

Evaluating Observed vs. Expected Mortality Rates in US Dialysis Patients Amid Secular Declines

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Introduction

- The revision to the label for erythropoiesis stimulating agents (ESA) in 2011 was aimed at reducing high Hb levels with the added benefit of reducing the potential risks of mortality and cardiovascular events.
- ESA use, dose and Hb levels have fallen substantially in US dialysis patients since the 2011 ESA label and reimbursement policy changes. Effects on mortality and CV events in dialysis patients, however, have not been carefully evaluated.
- To perform this evaluation, one must take into account the secular change in these outcomes and to facilitate such an analysis, the expected rate of these major events must be predicted and compared against observed rates.
- We modeled secular trends of mortality 2005-2009 in US dialysis patients and calculated the expected mortality rate of 2010, then compared the 2010 observed with expected.

Methods

- End-stage renal disease (ESRD) data from the Centers for Medicare and Medicaid services were used and included information from the ESRD Medical Evidence Form, the ESRD Death Notification Form, and Medicare Parts A and B claims, as well as data on transplantation and Medicare coverage.
- We created annual cohorts of prevalent and incident patients receiving peritoneal dialysis or in-center hemodialysis between January 1, 2005, and December 31, 2010, aged at least 18 years, with 9 months on dialysis and 6 months with Medicare as primary payer (MPP) for both Parts A and B.
- Patients were followed from January 1 or day 1 of the first calendar month after criteria were met, each year, to the earliest date of death, loss of MPP, modality change, kidney transplant, or years end.
- Mortality rates were calculated as the number of deaths divided by total follow-up time, expressed per 100 patient-years.
- Time trends of death were modeled using Poisson regression with log link for 2005-2009 and adjusted for patient characteristics.
- Two different functions were used for trends: (1) A quadratic polynomial of year and (2) a piecewise linear function of year with 2008 as the node for log rate ratios (RRs). A piecewise linear function for log RR corresponds to a piecewise exponential function for rate.
- Adjustment variables included patient age, race, sex, ESRD cause, modality, body mass index (BMI), renal network, and 21 comorbid conditions.
- The linear trend from 2008-2009, which is part of the piecewise function 2005-2009, and the quadratic function were extrapolated to 2010. Based on patient characteristics, fitted trends, and the extrapolation, the expected mortality rates from 2005-2010 were calculated and the expected rate of 2010 was compared to the observed.
- Bootstrapping was used to calculate 95% confidence intervals and to compare the expected rate to the observed rate.

Results

- In total, 1,014,970 patients were included; most patients contributed data to multiple years. The number of patients increased over years (from 252,276 in 2005 to 278,713 in 2010; Table 1).
- The mean age of patients was nearly constant, but the percentage of men, black and other race, diabetes as primary ESRD cause, and mean BMI rose over time (Table 1).
- The overall (2005-2010) mortality rate was 21.3 per 100 patient-years. It fell from 22.9 per 100 patient-years in 2005 to 18.9 in 2010 (Figure 1).
- The fitted log RRs 2005-2009 were very close to the observed for both the quadratic and piecewise linear trend (Figure 2). The expected log RRs for 2010 from the two trend functions were nearly identical to each other and to the observed RR.
- The corresponding expected rate curves 2005-2009 and the expected rates for 2010 are shown in Figure 1; they are very close to the observed rates. The expected 2010 death rate was 19.8 per 100 patient-years from both models and the observed rate was 19.9.

Table 1. Numbers of patients and patient characteristics over the years.

	2005	2006	2007	2008	2009	2010
Number of patients	252,276	254,570	259,316	264,006	269,873	278,713
Mean age (years)	62.2	62.2	62.2	62.2	62.2	62.2
Sex (% male)	54.1	54.4	54.6	54.9	55.1	55.2
Race						
White	43.5	42.8	42.5	42.1	41.7	41.2
Black	37.9	38.3	38.3	38.3	38.2	38.4
Other	18.6	18.8	19.1	19.6	20.0	20.3
ESRD cause						
Diabetes	42.9	43.2	43.5	43.7	43.9	44.1
Hypertension	29.2	29.2	29.0	29.0	29.0	29.1
GN	11.7	11.3	10.9	10.6	10.4	10.1
Other	16.2	16.3	16.5	16.7	16.7	16.7
Mean BMI (kg/m ²)	28.0	28.3	28.6	28.8	29.1	29.3

Figure 1. Mortality rates: observed and expected with log piecewise linear and log quadratic trend over time.

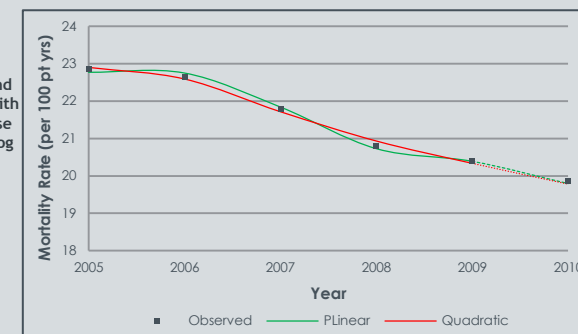
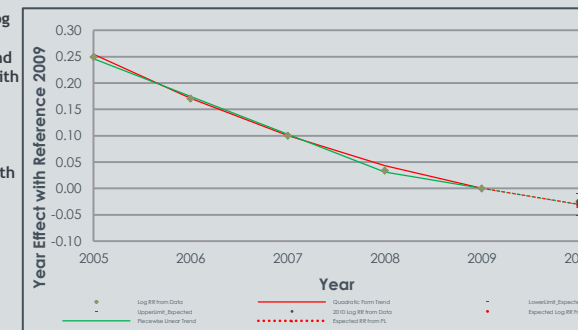


Figure 2. Log rate ratios: observed and expected with piecewise linear and quadratic trend over time and with 2009 as the reference.



Discussion

- Using the 2005-2009 data, we were able to accurately predict the 2010 mortality rate in dialysis patients by taking into account the temporal trend.
- Our study sets the groundwork for future work where we will examine the deviance of observed 2011/2012 mortality and other rates, from expected rates based on complete 2005-2010 data
- Limitations:
 - Only the quadratic and piece-wise linear functions were evaluated in this analysis. Other functional forms may need to be explored.
 - The observed/expected comparison was done for only one year (2010); additional years comparing observed with expected may be important.



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