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cardiovascular special studies

Out-worn heart, in a time out-worn,
Come clear of the nets of wrong and right;
Laugh heart again in the gray twilight,
Sigh, heart, again in the dew of the morn.
William Butler Yeats, “Into the Twilight”
The greatest increase in treated end-stage renal disease is occurring in patients with the highest risk of cardiovascular disease, older patients, and those with diabetic nephropathy. These trends, and the attendant cardiovascular disease burden, are not, however, restricted to the small population of patients with ESRD, as a similar phenomenon is occurring in the general U.S. population. The greatest understanding of cardiovascular disease in ESRD patients will therefore come from a description of cardiovascular epidemiology in the ESRD population and also, more importantly, in the general population, which includes the much larger group of patients with varying degrees of chronic kidney disease.

The central mission of the USRDS Cardiovascular Special Studies Center is to provide new insights on cardiovascular disease in ESRD patients, with the goal of improving their health and welfare. In this ADR we present data highlighting the impact of diabetes on cardiovascular morbidity and mortality in ESRD patients. For this retrospective study of Medicare-eligible incident dialysis patients in 1995–1999 we analyzed cardiovascular event rates and survival in patients who survive one year after initiating dialysis. Followup time begins one year after initiation, and our end points are acute myocardial infarction, congestive heart failure, cardiac arrest, peripheral vascular disease, cardiac death, cerebrovascular accident and transient ischemic attack, coronary revascularization, and all-cause mortality.

We compare four distinct groups of patients. Group 1 contains patients whose primary cause of ESRD (listed on the Medical Evidence form) is diabetes. Group 2 patients have other primary causes of renal failure (besides diabetes), and diabetes is identified on the Medical Evidence form as a comorbid condition at initiation. Group 3 patients do not have diabetes at initiation, but a new diagnosis of diabetes is identified in the claims data during the year following initiation. And patients in Group 4 do not have diabetes as a primary diagnosis or a comorbidity at initiation, and have no claims related to diabetes in the first year after dialysis initiation.

This grouping follows a logical clinical order. The highest cardiovascular event rates are consistently seen in Group 1 patients and the lowest rates in Group 4 patients, while patients in Groups 2 and 3 have event rates of intermediate levels.

Figure 10.3 displays adjusted overall composite event rates for all-cause death, cardiac death, and any cardiovascular event (AMI, CHF, cardiac arrest, PVD, CVA/TIA, and myocardial infarction).
There are several noteworthy points in this figure. There is, for example, a gradient of cardiovascular risk related to diabetes. Diabetic ESRD patients have the highest risk, and non-diabetic patients the lowest. The adjusted composite all-cause death rate for Group 1 patients declined from 281 deaths per 1,000 patient years in 1995 to 252 in 1998. Cardiac mortality in dialysis patients mirrors all-cause mortality, with a decline from 136 to 112 over the same period. A decline in cardiovascular events has also occurred for incident diabetic ESRD patients, with an event rate of approximately 1,300 cardiovascular events per 1,000 patient years in 1995 versus 925 in 1998. Caution should be exercised in interpreting event rates for 1999 incident patients, as followup time is shorter and the mortality estimate error larger for the most recent patients.

The following spread illustrates demographic characteristics of the patient groups, distribution of comorbid conditions, and geographic variations in cardiovascular comorbidity in diabetic ESRD (Group 1) patients. We then present detailed information on cardiovascular event rates and event-free survival, followed by data on survival after cardiovascular events. One special long-term interest of the Cardiovascular Special Studies Center has been the dismal long-term survival of dialysis patients suffering acute myocardial infarction. It is noteworthy that Group 4 patients—those without diabetes—consistently have the best outcome for each cardiovascular event. A geographic snapshot accompanies this series of figures, illustrating regional variations in mortality rates after acute myocardial infarction and cardiac arrest.

On the last spread we look beyond the impact of diabetes on cardiovascular morbidity and mortality, presenting cardiovascular event rates in patients receiving renal replacement therapy with hemodialysis, peritoneal dialysis, or kidney transplants. We also present disease maps showing geographic variations in the rate of cardiovascular events for both the dialysis and general Medicare populations. These data are intended to provide a broad picture of the burden of cardiovascular disease in the U.S. We believe that enlarging the scope of our inquiry to include the far larger population of general Medicare patients will further our understanding of the development of cardiovascular morbidity and mortality in ESRD patients.

Cardiovascular disease continues to be the major cause of morbidity and mortality in patients with end-stage renal disease. Future research should focus on the developing burden of cardiovascular comorbidity in patients with chronic kidney disease who have not yet progressed to ESRD. Such research will further the health and welfare of all patients.
Figures 10.4–6 summarize the demographics of our study populations by age, gender, and race. In the entire study cohort, 17 percent of patients are younger than 45, 37 percent are 45–64, 26 percent are 65–74, and 20 percent are 75 or older. The highest proportion of elderly patients occurs in Group 3 (claims diabetes), in which two-thirds of the patients are 65 or older. Fifty-three percent of patients are male, and 59 percent are white, while 33 percent are black, two percent are Native American, and four percent are Asian. The racial distribution across the patient groups is nearly identical.

There is a striking difference in the prevalence of cardiovascular comorbidity in Groups 1, 2, and 3 compared to Group 4 (Figure 10.7). Patients with primary diabetes, diabetes identified on the Medical Evidence form, or diabetes appearing in claims after initiation are more alike in terms of cardiovascular disease burden than they are similar to non-diabetic patients. The prevalence of ASHD as a comorbid condition, for example, is 48–52 percent in the first three groups, and only 27 percent in Group 4. CHF appears in 54–57 percent of patients in Groups 1–3, but 32 percent of non-diabetic patients. Other types of cardiac disease appear in 33–51 percent of Group 1–3 patients and 27 percent of those in Group 4.

Cerebrovascular accidents or transient ischemic attacks are reported in 19–25 percent of Group 1–3 patients, versus 12 percent in Group 4. Peripheral vascular disease occurs in 53 percent of Group 1 patients, 54 percent of Group 2 patients, and 68 percent of Group 3 patients, but only 35 percent of the patients in Group 4.

In terms of non-cardiovascular comorbidity, 17 percent of the entire study cohort had COPD at dialysis initiation, ranging from a low of 15 percent in the non-diabetic patients to a high of 29 percent in Group 3 patients. Eleven percent of the cohort was reported to have cancer, ranging from a high of 18 percent in Group 3 patients to a low of eight percent in Group 1 patients. Gastrointestinal comorbidity was present in 11 percent of incident patients from the entire cohort, ranging from a low of eight percent in Group 4 to a high of 19 percent in Group 3.

Figure 10.8 illustrates the geographic variation in the cardiovascular comorbidity of Group 1 patients at the initiation of dialysis. There appear to be relatively fewer patients with ASHD, CHF, PVD, and CVA/TIA in the western portion of the U.S., while there is a greater proportion of patients with ASHD in the Midwest, Appalachia, and the Northeast.
These figures represent reported comorbidity at the time of dialysis initiation. The geographic variation in comorbid conditions could be different in patients with chronic kidney disease who have not progressed to ESRD, as many patients with significant cardiovascular disease may not survive long enough to require renal replacement therapy.

Figures 10.4–7 incident dialysis patients, 1995–1999 combined, who survive at least one year. Figure 10.8 rate per 1,000 patient years at risk, Group 1 incident dialysis patients with diabetic ESRD who survive at least one year, 1995–1999 combined, by HSA, unadjusted.

**Patient groups**
- Group 1: Diabetes as primary cause of ESRD.
- Group 2: Diabetes on Medical Evidence form, but not primary diagnosis.
- Group 3: Diabetes on claims during study period.
- Group 4: No diabetes
Data on this spread highlight cardiovascular events, cardiac mortality, and all-cause mortality. Two overall trends are noteworthy. There is, first of all, a progressive gradient of cardiovascular risk demonstrated in the four groups of patients. Group 1 patients—those with diabetic ESRD—consistently display the highest event rates for all cardiovascular events, and the worst outcomes. The lowest event rates and best outcomes, in contrast, occur in dialysis patients without diabetes. Patients in Groups 2 and 3 have intermediate risks.

Also of note is the increase in event rates in the second, third, and fourth followup years, particularly for diabetic ESRD patients. As illustrated in the Précis (Figure p.31), mortality rates are related to a vintage effect, with rates increasing for patients who are on dialysis more than three years. The rise in cardiovascular event rates in the second through fourth followup years might be reflected in this increased mortality.

Patients with diabetic ESRD in the first year have an AMI event rate of 75 per thousand patient years, rising to 129 at year four (Figure 10.9). The patterns seen with CHF and PVD differ from those seen with other cardiovascular events, in that rates for all four groups are highest in the first year and decline significantly in the following year (Figures 10.10 and 10.13). Dialysis patients are at high risk for congestive heart failure, which occurs in half of all patients in the first two years.

Cardiac arrest is a devastating clinical event in dialysis patients. Nearly 60 percent of patient deaths reported in the USRDS database are attributed to either unexpected sudden death or dysrhythmia. The estimated cardiac arrest rate in the first year is 93 events per thousand patient years, and this rises to 164 in the fourth year (Figure 10.11). Diabetic ESRD patients comprise a particularly high-risk group for this event, with event rates ranging from 110 in the first year to 208 in the fourth. Even patients with the lowest risk, those without diabetes, have a first-year event rate of 70 and a fourth-year rate of 131. These rates suggest that the hazard of cardiac arrest is not uniform over time, but rather increases with the amount of time patients have spent on dialysis.

The impact of cardiovascular events which are relatively common and characterized by high lethality should stimulate the use of clinical strategies designed either to prevent these events from occurring or to reduce the associated likelihood of death when they cannot be prevented. Acute myocardial infarction and cardiac arrest would qualify as logical clinical targets in

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**Event rates & adjusted event-free survival: acute myocardial infarction**

**Event rates & adjusted event-free survival: congestive heart failure**

**Event rates & adjusted event-free survival: cardiac arrest**

**Event rates & adjusted event-free survival: cardiac death**

**Event rates & adjusted event-free survival: peripheral vascular disease**

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Chapter Ten

Cardiovascular event rates

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10.14 · Event rates & adjusted event-free survival: cerebrovascular accident/transient ischemic attack

The rate of cerebrovascular accident and transient ischemic attack has increased slightly over time (Figure 10.14). For the entire cohort the first-year rate is 118 events per thousand patient years versus 137 in the fourth year.

10.15 · Event rates & adjusted event-free survival: coronary revascularization

Given the event rates for AMI and cardiac death, coronary revascularization event rates (percutaneous and surgical; Figure 10.15) seem relatively low. The impact of increased coronary revascularization rates is speculative, but it is noteworthy that even patients in the highest cardiovascular risk group, those with diabetic ESRD, have a coronary revascularization rate of only 32 events per thousand patient years in the first year, rising to 43 in year four.

10.16 · Event rates & adjusted event-free survival: all cardiac events

Figures 10.16–18 reinforce the point that the dialysis population is at extraordinarilly high risk for cardiovascular disease and death. In particular, dialysis patients with diabetes have a heightened risk of cardiovascular morbidity and mortality, and this hazard increases over time.

10.17 · Event rates & adjusted event-free survival: all-cause death

For definitions of the study groups see page 169.
In this section we analyze several cardiovascular events from a different perspective—that of survival after the event. Figure 10.19 illustrates the dismal survival of dialysis patients following acute myocardial infarction. In this 1995–1999 incident population, the two-year mortality after AMI is 73 percent, identical to that reported by Herzog et al for dialysis patients sustaining an AMI in 1977–94. The persistently abysmal outcomes of these patients remains a subject of great concern to the Cardiovascular Special Studies Center. For this reason, the first special study conducted by the SSC, and currently underway, relates to the clinical characteristics of U.S. dialysis patients who sustain an acute myocardial infarction.

For reasons that are probably complex, the risk of death in dialysis patients after acute myocardial infarction is not uniformly distributed across the country (Figure 10.20). Future research (including our AMI special study) on differences in clinical characteristics and treatment patterns should provide insight into these regional variations.

Peripheral vascular disease and cerebrovascular disease in dialysis patients are also associated with poor survival (Figures 10.21–22). Two-year mortality after PVD is 57 percent for the entire cohort, and 61 percent for patients with diabetic ESRD; after cerebrovascular accident or transient ischemic attack, mortality is 64 and 68 percent, respectively. Outcomes after cerebrovascular ischemia are, therefore, nearly as poor as those following acute myocardial infarction.

Among the four patient groups there are small differences in survival after cardiac arrest, ranging from a one-year mortality of 83 percent in the non-diabetic Group 4 patients to 87 percent in those with diabetic ESRD (Group 1; Figure 10.23). None of these groups, however, have favorable outcomes. One logical inference is that clinical measures designed to either prevent or reduce the lethality of cardiac arrest could significantly improve the long-term survival of dialysis patients.

Mortality rates after cardiac arrest by region vary across the country (Figure 10.24). For all patients the two-year mortality rate after congestive heart failure is 54 percent, and 57 percent for Group 1 patients (Figure 10.25). The best survival occurs in non-diabetic patients, who have a 50 percent mortality rate at two years. Although the poor outcomes after acute myocardial infarction are considerably worse than those after CHF, the CHF patients have a very high cardiovascular risk.

Two-year mortality after coronary revascularization (surgical or percutaneous) is 51 percent for patients with non-diabetic ESRD (Group 4; Figure 10.26). Among the four groups there are small differences in survival after cardiac arrest, ranging from a one-year mortality of 83 percent in the non-diabetic Group 4 patients to 87 percent in those with diabetic ESRD (Group 1; Figure 10.23). None of these groups, however, have favorable outcomes. One logical inference is that clinical measures designed to either prevent or reduce the lethality of cardiac arrest could significantly improve the long-term survival of dialysis patients.

For all patients the two-year mortality rate after congestive heart failure is 54 percent, and 57 percent for Group 1 patients (Figure 10.25). The best survival occurs in non-diabetic patients, who have a 50 percent mortality rate at two years. Although the poor outcomes after acute myocardial infarction are considerably worse than those after CHF, the CHF patients have a very high cardiovascular risk.

Two-year mortality after coronary revascularization (surgical or percutaneous) is 51 percent for patients with non-diabetic ESRD (Group 4; Figure 10.26).
percent for the entire patient cohort; rates are highest (53 percent) in patients with diabetic ESRD, and lowest (47 percent) in non-diabetic patients (Figure 10.26). From the perspective of the general population without ESRD this survival is poor, but it is considerably better than that occurring after acute myocardial infarction or cardiac arrest. One key clinical cardiovascular issue in the dialysis population is whether the identification of ischemic heart disease and subsequent coronary revascularization can reduce the likelihood of acute myocardial infarction, cardiac arrest, and cardiac death.

Data presented here provide confirmation of the high mortality associated with cardiovascular disease in dialysis patients. The worst outcomes occur after acute myocardial infarction and cardiac arrest, and both of these events are potential targets for the prevention and reduction of lethality after the event. Cardiac arrest should be a special target for intervention.

Successful reduction in the occurrence of fatal cardiac arrest might be achieved through a variety of clinical strategies, including alterations in dialytic therapy (to normalize volume status and reduce the degree of electrolyte shift); more effective treatment of hypertension, ischemic heart disease, and congestive heart failure; and the potential use of percutaneous cardioverter defibrillators.


Figures 10.20 & 10.24 deaths per 1,000 patient years, Group 1 (diabetic nephropathy) patients, by HSA, unadjusted.

For definitions of the study groups see page 169.
In these snapshots of cardiovascular disease we change both the subject and the camera. Our dialysis cohort in this section is a population of prevalent 1997 dialysis patients, and we look as well at patients age 65 and older in the general Medicare population. We also provide a broad picture of cardiovascular event rates over time in transplant patients. There are striking differences in the rate of all cardiovascular events by modality.

On this spread we have juxtaposed event rates related to ESRD treatment modalities, geography, and cardiovascular disease. (Overall rates for each map on this spread are listed in the chapter summary on page 176.) The more benign outcomes of transplant patients versus those on dialysis is obvious. In 1997 the first-year AMI rate was 10.4 events per thousand patient years for transplant patients (Figure 10.34), and 66 for patients on dialysis (Figure 10.27). In the general Medicare population, the AMI event rate in 1997 was 14.5 events per thousand patient years, higher than for patients with renal transplants.

For the cardiovascular events analyzed here, it is noteworthy that rates in the general Medicare population are similar to and in some cases higher than those in renal transplant patients. The exception is peripheral vascular disease, with a rate of 84 events per thousand patient years in the 1997 transplant patient cohort versus 43 in the general Medicare population (Figure 10.31). The cardiac arrest event rate for 1997 prevalent dialysis patients is 113 events per thousand patient years, but only 11 for transplant patients and eight in the general Medicare population (Figures 10.29 and 10.24).

The focus of this comparison is not the event rates themselves, but the general magnitude of risk, as it allows a broad categorization of cardiovascular risk in large patient groups. Renal transplant patients have been viewed as a population at high risk for cardiovascular disease. We would argue that the general Medicare population—a much larger group of patients—should also be viewed as having high cardiovascular risk, comparable to that of patients with renal transplants. These two patient groups also have better outcomes than those seen in dialysis patients. It is likely that the general Medicare population could be further divided to identify subsets of patients with higher risks. Given the large number of patients with chronic kidney disease who are not receiving renal replacement therapy, a logical target of future inquiry is the cardiovascular morbidity and mortality in general Medicare patients with chronic kidney disease, and the outcomes of these patients over time.
10.31 - Geographic variations in event rates: peripheral vascular disease

Figure 10.27 shows geographic variations in the rates of AMI for dialysis and general Medicare populations. The relative distribution of AMI is similar for the midwestern and northeastern portions of the U.S., but not for the western states. For congestive heart failure, the event rate in the general Medicare population is lower in the west, a pattern roughly echoed in the dialysis population (Figure 10.28). Although some of these areas are similar in the dialysis population, dialysis patients in parts of the western U.S. have higher rates of cardiac arrest. For both peripheral vascular disease and cerebrovascular disease (CVA/TIA; Figures 10.31–32), lower event rates occur in the western states for both populations. The absolute magnitude of risk for PVD and CVA is much greater, however, in the dialysis population, particularly for PVD.

Although rates of coronary revascularization are higher in the Midwest for both dialysis and general Medicare populations, there are also significant regional differences (Figure 10.33). The overall coronary revascularization rate is about 26 procedures per thousand patient years for dialysis patients, and 12 for the general Medicare population. Given the much larger difference in other cardiovascular event rates, particularly AMI, this suggests a relative underutilization of coronary revascularization procedures in dialysis patients compared to the general Medicare population.

10.32 - Geographic variations in event rates: cerebrovascular accident/transient ischemic attack

10.33 - Geographic variations in event rates: coronary revascularization

10.34 - Trends in first-year event rates after transplant

Figures 10.27–29 & 10.31–33 per 1,000 patient years; dialysis: prevalent dialysis patients, 1997; general Medicare: prevalent general Medicare patients age 65 or older on January 1, 1997 or on the first day of the month of Medicare enrollment in 1997; by HSA, unadjusted.

Figure 10.30 prevalent ESRD patients, 1997, & prevalent general Medicare patients age 65 or older on January 1, 1997 or on the first day of the month of Medicare enrollment in 1997, unadjusted. Figure 10.34 adjusted for age, gender, race, & diabetic status.
Chapter Ten

Maps: National means & patient populations

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Patient populations & analytical methods

- Event rates and adjusted event-free survival are depicted in Figures 10.9–18, and characterized from incident dialysis patients, 1995–1999 combined, who survive at least one year. Rates are adjusted for age, gender, race, and major comorbidities. The reference population is the overall patient distribution for each event.
- Figures 10.19–26 illustrate survival following each event. Percent survival is characterized for incident dialysis patients, 1995–1999 combined, with adjustments for age, gender, race, and major comorbidities. The follow-up period begins at the occurrence of the event, and age and comorbidities are recalculated at time zero.
- For Figures 10.27–33, the study cohort for the general Medicare population is derived from the general Medicare files for 1997–1999. Included are patients enrolled in Medicare, both Part A and Part B, as of January 1, 1997 or at any time during 1997, who are age 65 years or older as of January 1, 1997 or at the time of Medicare enrollment in 1997, and who do not carry a diagnosis of ESRD prior to followup.

Conclusions

- Diabetes is associated with a “gradient of cardiovascular risk” in dialysis patients. The highest rates of cardiovascular morbidity and mortality and of all-cause mortality occur in patients with diabetic ESRD, while the lowest rates are present in non-diabetics. Dialysis patients identified as diabetic on the Medical Evidence form (but whose diabetes is not the primary cause of ESRD) or whose diabetes is identified on claims constitute groups with intermediate risk.
- Comorbid cardiovascular conditions are common in patients beginning dialysis therapy.
- Rates of reported comorbid cardiovascular conditions in incident dialysis patients with diabetic ESRD vary across the country. The lowest burden of cardiovascular comorbidity occurs in the western half of the United States.
- Time on dialysis, or “vintage,” appears to have an effect on the cardiovascular events of acute myocardial infarction and cardiac arrest. In the study cohort of incident dialysis patients surviving at least one year, the rate of these events progressively increases over time after dialysis initiation. This observation may in part explain the phenomenon of increasing mortality noted in dialysis patients with longer times on dialysis (see Figure p.31 in the Précis).
- Event rates for congestive heart failure and peripheral vascular disease vary over time after dialysis initiation.
- The cardiovascular events with the highest degree of lethality are cardiac arrest and acute myocardial infarction. Increasing rates (related to dialysis vintage) for these events would be expected to lead to increased cardiac and all-cause mortality.
- The greatest immediate impact on cardiovascular mortality would be obtained by targeting cardiac arrest and acute myocardial infarction for clinical intervention, particularly through efforts to prevent these events associated with high mortality, and to improve the likelihood of survival after their occurrence.
- There are significant geographic variations in the survival of dialysis patients after cardiovascular events. In the western U.S., for example, the mortality rate after acute myocardial infarction is higher than in New England. The potential impact of regional variations in clinical practice is an appropriate area for future research.
- Cardiovascular event rates for dialysis patients and the general Medicare population (age 65 and older) vary by geographic region.
- Cardiovascular event rates are markedly higher in dialysis patients compared to renal transplant recipients.
- Renal transplant recipients are acknowledged to be at “high-risk” for cardiovascular disease, though their outcomes are considerably better than those of dialysis patients.
- Patients in the general Medicare population (age 65 and older) have the same magnitude of cardiovascular disease risk as renal transplant recipients.
- The focus of future research on cardiovascular disease in patients with chronic kidney disease should be enlarged to include the much larger population of patients who do not have ESRD.
- Given the enormous societal burden of cardiovascular disease in the elderly, the general Medicare population (age 65 and older) should be a high priority target for research on cardiovascular disease prevention and treatment.