for HD patients were 9.7 (95% CI, 9.5–10.0) and 10.0 (95% CI, 9.7–10.3) in 2009 and 2010, respectively, and these were lower than that of PD patients: 13.6 (95% CI, 12.8–14.4) in 2009 and 17.2 (95% CI, 16.3–18.2) in 2010 (Table 2). Among patients aged 30–39 years and 40–49 years, however, the SMR for HD patients was higher compared with PD patients, though the SMR was comparable between HD patients and PD patients aged 50–59 years. In all other age groups, the SMR for HD patients was lower compared with that of PD patients (Fig. 2).

Discussion

In the present study, we examined the mortality rate among Korean patients on maintenance dialysis therapy in 2009 and 2010 using the HIRA database. In addition, we calculated the SMR of ESRD patients according to age categories, sex, and dialysis modality by comparing mortality rates in the whole population.

The overall prevalence in this study was 1,214.0 PMP in 2009 and 1,267.8 PMP in 2010, which is slightly higher than that for Korean ESRD patients in a previous report [5], and lower than reported in epidemiology studies from the United States (US) renal data system [13]. We originally thought that the prevalence in this study would be much higher than that of KSN registry data because the KSN registry program did not include all Korean dialysis patients. The differences in reported prevalence may stem from differences in the exclusion criteria. We excluded patients who survived for fewer than 90 days from the date of dialysis initiation according to the 90-day rule of the US renal data system, which is still widely accepted and has been used in most recent major studies [14,15]. In addition, we defined the class of dialysis modality as the treatment modality at the 90th day after commencement of dialysis without consideration of modality change afterwards, and thus the numbers of patients on HD or PD were different from the registry data.

The overall age- and sex-adjusted SMRs in this study were 10.3 and 10.9 in 2009 and 2010, respectively. These rates are higher than those of the US renal data system, which were 6.5–7.9 [13]. In addition, SMR for cardiovascular and non-cardiovascular death were reported as 8.8 and 8.1, respectively, in a European cohort of adults starting dialysis [16]. Furthermore, the SMR for all-cause mortality among Japanese dialysis
patients was 4.6 [17], which was much lower than that of our study. Life expectancy in the general population differs by country [18], so the comparison of the mortality rate among Korean dialysis patients with those of other countries could provide us with more straightforward information. The mortality rate in Japan was 94.1 per 1,000 person-years in 2008–2009, and that in the US was 284 deaths per 1,000 person-years in 2011 [13,17]. Although we could not calculate the death rate per 1,000 person-years in this study, the overall survival rate of Korean dialysis patients in the KSN registry data was lower than those observed in the US and Japan [5]. The overall SMR in this study, however, seemed to be higher than those in other countries. The possible reason(s) for the discrepancy should be explored.

In agreement with the results of a previous report [19], the SMR decreased as the age of both male and female patients increased, thus older Korean patients on maintenance dialysis had a lower risk for excess mortality. There was, however, a significant difference in the method of calculating the number of expected deaths between the previous study [19] and ours. Direct comparison of the respective values may therefore not be possible.

Although life expectancy is usually longer for females than for males in the general population, sex has not been considered to be a risk factor for death in Korean ESRD patients [5]. The SMR of females calculated in this study, however, was 2.1-fold higher than that of males, which is similar to a previous report [19]. As the survival rate of female patients was not much different from that of male patients [20], we must recognize that the outcomes for female patients on dialysis are severely compromised compared with the general population.

Next, we compared the SMR between patients on HD and PD. In this study, the overall SMR for PD patients was higher than that for HD patients, which is consistent with a previous report [19]. However, the SMR for PD patients was lower than that for HD among patients aged 30–49 years, whereas opposite results were shown in other age groups. In addition, throughout all age groups, the SMR of female patients was higher than that of male patients, regardless of dialysis modality.

This study has limitations inherent in its study design. First, we could not gather the cause of death for all individuals. Second, potential confounding factors for mortality were unavailable, such as data regarding residual renal function, critical laboratory results, biomarkers of inflammation or nutrition, and doses of dialysis. Third, we were not able to get the exact date of death because the clinics only reported the death date of all patients to the HIRA once a month. Finally, the patients were followed for only 2 years, which was the time period from the claim data to the HIRA.

In spite of these limitations, our study has provided several clinically-relevant points. We were able to gather all data of patients on dialysis [21] and provide us with more straightforward information. The life expectancy in the general population differs by country [18], so the comparison of the mortality rate among Korean dialysis patients with those of other countries could provide us with more straightforward information. The mortality rate in Japan was 94.1 per 1,000 person-years in 2008–2009, and that in the US was 284 deaths per 1,000 person-years in 2011 [13,17]. Although we could not calculate the death rate per 1,000 person-years in this study, the overall survival rate of Korean dialysis patients in the KSN registry data was lower than those observed in the US and Japan [5]. The overall SMR in this study, however, seemed to be higher than those in other countries. The possible reason(s) for the discrepancy should be explored.

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In spite of these limitations, our study has provided several clinically-relevant points. We were able to gather all data of...
prevalent Korean patients on dialysis, therefore the results of this study regarding prevalence, overall SMR, and SMR according to age, sex, and dialysis modality could be used for baseline epidemiologic data for future studies.

Taken together, the present findings suggest that the SMR among Korean ESRD patients is likely to be higher than in other countries. Further studies therefore are needed to evaluate the reasons for these differences and to improve the outcomes.

Conflicts of interest

None.

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