The effect of diabetes on incidence and mortality in end-stage renal disease in Germany

Falk Hoffmann1, Burkhard Haastert2, Michael Koch3,4, Guido Gian5, Gerd Glaeske1 and Andrea Icks5,6

1Division Health Economics, Health Policy and Outcomes Research, Centre for Social Policy Research, University of Bremen, Germany, 2mediStatistica, Neuenrade, Germany, 3Center of Nephrology, Mettmann, Germany, 4Clinic of Nephrology, Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany, 5Institute of Biometrics and Epidemiology, German Diabetes Center, Leibniz Center for Diabetes Research, Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany and 6Department of Public Health, Institute of Medical Sociology, Heinrich-Heine-University Düsseldorf, Germany

Correspondence and offprint requests to: Falk Hoffmann; E-mail: hoffmann@zes.uni-bremen.de

Abstract

Background. We aimed to examine the epidemiology and mortality risk of patients with incident end-stage renal disease (ESRD) in diabetic and non-diabetic individuals and to determine differences between sexes.

Methods. We used the claims data of a statutory health insurance company. Patients aged 30 years and older who started dialysis or had pre-emptive kidney transplantation between 1 April 2006 and 7 October 2008 were included. We estimated incidence rates of ESRD according to diabetes status, sex and age as well as relative and attributable risks due to diabetes. Using Cox regression, we studied survival and estimated time-dependent hazard ratios (HR).

Results. We included 623 patients with incident ESRD (n = 254 had diabetes); 477 (76.6%) were male, and the mean age was 66.5 years. Standardized to the German population, incidences of ESRD in patients with and without diabetes were 157.9 and 25.6 per 100 000 person-years respectively (6.2-fold increased risk). The impact of diabetes on mortality was time-dependent. Diabetics had an increased mortality risk after the first year. An interaction of diabetes with time (per additional year of follow-up) was found in the whole population (HR 2.01, 95% CI

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1.21–3.33) and in females (HR 3.27, 95% CI 1.03–10.39); however, males did not reach statistical significance (HR 1.78, 95% CI 0.99–3.18). The fixed baseline effect of diabetes in these models was non-significant (HR ~0.7–0.8).

Conclusions. Diabetes is an important risk factor for ESRD. We provide further evidence that the impact of diabetes on survival after ESRD is time-dependent and that differences between sexes might exist.

Keywords: diabetes; dialysis; end-stage renal disease; sex; survival

Introduction

Due to its complications, diabetes is a major public health problem. Because of an increasing number of patients with type 2 diabetes, diabetes has become the leading cause of end-stage renal disease (ESRD) worldwide [1–5]. However, very little data from population-based studies concerning the incidence of ESRD in patients with diabetes compared to those without diabetes are available. Also, there have been only a few studies with conflicting results analysing the impact of diabetes on mortality after initiating treatment for ESRD. Some studies found no differences in mortality when comparing patients with and without diabetes [6–8]; some were not population-based, or some analysed patients with and without diabetic nephropathy instead of diabetes [9]. Furthermore, only a few studies conducted survival analysis stratified by sex. In a recent study, a time-dependent effect of diabetes on mortality in patients with ESRD was found, but only in women and not in men [10].

The objectives of this study were to examine the epidemiology and mortality risk of patients with incident ESRD in diabetic and non-diabetic individuals and to determine whether outcomes differ between sexes.

Materials and methods

Database

We analysed the claims data of the Gmünder ErsatzKasse (GEK), a statutory health insurance company in Germany. A total of 70 million of the 82 million German inhabitants are insured in one of the 215 statutory health insurance companies (as of December 2008). Historically, these insurance funds were introduced for certain population groups (e.g. industrial workers, office employees, etc.). More recently, almost all insurance companies (as of December 2008) were statutory health insurance companies [11–13]. A person was identified as a diabetic patient if at least one of the following criteria was fulfilled in the baseline year:

(i) outpatient diabetes diagnoses (ICD-10 codes: E10–E14) in at least three of the four quarters,
(ii) at least two prescriptions of antidiabetic medication (ATC code: A10), and
(iii) at least one prescription of an antidiabetic medication and one diabetes diagnosis or one measurement of blood glucose or HbA1c in ambulatory care.

Statistical analysis

The main analyses performed were stratified by sex.

For the incidence analysis, follow-up started on 1 April 2006 and ended at the index date or at 7 October 2008 (the last possible index date). Incidence rates of ESRD (per 100 000 person-years at risk) were estimated for patients with and without diabetes. We used the following age groups: 30–49, 50–59, 60–69, 70–79 and 80+ years. Our incidences were directly standardized to the German population of December 2004. Additionally, we estimated incidences in the diabetic population standardized to the estimated German diabetic population using prevalences from our cohort in the baseline year. We estimated incidence rate ratios (diabetic versus non-diabetic patients), as well as attributable risks among exposed (ARE) and the population attributable risk due to diabetes (PAR), alongside with 95% confidence intervals (95% CI) [14]. For the mortality analysis, patients with incident ESRD were followed up from the index date up to death or the end of the study period (31 December 2008), whichever came first. Crude survival in patients with and without diabetes was assessed using the Kaplan–Meier method. Differences between both groups were planned to be statistically compared using the log-rank test, if the proportional hazard assumption was not violated, which was statistically tested by a test of Cox [15]. However, the proportional hazard assumption was not met. We then performed Cox regression using time-dependent risks for diabetes at baseline to evaluate predictors for death in multivariate analyses. As predictors, we included diabetes, interaction of diabetes with time since ESRD incidence (time-dependent), and age (as continuous variable). In another sensitivity analysis, we further adjusted for co-morbidities that were assessed in the baseline year. These were: hypertension (ICD-10 codes: I10–I15), coronary heart disease (ICD-10 codes: I20–I25), heart failure (ICD-10 code: I50) and peripheral arterial vascular disease (ICD-10 code: I73.9).

Results were considered statistically significant if P-values were <0.05. We used SAS 9.2 for all analyses.

Identification of patients with ESRD and diabetes

We assessed all patients with incident chronic ESRD (defined as first dialysis or a pre-emptive kidney transplantation) after 1 April 2006. Kidney transplantations were identified by using specific operation procedure codes. Occurrence of dialysis was defined as at least one relevant physician service (haemofiltration, haemodialysis, haemodiafiltration and peritoneal dialysis) or related consultation fee in an outpatient or hospital setting. To fulfil our criteria of chronic dialysis, these dialysis claims had to be documented at least once per week over a period of 12 consecutive weeks. Patients who died within a period of 12 weeks after starting dialysis were also included. However, we did not include hospitalized patients with acute renal failure, defined as an admission or discharge ICD-10 code of N17 (acute renal failure) or no code of N18 (chronic renal failure), and died within these 12 weeks. The index date was the day of the first related claim.

In a sensitivity analysis, we additionally excluded all patients who died within 12 weeks after initiating treatment. This definition is often used, e.g. by Lok et al. [2], because it excludes episodes of acute renal failure.

To estimate the incidence of ESRD in the population under risk, we excluded individuals with prevalent dialysis, kidney transplantation or condition after transplantation from our cohort. Patients with at least 12 consecutive weeks under dialysis before 1 April 2006 were defined as prevalent cases. Whether patients were transplanted or had a claim that indicates a condition after transplantation before study entry was assessed between 1 April 2005 and 31 March 2006 (the baseline year). Diabetes status was assessed according to an established algorithm that has been used in several studies analysing the claims data of German statutory health insurance companies [11–13]. A person was identified as a diabetic patient if at least one of the following criteria was fulfilled in the baseline year:

(i) outpatient diabetes diagnoses (ICD-10 codes: E10–E14) in at least three of the four quarters,
(ii) at least two prescriptions of antidiabetic medication (ATC code: A10), and
(iii) at least one prescription of an antidiabetic medication and one diabetes diagnosis or one measurement of blood glucose or HbA1c in ambulatory care.
Results

Study population and baseline characteristics

The flow of patients is shown in Figure 1. A total of 1.94 million person-years under risk were included. Of the 623 patients with incident ESRD, 477 (76.6%) were male, and the mean age was 66.5 years (SD: 13.6). Overall, 254 of the 623 incident patients (40.8%) had diabetes. Patients with diabetes were older than those without diabetes (mean age: 69.1 versus 64.7 years).

Incidence of ESRD and relative risks

The incidence of ESRD increased with age in patients with and without diabetes in both sexes. Patients with diabetes had a high relative risk (RR) of ESRD, which decreased with increasing age in males from 19.7 (95% CI 11.6–33.3) in persons aged 30–49 years to 2.0 (95% CI 1.3–3.2) in those aged 80 years and older. The same trend was found in females with relative risks of 35.4 (95% CI 13.7–91.3) and 3.7 (95% CI 2.0–7.0) when comparing patients aged 30–49 years with those who were aged ≥80 years. In both sexes, the major peak was found in patients aged 30–49 years (Table 1). The ARE was highest in younger age groups, whereas the PAR, which includes the diabetes prevalence, was highest in the middle age groups.

Standardized to the German population aged 30 years and older, the incidences of ESRD were 157.9 (95% CI 124.2–191.5) and 25.6 (95% CI 22.6–28.6) per 100 000 person-years in patients with and without diabetes respectively, which corresponds to an overall 6.2-fold increased risk of ESRD. Eighty-four per cent (95% CI 79–87%) of the ESRD risk in diabetic individuals and 32% (95% CI 26–37%) of the ESRD risk in the entire population were attributable to
Incidence of ESRD and relative risks

<table>
<thead>
<tr>
<th>Age group, in years</th>
<th>Incidence rates per 100 000 person-years (95% CI)</th>
<th>Relative and attributable risks (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With diabetes</td>
<td>Without diabetes</td>
</tr>
<tr>
<td>Males</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30–49 (n = 71)</td>
<td>172.1 (94.7–249.4)</td>
<td>8.7 (6.4–11.1)</td>
</tr>
<tr>
<td>50–59 (n = 70)</td>
<td>107.3 (63.4–151.1)</td>
<td>18.2 (13.0–23.4)</td>
</tr>
<tr>
<td>60–69 (n = 106)</td>
<td>125.5 (86.6–164.4)</td>
<td>39.4 (29.9–48.9)</td>
</tr>
<tr>
<td>70–79 (n = 156)</td>
<td>324.4 (250.5–398.3)</td>
<td>107.3 (84.1–130.6)</td>
</tr>
<tr>
<td>80+ (n = 74)</td>
<td>438.1 (281.3–594.8)</td>
<td>218.9 (154.2–283.6)</td>
</tr>
<tr>
<td>Standard: diabetic population</td>
<td>186.6 (147.6–225.7)</td>
<td>41.0 (35.6–46.5)</td>
</tr>
<tr>
<td>Standard: diabetic population</td>
<td>244.1 (204.8–283.5)</td>
<td></td>
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<tr>
<td>Females</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30–49 (n = 21)</td>
<td>142.9 (28.6–257.2)</td>
<td>4.0 (2.0–6.1)</td>
</tr>
<tr>
<td>50–59 (n = 15)</td>
<td>61.9 (1.2–122.6)</td>
<td>7.9 (3.2–12.5)</td>
</tr>
<tr>
<td>60–69 (n = 27)</td>
<td>79.7 (30.3–129.2)</td>
<td>16.9 (8.9–24.9)</td>
</tr>
<tr>
<td>70–79 (n = 45)</td>
<td>220.3 (137.2–303.3)</td>
<td>34.9 (18.8–51.0)</td>
</tr>
<tr>
<td>80+ (n = 38)</td>
<td>290.0 (166.0–414.1)</td>
<td>78.3 (41.1–115.5)</td>
</tr>
<tr>
<td>Standard: diabetic population</td>
<td>135.1 (79.8–190.4)</td>
<td>15.4 (11.8–19.0)</td>
</tr>
<tr>
<td>Standard: diabetic population</td>
<td>163.4 (124.5–202.3)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard: diabetic population</td>
<td>157.9 (124.2–191.5)</td>
<td>25.6 (22.6–28.6)</td>
</tr>
<tr>
<td>Standard: diabetic population</td>
<td>198.7 (171.2–226.3)</td>
<td></td>
</tr>
</tbody>
</table>

CI, confidence interval; ESRD, end-stage renal disease; RR, relative risk; ARE, individual attributable risk of diabetes among exposed (portion of the incidence of ESRD in patients with diabetes that is due to diabetes); PAR, population attributable risk of diabetes (portion of the incidence of ESRD in the population—patients with and without diabetes—that is due to exposure).

Mortality after incidence

The median follow-up for patients with incident ESRD was 10.9 months (range 0–33 months). A total of 246 individuals died within the study period. Figure 2 shows the Kaplan–Meier curves for both sexes stratified by diabetes. After 6 months, the cumulative survival was 74.3% (95% CI 68.0–80.7%) versus 72.5% (95% CI 67.3–77.7%) (with versus without diabetes) in males and 74.9% (95% CI 64.6–85.2%) versus 75.6% (95% CI 66.1–85.1%) in females, respectively. The cumulative survival in patients with and without diabetes was virtually the same up to ~9–12 months for both sexes. After that, the curves diverged.

As shown by the graphs, the assumption of proportional hazards seemed to be violated. This was underlined by the Cox test, investigating diabetes and the interaction between diabetes at baseline and time (since baseline) as independent variables in the Cox regression model. The interaction of diabetes with time was significant in the whole study population (P = 0.0051) as well as in males (P = 0.0497) and in females (P = 0.0335). This means that the relative mortality risk due to diabetes was time-dependent. Shortly after the index date, diabetes seems to have no impact on survival. But in the time course, patients with diabetes had an increased mortality risk. This was similar when we adjusted for age. Statistically significant interactions (per additional year of follow-up) were found in the whole population (HR 2.01, 95% CI 1.21–3.33) and in females (HR 3.27, 95% CI 1.03–10.39); however, males did not reach statistical significance (HR 1.78, 95% CI 0.99–3.18). The fixed baseline effect of diabetes in these models was non-significant with HR between 0.7 and 0.8 (Table 2). Higher age was associated with an increased mortality risk in both sexes. Adjusting for further co-morbidities did not alter these results (data not shown).

Sensitivity analysis

After exclusion of all persons who died within 12 weeks after initiating treatment, the cohort consisted of 505 patients with incident ESRD. Three quarters of them were men (76.2%); the mean age was 65.1 years (SD: 13.9), and 209 (41.4%) had diabetes. As expected, the standardized incidences of ESRD decreased to 139.0 and 19.7 per 100 000 person-years in patients with and without diabetes respectively, which corresponds to a 7-fold increased risk. The trends in incidence, ARE and PAR as well as differences between sexes were not changed substantially. As one would expect, cumulative survival at 6 months was higher in our sensitivity analysis (~90% irrespective of diabetes status). But the time-dependent mortality risk due to diabetes remained in principle, and the survival curves diverged at ~9–12 months in both sexes (data not shown).

Discussion

Incidence of ESRD and relative risks

In this study, using the claims data, we were able to analyse a total of 1.94 million person-years under risk. As expected, we found that the incidence of ESRD was higher...
in patients with diabetes (4.6-fold in males and 8.8-fold in females). This was much lower compared with an earlier American study which found a 12.7-fold increase of the relative risk of ESRD due to diabetes in men [1]. However, this study was performed in men aged 35–57 years at baseline, the follow-up of 16 years ended in 1990 and medications were used as a proxy for diabetes. Although the incidence rate of ESRD in diabetic males was fairly comparable with our data (199.8 versus 186.6 per 100,000 person-years), the incidence rate in patients without diabetes was not (13.7 versus 41.0 per 100,000 person-years). In a recent population-based study, the data of a regional dialysis centre in Germany were analysed over 7 years [16]. Compared with our data, this study found quite similar incidence rates in women (130.2 versus 16.4 per 100,000 person-years in patients with versus without diabetes; RR: 8.0) but somewhat smaller ones in males (213.6 versus 26.9; RR: 7.9). In line with the existing evidence, however, the relative risk of ESRD in patients with diabetes and the attributable risk among exposed decreased significantly with increasing age.

Mortality after incidence

We further assessed the impact of diabetes on mortality in our 623 patients with incident ESRD. As expected from other studies [5, 8–10, 17], these patients had a poor prognosis, irrespectively of diabetes status. There are two issues which need to be discussed. First, several studies published in recent years have shown that sex, which was not usually seen as a risk factor for mortality in patients with ESRD, should be considered. It has been shown that ESRD cancels out the survival advantage of women which can be noted in the general population [9], and that especially older females with type 2 diabetes had a worse prognosis compared with males [5, 17, 18]. Diabetes itself seems to be associated with an increased mortality risk in females compared with males [19, 20]. Second, the impact of diabetes on mortality after incident ESRD seems to be time-dependent. In the first 12 months of our study, diabetes had no influence on mortality, and thereafter, it became a risk factor. The interaction between diabetes at baseline and time (since baseline) was significant in the Cox regression model. Differences between men and women may be present; after adjusting for age and comorbidities, the interaction of diabetes with time remained only significant in the whole population and in women, not in men. However, P-values are very close to the significance level for males (e.g. P = 0.0526). Nevertheless, the HRs (1.78 versus 3.27) and diverging Kaplan–Meier curves are more predominant in females. A recently published study from France showed quite similar results in patients with diabetes (4.6-fold in males and 8.8-fold in females). This was much lower compared with an earlier American study which found a 12.7-fold increase of the relative risk of ESRD due to diabetes in men [1]. However, this study was performed in men aged 35–57 years at baseline, the follow-up of 16 years ended in 1990 and medications were used as a proxy for diabetes. Although the incidence rate of ESRD in diabetic males was fairly comparable with our data (199.8 versus 186.6 per 100,000 person-years), the incidence rate in patients without diabetes was not (13.7 versus 41.0 per 100,000 person-years). In a recent population-based study, the data of a regional dialysis centre in Germany were analysed over 7 years [16]. Compared with our data, this study found quite similar incidence rates in women (130.2 versus 16.4 per 100,000 person-years in patients with versus without diabetes; RR: 8.0) but somewhat smaller ones in males (213.6 versus 26.9; RR: 7.9). In line with the existing evidence, however, the relative risk of ESRD in patients with diabetes and the attributable risk among exposed decreased significantly with increasing age.

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Table 2. Cox regression for the effect of diabetes on mortality after incident ESRD, by sex

<table>
<thead>
<tr>
<th>Hazard ratio (95% CI)</th>
<th>Male (n = 477)</th>
<th>P-value</th>
<th>Female (n = 146)</th>
<th>P-value</th>
<th>Total (n = 623)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (male versus female)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.30 (0.96–1.77)</td>
<td>0.09</td>
</tr>
<tr>
<td>Diabetes (yes versus no)</td>
<td>0.78 (0.53–1.15)</td>
<td>0.21</td>
<td>0.70 (0.34–1.43)</td>
<td>0.32</td>
<td>0.76 (0.54–1.07)</td>
<td>0.12</td>
</tr>
<tr>
<td>Diabetes × time since incident ESRD</td>
<td>1.78 (0.99–3.18)</td>
<td>0.0526</td>
<td>3.27 (1.03–10.39)</td>
<td>0.0446</td>
<td>2.01 (1.21–3.33)</td>
<td>0.007</td>
</tr>
<tr>
<td>Age (years) (continuously)</td>
<td>1.04 (1.03–1.06)</td>
<td>&lt;0.0001</td>
<td>1.04 (1.02–1.07)</td>
<td>0.0012</td>
<td>1.04 (1.03–1.05)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

CI, confidence interval; ESRD, end-stage renal disease.

*Hazard ratios of age and diabetes × time since incident ESRD with regard to 1-year change.
Diabetes and ESRD: incidence and mortality

They found the effect of diabetes to be time-dependent only in women and not in men. Kaplan–Meier curves were virtually similar between patients with and without diabetes for up to 12 months in both sexes in the French study as in ours. On the other hand, a recent population-based study using the data of a regional dialysis centre in Germany found a significant interaction between diabetes and time only in the whole population and in men [21]. Of note, in all these studies including ours, there might be concerns about statistical power when analyses were stratified by sex and diabetes. But taken together, there is strong evidence to suggest that the risk of diabetes on mortality after incident ESRD is time-dependent in both sexes. Whether its impact is somewhat higher in women needs further investigation. Diabetes seems not to be a simple risk factor for mortality in patients with ESRD [6,7].

Strengths and limitations

The main strength of our study is that we were able to analyse a large population-based dataset and that diabetes status could directly be assessed at study entry. Several studies used diabetic nephropathy as a proxy for diabetes [9], which is one but not the only reason for ESRD in patients with diabetes [16,22]. Classification according to type 1 or type 2 diabetes was not possible because a large amount of diagnoses are coded as unspecified diabetes mellitus (ICD-10 code: E14).

The main limitation of our study was the impossibility to validate the case-selection algorithm used for the identification of patients with ESRD and diabetes. Although the algorithm for diabetes status has been used in several studies analysing the claims data of German statutory health insurance companies [11–13], its validity has never been assessed against a ‘gold standard’. The identification of patients on dialysis using health insurance claims data was challenging, this is also documented in an American study [23]. Our main difficulty was to distinguish patients with acute renal failure from those with chronic ESRD since both require dialysis. The main distinctive feature is the duration of treatment, but this would exclude patients who die shortly after initiating dialysis. We, therefore, used an algorithm which included patients who died within 12 weeks after the first treatment so long as they had further evidence of chronic renal failure. In contrast, Lok et al. [2] defined chronic dialysis only as total treatment for >90 days, a strategy which excludes all patients dying within this period. We used this definition in a sensitivity analysis. However, the time-dependent effect of diabetes on mortality still remained.

The exclusion of persons co-insured as a dependent and of those who left the GEK for reasons other than death (Figure 1) might result in bias. However, these exclusions were necessary due to validity concerns. The insurants of the GEK are not fully representative for the German population with respect to age, sex and socioeconomic position [24], which might have some impact on morbidity and on the utilization of healthcare resources. However, we assume that the relative risk should not be largely influenced. Although patients with incident ESRD are more often male [10,16,19], the high proportion of men (76.6%) also represents a feature of the population used. The GEK insures more males than females in the relevant age groups. We, therefore, standardized our results with respect to sex and age. But this does not necessarily account for differences in socioeconomic status.

In conclusion, diabetes is an important risk factor for ESRD. This study provides further evidence that the impact of diabetes on survival after ESRD is time-dependent and that differences between sexes might exist.

Acknowledgements. This study was supported by a grant of the German Ministry of Health and the German Diabetes Foundation. The German Diabetes Center is financed by the German Ministry of Health and by the Northrhine-Westphalian Ministry of Science. We thank the Gmünder ErsatzKasse (GEK) for providing the data and for supporting us in the data managing.

Conflict of interest statement. None declared.

References

Cardiac disease is a significant cause of morbidity and mortality in children with end-stage renal disease (ESRD). This study aimed to report the frequency of cardiac disease diagnostic methods used in US pediatric maintenance hemodialysis patients.

Methods. A cross-sectional analysis of all US pediatric (ages 0.7–18 years, n = 656) maintenance hemodialysis patients was performed using data from the Centers for Medicare and Medicaid Services ESRD Clinical Performance Measures Project. Clinical and laboratory information was collected in 2001. Results were analysed by age, sex, race, Hispanic ethnicity, dialysis duration, body mass index (BMI), primary ESRD cause and laboratory data.

Results. Ninety-two percent of the patients had a cardiovascular risk factor (63% hypertension, 38% anemia, 11% BMI >94th percentile, 63% serum phosphorus >5.5 mg/dL and 55% calcium–phosphorus product ≥55 mg²/dL²). A diagnosis of cardiac disease was reported in 24% (n = 155) of all patients: left ventricular hypertrophy/enlargement 17%, congestive heart failure/pulmonary edema 8%, cardiomyopathy 2% and decreased left ventricular function 2%. Thirty-one percent of patients were not tested. Of those tested, the diagnostic methods used were chest X-rays in 60%, echocardiograms in 35% and electrocardiograms in 33%; left ventricular hypertrophy/enlargement was diagnosed using echocardiogram (72%), chest X-ray (20%) and electrocardiogram (15%).

Conclusions. Although 92% of patients had cardiovascular risk factors, an echocardiography was performed in only one-third of the patients. Our study raises the question of why echocardiography, considered the gold standard for cardiac disease diagnosis, has been infrequently used in pediatric maintenance dialysis patients, a high-risk patient population.

Keywords: cardiac disease; end-stage renal disease; hypertension; maintenance hemodialysis; pediatric