Age may explain the association of an early dialysis initiation with poor survival

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Summary

Background: Some studies postulate that early dialysis initiation may increase mortality.

Aim: The aim of the present study was to assess to what extent this was due to confounding by age.

Design: Observational retrospective cohort study.

Methods: We studied all patients starting dialysis therapy between 1 January 1995 and 31 December 2009 in our center. The following variables at dialysis initiation in end-stage renal disease (ESRD) patients were analysed: estimated glomerular filtration rate (eGFR), age, gender, diabetes mellitus, serum albumin, hemoglobin, period of dialysis initiation, history of ischemic heart disease and stroke. Multivariate Cox model was used to calculate adjusted patient survival.

Results: Over the last 15 years, 428 patients initiated dialysis therapy in our reference area. Median eGFR at dialysis initiation was 8.16 ml/min. In the univariate analysis, increased eGFR, age, dialysis initiation 1995–1999/2000–2004, diabetes and history of ischemic heart disease were associated (P<0.05) with increased mortality in ESRD. Patients that started dialysis program with eGFR > 8.16 were older than those who did it with eGFR < 8.16 (66 vs. 61 years, P<0.001). The association between mortality and eGFR in the crude multivariate Cox model was lost when the model was adjusted by age. In the multivariate Cox model, dialysis initiation period, serum albumin and history of ischemic heart disease were associated with mortality.

Conclusion: History of ischemic heart disease, serum albumin and dialysis start before 2005 were risk factors for mortality in ESRD patients. Older age is usually associated with early dialysis initiation, so age adjustment is needed to perform studies aimed to calculate the effect of eGFR at dialysis initiation on survival.

Introduction

There is considerable variation in the timing of the initiation of maintenance dialysis for patients with stage 5 chronic kidney disease (CKD), with a general trend toward early initiation until 2 years ago. Several publications that included guidelines for dialysis initiation promoted that early initiation of dialysis was necessary to prevent and reverse deterioration of nutritional status associated with declining renal function. In addition, those reports claimed that diabetics required earlier dialysis initiation than non-diabetics, and that waiting until estimated glomerular filtration rate (eGFR) below 6 ml/min/1.73 m² to initiate dialysis was dangerous. In contrast, some studies showed that early initiation of dialysis in CKD patients was not
associated with an improvement in survival or clinical outcomes.4–9 The randomized clinical trial of the Initiating Dialysis Early and Late (IDEAL) demonstrated that early initiation of dialysis in patients with CKD Stage 5 was not associated with an improvement in survival or clinical outcomes. The results showed that with careful clinical management, dialysis may be delayed until either the eGFR drops below 7 ml/min or more traditional clinical indicators for the initiation of dialysis are present.5

Using data from the Catalan Renal Registry, we examined trends in the timing of dialysis initiation between 1995 and 2009, survival associated with age and eGFR at dialysis initiation in our center. We studied parameters that might be associated with increased risk for mortality such as history of diabetes, prior diagnosis of ischemic heart disease and first vascular access. The main objective of the study was to assess to what extent the influence of high or low eGFR at dialysis initiation on patient survival is confounding by advanced age.

Methods

Patients and data source

We obtained data from the Catalan Renal Registry, a mandatory population-based registry collecting information of all patients with end-stage renal disease (ESRD) requiring renal replacement therapy. All dialysis service providers of Catalonia collect the data by completing survey forms for each patient at the initiation of dialysis and yearly thereafter. We analysed data for all patients who initiated hemodialysis between 1 January 1995 and 31 December 2009 in our Nephrology department. Patients with renal replacement therapy in the past, peritoneal dialysis or active malignancy were excluded from the study. The reference area of our Hospital covers 353,248 inhabitants. Patient characteristics are shown in Table 1.

Definitions

We used the modification of diet in renal disease equation (MDRD) \( (186 \times SCr^{-1.154} \times \text{age}^{-0.203} \times 0.742 \) [if female] \( \times 1.21 \) [if black]) to determine eGFR.10 For this calculation, we used the last recorded serum creatinine measurement before initiation of dialysis.

Vascular access for initial dialysis was by arteriovenous fistula, arteriovenous graft or central venous catheter. We documented the presence or absence of diabetes mellitus, coronary artery disease (angina, myocardial infarction or coronary artery bypass surgery), peripheral vascular disease and cerebrovascular disease. We also recorded the following variables at dialysis start: age, eGFR, gender, serum albumin, hemoglobin and period of dialysis initiation (1995–1999, 2000–2004 and 2005–2009). Dialysis was started under three different conditions: natural evolution of CKD (planned dialysis), acute exacerbation in known CKD patients (exacerbation) or acute kidney disease (unplanned).

Statistical analyses

Statistical analyses were performed using SPSS for Windows software version 18.0. In the univariate analysis, comparisons between groups were performed by chi-square test for categorical data, and t-Student for continuous data (\( P<0.05 \) was considered significant). Cumulative survival was calculated using the Kaplan–Meier method. In the multivariate analysis, hazard ratios were calculated by Cox’s proportional hazards model. Initially, we studied the crude (unadjusted) effect of eGFR at start on mortality as hazard ratio, and then the same effect adjusted for age. Hazard ratios were also adjusted for eGFR, age, gender, diabetes mellitus, serum albumin, hemoglobin, period of dialysis start (1995–1999, 2000–2004 and 2005–2009), history of ischemic heart disease and stroke at the point of inclusion. Finally, we also adjusted the model for receiving a kidney transplantation (KT).

Results

Characteristics of the patients

We included 428 patients who initiated dialysis between 1995 and 2009 in our Nephrology Department. Baseline characteristics of the study population by period are presented in Table 1. Globally, mean age was 64 ± 14 years and included 65% males. The median eGFR at dialysis initiation was 8.16 ml/min/1.73m² (range 1.44–29.94). The distribution of eGFR at dialysis initiation is showed in Figure 1. We considered early initiation when eGFR was greater than 8.16 ml/min. In addition, 34.6% of the patients had diabetes mellitus, 19.2% had history of ischemic heart disease, 39.6% had history of congestive heart failure and 17.8% had a history of cerebrovascular disease. Dialysis initiation with a central venous catheter was more frequent in the last period (2005–2009) compared with the first and second periods. In addition, diabetes mellitus as a cause of renal failure was more frequent in the second and third periods when
compared with the first period. Finally, eGFR at initiation was higher in the third period when compared with the previous periods. Although patients had increased comorbidities, mortality was decreased in the second and third periods when compared with the first period.

Table 1  Patient characteristics at initiation of dialysis therapy and survival

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<tr>
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<tbody>
<tr>
<td>Number of patients</td>
<td>141</td>
<td>115</td>
<td>172</td>
<td></td>
</tr>
<tr>
<td>Mean age (years, mean ± SD)</td>
<td>65.0 ± 12.7</td>
<td>64.6 ± 13.5</td>
<td>62.7 ± 14.6</td>
<td>0.285</td>
</tr>
<tr>
<td>Male gender [n (%)]</td>
<td>87 (61.7%)</td>
<td>81 (69.8%)</td>
<td>110 (64.3%)</td>
<td>0.418</td>
</tr>
<tr>
<td>eGFR (ml/min)</td>
<td>8.15 ± 3.44</td>
<td>8.43 ± 3.64</td>
<td>9.59 ± 4.02</td>
<td>0.002</td>
</tr>
<tr>
<td>Initial dialysis condition</td>
<td>Unplanned</td>
<td>16 (11.8%)</td>
<td>11 (9.5%)</td>
<td>15 (8.9%)</td>
</tr>
<tr>
<td>  Exacerbation</td>
<td>59 (43.4%)</td>
<td>41 (35.3%)</td>
<td>67 (39.9%)</td>
<td></td>
</tr>
<tr>
<td>  Planned</td>
<td>61 (44.9%)</td>
<td>64 (55.2%)</td>
<td>86 (51.2%)</td>
<td></td>
</tr>
<tr>
<td>First vascular access</td>
<td>Temporal catheter</td>
<td>37 (26.2%)</td>
<td>37 (32.1%)</td>
<td>80 (46.5%)</td>
</tr>
<tr>
<td>  Tunneled catheter</td>
<td>0 (0%)</td>
<td>1 (0.9%)</td>
<td>1 (0.6%)</td>
<td></td>
</tr>
<tr>
<td>  Native AVFa</td>
<td>104 (73.8%)</td>
<td>73 (63.5%)</td>
<td>87 (50.6%)</td>
<td></td>
</tr>
<tr>
<td>  Graft</td>
<td>0 (0%)</td>
<td>4 (3.5%)</td>
<td>4 (2.3%)</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Diabetes mellitus</td>
<td>34 (24.1%)</td>
<td>48 (41.7%)</td>
<td>66 (38.4%)</td>
</tr>
<tr>
<td>  Ischemic heart diseases</td>
<td>34 (24.1%)</td>
<td>20 (17.4%)</td>
<td>28 (16.3%)</td>
<td>0.184</td>
</tr>
<tr>
<td>  Congestive heart failure</td>
<td>59 (41.8%)</td>
<td>31 (27%)</td>
<td>68 (39.5%)</td>
<td>0.032</td>
</tr>
<tr>
<td>  Cerebrovascular diseases</td>
<td>27 (19.1%)</td>
<td>26 (22.6%)</td>
<td>23 (13.4%)</td>
<td>0.116</td>
</tr>
<tr>
<td>Survival</td>
<td>1 year</td>
<td>82.3%</td>
<td>81.0%</td>
<td>91.2%</td>
</tr>
<tr>
<td>  2 years</td>
<td>75.9%</td>
<td>72.4%</td>
<td>82.8%</td>
<td></td>
</tr>
<tr>
<td>  3 years</td>
<td>63.1%</td>
<td>63.8%</td>
<td>69.0%</td>
<td></td>
</tr>
</tbody>
</table>

aAVF, arteriovenous fistula.

Figure 1. Distribution of MDRD eGFR in ml/min per 1.73 m² at dialysis initiation.

Cause-specific mortality

Of the 428 patients, 222 (52%) died during the follow-up period. In these patients, the median time from dialysis start to death was 29 months. Cause of death was available for 220 of the patients who died. Main causes of mortality were: cardiac death (25%), infections (24.5%), neoplasms (10.5%) and stroke (8.6%). During the study period, 88 out of the 428 patients underwent KT.

Trends in mortality

By unadjusted hazard ratios for death, higher age, diabetes, history of ischemic heart disease, lower serum albumin levels, periods 1995–1999 and 2000–2004 of renal replacement therapy start were risk factors for mortality (P<0.05, see Table 2). In addition, using Kaplan–Meier survival method, we confirmed a worse survival rate in older patients (age > 67 years), diabetes, history of ischemic heart disease, early initiation of dialysis (eGFR > 8.16 ml/min/1.73 m²), periods 1995–1999 and 2000–2004 of renal replacement therapy start and patients who did not receive a kidney transplant (Figure 2). No differences in mortality were observed comparing the type of vascular access (catheter vs. graft/native arteriovenous fistulae) at dialysis initiation (data not shown).
before 2005 were independent risk factors for higher mortality in ESRD patients, and high serum albumin level was a protective factor associated for improved survival. In addition, elevated eGFR at renal replacement initiation was independently associated with an increased risk of death. This risk was lost when the model was adjusted by age, indicating that this adjustment is needed to perform studies aimed to calculate the effect of eGFR at dialysis initiation on survival. Age is a confounding factor when analysing the impact of high eGFR at dialysis initiation on patient survival.

In the IDEAL study, with a median follow-up duration of 3.6 years, the investigators found that among patients with progressive CKD, clinical outcomes, including survival, were similar between patients in whom dialysis is initiated early and those for whom dialysis is electively delayed. Their results showed that with careful clinical management, dialysis may be delayed until either the eGFR drops below 7.0 ml/min or more traditional clinical indicators for the initiation of dialysis are present. In agreement, our study shows that mortality does not depend on eGFR at renal replacement therapy initiation. A Canadian study suggests a possible harmful effect of early dialysis initiation. A higher GFR at initiation of dialysis was associated with an increased risk of death that was not fully explained by differences in baseline characteristics. The authors postulated that the differences with IDEAL study were the different analysed population and the markedly higher GFR in their study when compared with the IDEAL trial. In concordance, we also found that higher GFR was associated with increased mortality. However, this effect was lost when the model was adjusted by age, suggesting that older patients with increased morbidity started dialysis program with increased GFR when compared with the younger ones. In concordance, studies from a Japanese and Dutch cohort also showed that higher eGFR at dialysis initiation was not associated with higher mortality after adjusting for a number of covariates including age. Hwang et al. in a national cohort study in Taiwan found that age and comorbidity accounted for a proportion of the excess mortality risk with high eGFR at dialysis initiation. The first meta-analysis that examined the association between GFR at dialysis initiation and increased mortality concluded that higher GFR at dialysis initiation was associated with a higher mortality; however, they did not adjust for age. The study included 16 heterogeneous cohort studies ($I^2 = 97\%; P < 0.001$) and one randomized controlled trial ($n = 1081 116$).

Malnutrition and reduced serum albumin levels at dialysis initiation are independent predictors of

### Table 2 Unadjusted hazard ratios for death

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted HR</th>
<th>95% Confidence interval</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, mean ± SD)</td>
<td>1.07</td>
<td>1.052–1.081</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>2.11</td>
<td>1.575–2.827</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.54</td>
<td>1.171–2.017</td>
<td>0.002</td>
</tr>
<tr>
<td>eGFR &gt;8.16 ml/min</td>
<td>1.62</td>
<td>1.235–2.115</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Serum albumin levels (g/dl)</td>
<td>0.79</td>
<td>0.642–0.970</td>
<td>0.024</td>
</tr>
<tr>
<td>Dialysis initiation period</td>
<td>1.87</td>
<td>1.309–2.683</td>
<td>0.003</td>
</tr>
<tr>
<td>1995–1999 periodb</td>
<td>1.47</td>
<td>0.996–2.156</td>
<td></td>
</tr>
<tr>
<td>2000–2004 periodb</td>
<td>1.47</td>
<td>0.996–2.156</td>
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</table>

*HR, hazard ratio.

### Age and survival

In the crude unadjusted Cox proportional hazards models, eGFR at dialysis initiation was an independent factor for mortality (Table 3). After adjustment by age, the association between mortality and eGFR was lost. Interestingly, in our cohort, patients that started renal replacement therapy with higher eGFR levels (>8.16 ml/min/1.73m²) were older than the patients with lower eGFR (<8.16 ml/min/1.73m²) (67 vs. 62 years, $P < 0.001$). In the multivariate Cox regression model adjusted for the potential confounding variables, period dialysis start, albumin and history of ischemic heart disease were independent factors for mortality (Table 3). Thus, history of ischemic heart disease, serum albumin levels and dialysis start before 2005 were independent factors for mortality in ESRD patients. All of them were risk factors except for serum albumin level, which was a protective factor.

In the multivariate Cox regression model excluding the patients that underwent KT, history of ischemic heart disease, serum albumin level, age and dialysis initiation before 2005 remained as independent factors for mortality in ESRD patients. Furthermore, when KT was included in the multivariate Cox regression model, history of ischemic heart disease, serum albumin level, age, KT and dialysis initiation before 2005 were independent risk factors for mortality in ESRD patients (Table 3).

### Discussion

We studied the patients that initiated renal replacement between 1 January 1995 and 31 December 2009 in our reference area. We found that age, history of ischemic heart disease and dialysis initiation period 0.003, Serum albumin levels (g/dl) 0.79 0.642–0.970 0.024, eGFR >8.16 ml/min 1.62 1.235–2.115 <0.001, Diabetes mellitus 1.54 1.171–2.017 0.002, Ischemic heart disease 2.11 1.575–2.827 <0.001.
Figure 2. Comparison of Kaplan–Meier survival curves by different parameters. (A) Diabetes, (B) eGFR, (C) dialysis initiation period, (D) ischemic heart disease, (E) age and (F) kidney transplantation.
mortality. Our study also found that reduced serum albumin levels in our dialysis population was an independent risk factor for mortality, suggesting that the malnutrition at the renal replacement therapy initiation worsens patient prognosis. A recent Swedish study suggests that poor outcome in incident dialysis patients with high eGFR, but not with high measured GFR (mGFR, with 24-h urine collection), is due to confounding by protein-energy wasting. Decreased creatinine levels in patients with malnutrition may lead to a false increase in eGFR (because plasma creatinine is in the denominator of the MDRD equation), but not in mGFR. In a multicentric prospective cohort study of 569 patients that compared eGFR vs. mGFR, the limits of agreement overestimated mGFR with only 0.8 ml/min/1.73 m² but ranged from -0.8 to +5.6 ml/min/1.73 m². Interestingly, the same group has previously demonstrated that serum albumin correlates poorly with several markers of nutritional status, thus its value as a reliable marker of nutritional status is limited.

Another study limitation is that we did not assess other protein-energy wasting markers such as lean body mass DEXA, hand-grip strength and subjective global assessment. Events rates in patients initiating dialysis therapy with prior diagnosed ischemic heart disease have an almost 2-fold increased risk for mortality, as previously reported. Patients with prior diagnosed coronary disease have a risk of non-fatal myocardial infarction greater by 5% and a risk of cardiac death greater by 14% when compared with patients without documented coronary disease. Even in patients without prior coronary disease, the competing risk of cardiac death remains high, as lean body mass DEXA, hand-grip strength and subjective global assessment are important factors in the management of current coronary disease management. Patients initiating dialysis therapy with prior diagnosed ischemic heart disease have an almost 2-fold increased risk for mortality, as previously reported.

| Variables                  | Crude Model | Relative risk | CI (95%)       | P    | Model 1 | Relative risk | CI (95%)       | P    | Model 2 | Relative risk | CI (95%)       | P    | Model 3 | Relative risk | CI (95%)       | P    |
|----------------------------|-------------|---------------|----------------|------|---------|---------------|----------------|------|---------|---------------|----------------|------|---------|---------------|----------------|------|---------|
| eGFR (ml/min/1.73 m²)      | 1.06        | 1.025–1.092   | <0.001         |      | 1.03    | 0.996–1.065  | 0.083           |      | 1.02    | 0.981–1.057  | 0.337           |      | 1.02    | 0.978–1.053  | 0.444           |      |
| Age (years)                |             | 1.07          | 1.050–1.080    | <0.001| 1.07    | 1.052–1.086  | <0.001          |      | 1.05    | 1.032–1.068  | <0.001          |      | 1.05    | 1.032–1.068  | <0.001          |      |
| 1995–1999 Periodb          |             | 2.35          | 1.582–3.492    | <0.001| 2.35    | 1.582–3.492  | <0.001          |      | 2.15    | 1.444–3.186  | <0.001          |      | 2.15    | 1.444–3.186  | <0.001          |      |
| 2000–2004 Periodb          |             | 1.68          | 1.087–2.6      |       | 1.68    | 1.087–2.6   | <0.000          |      | 1.66    | 1.075–2.573  | 0.022           |      | 1.66    | 1.075–2.573  | 0.022           |      |
| Albumin (g/dl)             |             | 0.65          | 0.506–0.835    |       | 0.65    | 0.506–0.835 | 0.002           |      | 0.71    | 0.552–0.914  | 0.008           |      | 0.71    | 0.552–0.914  | 0.008           |      |
| Ischemic heart disease     |             | 1.66          | 1.21–2.284     | 0.005 | 1.66    | 1.21–2.284  | 0.005           |      | 1.53    | 1.115–2.108  | 0.008           |      | 1.53    | 1.115–2.108  | 0.008           |      |
| KTc                        |             | 0.295         | 0.13–0.525     | <0.001| 0.259   | 0.13–0.525  | 0.001           |      | 0.207   | 0.102–0.421  | 0.001           |      | 0.207   | 0.102–0.421  | 0.001           |      |

aHazard ratios for mortality among patients for whom hemodialysis was initiated between 1995 and 2009.
cKidney transplantation.
Age and early initiation of dialysis

patient survival. In this study, early dialysis initiation (at higher eGFR) was associated with an increased risk of death. Older age, greater likelihood of diabetes and the presence of severe comorbid diseases may partly explain this effect. It is of note that in our study, mean age of patients showed a trend to decrease from the first to the third period; however, it did not reach statistical significance. This tendency may be ascribed to the increased young immigrant patients in our reference area.

In a seminal article, Wolfe et al. showed that KT significantly reduced the long-term risk of death, with initially higher mortality in the transplantation groups disappearing within less than half a year. The relative survival benefits of KT were similar for men and women, with the long-term risk of death decreasing by 66 and 70%, respectively, and the initially higher mortality disappearing within 8 and 7 months, respectively. In addition, they also demonstrated that KT improved longevity in all recipient groups, including patients who were 60–74 years old at the time of transplantation. In agreement, we also found that KT was a protective factor against mortality in ESRD patients.

Our results showed that ESRD patient mortality has changed over time. In the last 10 years (2000–2009) mortality was lower compared with that observed in patients initiating dialysis from 1995 to 1999. Moreover, in the last period of 5 years studied (2005–2009) mortality was lower compared with that observed in the preceding 10 years. We might speculate that these improvements could be related to younger age observed in incident ESRD patients in the last period and the advances in renal replacement therapies.

The native arteriovenous fistula is the preferred vascular access because of its longevity and lower rates of infection and intervention. Previous studies have demonstrated an association between the use of central venous catheters and higher risks of mortality and hospitalization. Furthermore, sustained use of tunneled central venous catheters for vascular access have been associated with higher risks of all-cause cardiovascular and infection-related mortality. Surprisingly, we did not find any association between vascular access and mortality in our studied cohort. It is likely that the low rate of catheter use in our department may partially explain this finding.

Our study has several limitations. Its retrospective nature precludes any causal relationship rationale for our findings. Our sample is relatively small, and some uncontrolled technical factors such as the improvement in dialysis machines and techniques may have confounded some of our results. It bases its conclusions in eGFR without data of mGFR, when it is well known especially in people with low GFR that the muscle mass will be more important in determinate plasma creatinine than the GFR. In addition, the Registry does not have some relevant data, such as the central venous catheter permanence or residual renal function. In contrast, our study has some strength in that it includes a patient cohort attended in a unique Nephrology Department for a long period of time, the Catalan Registry is one of the most important and long-term mandatory registries in Europe, with robust quality controls, and the yearly completed reports are reliable.

To summarize, history of ischemic heart disease, low serum albumin level, old age, dialysis initiation before 2005 and absence of KT were independent factors for mortality in ESRD patients. Patients with elevated eGFR at renal replacement initiation were older, and the relation with higher mortality in patients with higher eGFR was lost when the model was adjusted by age, thus confirming age as a confounding factor.

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Conflict of interest: None declared.

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