The Danish Registry on Regular Dialysis and Transplantation: completeness and validity of incident patient registration

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Abstract

Background. The Danish National Registry on Regular Dialysis and Transplantation (NRDT) provides systematic information on the epidemiology and treatment of end-stage chronic kidney disease in Denmark. It is therefore of major importance that the registry is valid and complete. The aim of the present study was to evaluate the registration of incident patients on chronic renal replacement therapy (RRT).

Methods. Incident patients on chronic RRT in the period 2001–2004 were identified in NRDT and in the National Patient Registry, which contains information on hospital admissions and treatments. In the National Patient Registry, identification of patients was as follows: patients receiving the procedure of dialysis during a minimum of 90 days and for a minimum of 12 times or the procedure of renal transplantation. Only patients with at least 2 years of dialysis-free interval before and never being transplanted were included. The completeness of NRDT was calculated as the percentage of new patients on chronic RRT registered in the National Patient Registry also found in NRDT. Validity of data in NRDT was assessed by information from medical records and analysed using kappa statistics.

Results. Completeness of NRDT. Of 3020 patients registered in the National Patient Registry as incident chronic RRT patients, 97.2% were found in NRDT but 22.5% with another year of entry. There were no differences in completeness between hospitals or regions. Validity of NRDT. Validity of common renal diagnoses and RRT modality was high: diabetic nephropathy (kappa = 0.98), adult polycystic kidney disease (kappa = 0.95), chronic glomerulonephritis (kappa = 0.78) and RRT modality (kappa = 0.94). The diagnosis CKD of unknown aetiology and type of diabetes were less valid (kappa = 0.62, 0.60 and 0.73, respectively). The date of RRT start had also high validity.

Conclusions. Completeness of incident patient registration in NRDT was highly acceptable. Validity of incident patient data was also good, except for type of diabetes.

Keywords: completeness; end-stage renal disease; national registry; validation

Introduction

The Danish National Registry on Regular Dialysis and Transplantation (NRDT) was established in 1990 in order to provide systematic information on the epidemiology and treatment of end-stage chronic kidney disease (CKD) in Denmark [1]. It contains data on all Danish patients being actively treated for end-stage renal disease. The registry is widely used for evaluation of treatment quality, trends of treatment activity and scientific studies [1–4]. Furthermore, data are transferred to the European Dialysis and Transplant (EDTA) Registry [5–7]. It is therefore of major importance that the registry is valid and complete [8].

The aim of the present study was to evaluate the registration in NRDT of incident patients on chronic renal replacement therapy (RRT).

Materials and methods

Identification of patients

Incident patients on chronic RRT are defined as first-time RRT patients with at least 3 months need of dialysis treatment or pre-emptive renal transplantation. The patients can be identified in NRDT, in the Danish National Patient Registry (NPR) or in medical records by their personal identification number assigned from birth to all people living in Denmark by the Danish Civil Registration System.

In the study of completeness, all patients registered in NRDT or NPR starting between 2001–2004 were included. In the study of validity of the information in NRDT, a 2% sample of incident patients registered in NRDT 1995–2004 were selected at random evenly distributed between the six nephrological centres in eastern Denmark including two university centres, two regional centres and two local centres. In order to further validate the information on diabetes, an additional sample of 25 patients with type 1 diabetes according to NRDT was randomly selected.

The Danish National Registry on Regular Dialysis and Transplantation

Data on patients receiving RRT are referred to the NRDT once a year. Identical software is used. One specific nephrologist in each of all region-
al nephrological centres in Denmark is responsible for referring the data. Data are based on medical records, and for incident patients the registration includes age, sex, renal diagnosis, treatment modality and dialysis centre. The material is checked for internal consistency, and appropriate corrections are made in agreement with the reporting centres. No private clinics exist. Only patients with at least 3 months need of RRT are included in the registry, thereby excluding acute renal failure.

The Danish National Patient Registry

The NPR is an administrative registry containing information on all hospital admissions including diagnoses, procedures, dates, hospitals and departments since 1977 and, from 1995, also information on out-patient treatment. It is mandatory for all hospital departments to report to NPR as payment is only received if information is reported to the NPR. The registry has proven to be valid and complete [9,10]. Incident chronic RRT patients were identified as follows: (i) patients who received the procedure dialysis during a minimum of 3 months (90 days) for a minimum of 12 times and with a dialysis-free interval of at least 2 years prior to the start of dialysis. For patients with more than 7 days between each dialysis, at least one procedure code of chronic dialysis was required. (ii) Patients who received the procedure renal transplantation with at least a 1-year dialysis-free interval before and who were never transplanted before.

Medical records

The medical records of the RRT patients for the validity study were located at the nephrological centres where the patients initiated RRT. Records were studied chronologically from referral to the department to at least 3 months after initiation of RRT to ensure chronicity of the treatment.

Completeness and validity studies

Completeness of NRDT Incident chronic RRT patients in the period 2001–2004 were identified in NPR as described above by the procedures peritoneal dialysis, haemodialysis and renal transplantation. These patients were linked by their personal registration numbers to NRDT. The completeness was calculated as the percentage of new patients registered in NPR who also found in NRDT. The completeness was compared between hospitals and regions.

Validity of information in NRDT In the period from 1995 to 2004, 6357 new patients were registered in NRDT. Two per cent of these patients were selected, creating a random sample of 120 patients. Medical records were studied by the same investigator who was blinded for data in NRDT. Four variables were identified: renal diagnosis, date of RRT initiation, dialysis modality and duration of RRT.

Renal diagnosis

Four common diagnoses were studied: The three well-defined diagnoses nephropathy, chronic glomerulonephritis (GN) and adult polycystic kidney disease (APKD) and the unspecific CKD of unknown aetiology. Diabetic nephropathy was verified by renal biopsy or deemed probable by anamnestic information of diabetes mellitus for at least 15 years with concomitant neuropathy and/or retinopathy. Diabetic patients with a history of treatment with an oral anti-diabetic drug or onset of the diabetes at the age of 40 years or older were classified as type 2 diabetes including patients on insulin. Patients treated with insulin and no history of type 2 diabetes were classified as type 1 diabetes. Chronic GN was verified by renal biopsy. APKD was verified by ultrasonography.

Start of renal replacement therapy

Start of treatment was defined as the date of the first dialysis or renal transplantation.

Renal replacement modality

Therapy modality was classified as: haemodialysis (HD), peritoneal dialysis (PD) or renal transplantation.

Statistics

Agreement on renal diagnosis and dialysis modality between NRDT and medical records was expressed by the proportion of concordance with the information of the medical records as gold standard. The kappa value was used to measure how much better the percentage of concordance was than expected by chance. The following definition of the kappa values was used: <0.41 poor agreement, 0.41–0.74 good agreement and >0.74 excellent agreement [11,12]. Sensitivity was defined as the proportion of patients with the same diagnosis according to medical records and NRDT compared to all patients with that diagnosis according to medical records. Specificity was defined as the proportion of patients not having a specific renal diagnosis in medical records and NRDT compared to all patients without that specific diagnosis according to the information of medical records. The positive predictive value was defined as the proportion of patients with the same diagnosis according to both medical records and NRDT compared to all patients with that diagnosis in NRDT. The negative predictive value was defined as the proportion of patients not having a specific renal diagnosis according to NRDT and medical records compared to all patients without that diagnosis in NRDT.

All statistical analyses were performed using SAS version 9.1, SAS Institute Inc.

Ethical considerations

The study was approved by the Danish Society of Nephrology, the Danish Data Protection Agency and the six nephrological departments involved in the validity study. Registry studies do not need approval from ethical committees.

Results

Completeness

The number of dialysis procedures registered in NPR 2001–2004 was 955 516 given to 8402 different persons. A total of 772 renal transplantations in 653 persons were registered in the NPR during the same period. In 2001–2004, 3020 patients were registered for the first time in NPR with the procedure of renal transplantation or dialysis for a minimum of 12 times and 90 days and a ratio of days per dialysis ≤7 days or at least one code of chronic dialysis. A total of 2934 (97.2%) of these patients were registered as new patients in NRDT from start of the registry to 2006 and 2255 (74.7%) in the period 2001–2004 (Table 1).

There was no regional variation of completeness or variation between hospitals.

Validity

Two of the 120 patients were withdrawn from the study because they had died more than 10 years ago, and medical records had been destroyed. It was verified that both had been chronic RRT patients.

None of the 120 patients received a renal transplant as the first form of RRT. Ten (8%) of the 118 patients died within 89 days of RRT (median 49 days, range 8–85). Six of these 10 patients suffered from CKD. Chronicity in the remaining four patients was unclarified.

Validity of renal diagnoses

Comparison of renal diagnoses between NRDT and the patient records is shown in Table 2. Twenty-six (22%) of the patients in NRDT had diabetic nephropathy in accordance with information of the medical records. One patient
(0.8%) with diabetic nephropathy according to the medical record (type 2 diabetes with diabetic retinopathy) had another renal diagnosis in NRDT. Agreement for diabetic nephropathy was 99%, for APKD 99% and for GN 97%, respectively. Thirty-five patients (30%) were diagnosed as CKD of unknown aetiology in NRDT. Five of these patients had another diagnosis in their medical records. Agreement of CKD of unknown aetiology was 83%.

Validity of diabetes type

Among patients with diabetic nephropathy, 13 patients (50%) were registered as type 1 diabetics in the NRDT. According to their medical records, seven of these patients were type 2 diabetics treated with insulin or oral anti-diabetic medication. Thirteen patients (50%) were registered as type 2 diabetics in the NRDT. According to their medical records, this was true for all (Table 3).

Due to the poor agreement in diabetes type between medical records and NRDT, additional 25 patients classified as type 1 diabetics in the NRDT, an additional were studied. According to their medical records, 11 (44%) of these patients were type 2 diabetics, and 2 (8%) suffered from diabetes secondary to chronic pancreatitis. Among the total sample of 38 type 1 diabetics in NRDT, 18 patients (47%) had type 2 diabetes according to their medical record. Six (33%) of these patients were being treated with an oral anti-diabetic drug at start of RRT, and 12 (67%) were being treated with insulin but had anamnestic information of previous treatment with diet or an oral anti-diabetic drug. Two patients (5%) had diabetes secondary to chronic pancreatitis, and 18 patients (47%) had type 1 diabetes according to their medical record. Sensitivity, specificity, predictive and kappa values are given in Table 4. The predictive values were generally high apart from type 1 diabetes. Sensitivity and specificity were high except for type 2 diabetes and chronic nephropathy of unknown aetiology. The kappa values showed excellent agreement for all diagnoses except for type of diabetes and CKD of unknown aetiology.

Validity of time for initiation of renal replacement therapy

Compared with medical records, 46% of the 118 studied patients were registered in NRDT as having started RRT on the exact date. Eighty-seven percent of the 118 patients were in the NRDT within a range of −30 to +30 days and 95% within −90 to +90 days from the date of registration in the medical records. The mean difference was +8.5 days. One patient; who had previously started dialysis in another country, was registered more than 1 year after start of RRT.

Validity of dialysis modality

None of the 118 incident RRT patients received a renal transplant as the initial treatment. According to medical re-

Table 2. Validity of common renal diagnoses in a randomly selected 2% sample of incident renal replacement therapy patients registered in The Danish Registry on Regular Dialysis and Transplantation (NRDT) (n = 118)

|                | In NRDT | Not in NRDT | Agreement
<table>
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<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>In medical records</td>
<td>Not in medical records</td>
<td>In medical records</td>
</tr>
<tr>
<td>Diabetic nephropathy</td>
<td>26</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>APKD</td>
<td>10</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Chronic GN</td>
<td>8</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>CKD of unknown aetiology</td>
<td>30</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

Agreement is calculated as the numbers positive in both medical records and NRDT and the numbers negative in both registries.
Diabetic nephropathy, type 1 6 (23%) 7 (27%)
Diabetic nephropathy, type 2 0 13 (50%)

The present study shows that 97% of incident RRT patients according to NPR could be found in NRDT with no significant regional variation, and the validity of data registration in the patients was generally acceptable. Data completeness was studied in a 4-year cohort of 3020 patients and data validity in a sample of 118 randomly selected patients from a 10-year cohort.

Though of great importance, validation of clinical registries rarely includes completeness because there are no accessible data for studying completeness. The use of the personal registration number in Denmark given to all citizens at birth makes possible the linkage between NRDT and the administrative NPR on which payment for any treatment is based. In the present study, incident chronic RRT patients were identified in NPR mainly by treatment codes instead of diagnostic codes. This seems to be the most reliable method for evaluation of completeness. To our knowledge, there are no previous studies on data completeness in renal registries. The US renal data system (USRDS) database is widely used, but completeness was not assessed in the previous validation study [13]. The predictive value of information and completeness of non-renal registries varied with completeness ranging from 85% to 100% [14–20].

The advantage of registry research in general is that an unselected large patient population is studied, but the data have to be complete and valid. If the registry is used to study incidence or prevalence, it is crucial that the registry is complete. In registries of frequent diseases, completeness might be assessed by comparison with a randomly selected sample of medical records. For rare diseases such as CKD, the only way to study registry completeness is by comparison with another independent registry. The validity of the data in the registry can be verified by the use of a randomly selected sample of medical records among patients included in the registry. A disadvantage of registry research is the limited amount of clinical data included in the registries and that the data may be unreliable. This has recently been discussed by Jager and Zoccali focusing on the importance of comorbidity data in renal registries. The need for valid data on comorbidity is crucial when adjusting mortality rates in RRT [21].

We found that three well-defined and frequent renal diagnoses, diabetic nephropathy, chronic GN and APKD, showed a very high agreement at 97–99% between medical records and NRDT. In nearly half of the 118 incident RRT patients, the treatment start date was correctly registered, and in 95% of all, the difference between the medical record date and the registry date was less than 3 months. Also, the registration of the treatment modalities pre-emptive renal transplantation, haemodialysis and peritoneal dialysis was correct in almost all patients. These results are in accordance with the USRDS data validation study, which was performed in 1986–1987 in a random sample of 1692 (2.6%) patients drawn from the total of 65 000 new RRT patients. The USRDS data were compared with information in medical records to assess reliability. The study showed a perfect agreement of date of RRT service start for 64% of the new RRT patients, and for 94% the difference between medical records and registry information on start date was 60 days or less. The agreement on RRT modality was 85.6%, and the overall agreement on primary diagnosis was 79.4% [13]. There are no published data on the validity of the European national renal registries.

By contrast, our study showed a rather low agreement between NRDT and medical records for the diagnosis CKD of unknown aetiology. This diagnosis is normally used in patients with severe renal failure when CKD is diagnosed because advanced renal disease often makes it impossible to establish the underlying renal disease. However, based on anamnestic information, a tentative specific renal diagnosis might be suggested. This probably explains the frequent discrepancy between medical record and NRDT regarding the diagnosis CKD of unknown aetiology [22].

Importantly, we found that information on the type of diabetes in NRDT was often incorrect when compared to medical record information. In the primary validated co-

<table>
<thead>
<tr>
<th>Diagnosis according to NRDT</th>
<th>Diagnosis according to medical record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic nephropathy type 1</td>
<td>6 (23%) 7 (27%)</td>
</tr>
<tr>
<td>Diabetic nephropathy type 2</td>
<td>0 13 (50%)</td>
</tr>
</tbody>
</table>

**Table 3. Validity of the diagnoses type 1 and 2 diabetes in incident renal replacement therapy patients with diabetic nephropathy in The Danish Registry on Regular Dialysis and Transplantation (NRDT) (n = 26)**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>kappa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic nephropathy</td>
<td>96</td>
<td>100</td>
<td>100</td>
<td>99</td>
<td>0.98</td>
</tr>
<tr>
<td>Diabetic nephropathy, type 1</td>
<td>100</td>
<td>94</td>
<td>46</td>
<td>100</td>
<td>0.60</td>
</tr>
<tr>
<td>Diabetic nephropathy, type 2</td>
<td>62</td>
<td>100</td>
<td>100</td>
<td>92</td>
<td>0.73</td>
</tr>
<tr>
<td>APKD</td>
<td>100</td>
<td>99</td>
<td>91</td>
<td>100</td>
<td>0.95</td>
</tr>
<tr>
<td>Chronic GN</td>
<td>80</td>
<td>98</td>
<td>80</td>
<td>98</td>
<td>0.78</td>
</tr>
<tr>
<td>CKD of unknown aetiology</td>
<td>67</td>
<td>93</td>
<td>86</td>
<td>82</td>
<td>0.62</td>
</tr>
</tbody>
</table>

**Table 4. Sensitivity, specificity, positive and negative predictive values (PPV and NPV) and kappa values of renal diagnoses in The Danish Registry on Regular Dialysis and Transplantation**
hort, 35% of the type 2 diabetic patients were incorrectly classified as type 1 diabetics, whereas no type 1 diabetics were misclassified as type 2. This misregistration in NRDT of diabetic type was verified in an additional sample of type 1 diabetics, which showed that 44% of these had type 2 diabetes according to their medical records. The frequently incorrect classification of type 2 diabetics is probably due to the use of insulin in approximately 2:3 of these patients at the time of initiation of RRT. Incorrect classification of type of diabetes needs to be taken into consideration when evaluating the epidemiology of diabetic nephropathy and the effect of renal protective therapy in diabetic nephropathy.

The good quality of data in the NRDT probably reflects that data reporting is well organized and highly prioritized among Danish nephrologists. Furthermore, there is only one consultant doctor responsible for referring data in each nephrological centre [1].

In conclusion, completeness and validity of incident patient registration in the Danish registry on chronic end-stage kidney disease is highly acceptable, except for type of diabetes as many type 2 diabetics seems to be incorrectly classified as type 1 diabetics. The registry contains data on all RRT patients in an ethnically homogeneous background population of 5.4 million people. With data being valid and the registry complete, it offers a good source of data for evaluation of treatment quality, prognosis of treatment activity and for epidemiological studies of kidney disease as the use of administrative and clinical registries is widespread in Denmark.

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Conflict of interest statement. None declared.

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