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Nephrology
Dialysis
Transplantation

Registry Report

Renal replacement therapy in Europe: the results of a collaborative effort by the ERA–EDTA registry and six national or regional registries

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Abstract

Background. In June 2000 a new ERA–EDTA Registry Office was opened in Amsterdam. This Registry will only collect core data on renal replacement therapy (RRT) through national and regional registries. This paper reports the technical and epidemiological results of a pilot study combining the data from six registries.

Methods. Data from the national renal registries of Austria, Finland, French-Belgium, The Netherlands, Norway, and Scotland were combined. Patients starting RRT between 1980 and 1999 ($n = 57\,371$) were included in the analyses. Cox proportional hazards regression was used to predict survival.

Results. The use of different coding systems for ESRD treatment by the registries made it difficult to merge the data. Incidence and prevalence of RRT showed a continuous increase with a marked variation in rates between countries. The 2-, 5- and 10-year patient survival was 67, 35 and 11% in dialysis patients and 90, 81 and 64% after a first renal allograft. Multivariate analysis showed a slightly better survival on dialysis in the 1990–1994 (RR 0.94, 95% CI 0.90–0.98) and the 1995–1999 cohort (RR 0.88, 95% CI 0.84–0.92) compared to the 1980–1984 cohort. In contrast, there was a much greater improvement in transplant-patient survival, resulting in a 56% reduction in the risk of death within the 1995–1999 cohort (RR 0.44, 95% CI 0.39–0.50) compared to the 1980–1984 cohort.

Conclusions. This study provides support for the feasibility of a 'new style' ERA–EDTA registry and the collection of data is now being extended to other countries. The improvement in patient survival over the last two decades has been much greater in transplant recipients than in dialysis patients.

Keywords: epidemiology; Europe; mortality; primary renal disease; renal replacement therapy; technique survival

Introduction

At the end of 1999 the ERA–EDTA closed its Registry Office in St Thomas' Hospital in London, and on 1 June 2000 a new Registry Office was opened in the Academic Medical Center (AMC) in Amsterdam. For a number of reasons the data collected through the Registry Office in London were meantime left in the United Kingdom [1]. One of the priorities of the Amsterdam Office has been to build a new relational database in order to acquire and analyse recent data on renal replacement therapy (RRT). Instead of collecting data from both individual renal units and national registries as the London Office did, it was decided that the Amsterdam Office would only collect

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data through national and regional registries from within the ERA–EDTA area.

During the summer of 2000 we started to build a database to test the technical aspects of combining data from different countries. The aims of this paper are firstly to describe the difficulties encountered in the process of combining these data, and secondly to report some recent renal epidemiology data for Europe, based on the data of the countries taking part in this pilot project.

Methods

Data collection

The renal registries of Austria, Finland, French-Belgium, The Netherlands, Norway, and Scotland were asked to participate in this project because of the expected quality and ready availability of their data over the last 20 years. All six registries agreed to participate. The Amsterdam Office asked for a data set comprising a limited number of patient and treatment variables. This set included a (meaningless) national registry patient identifier, date of birth, gender, primary renal disease, date of start of first RRT, history of RRT with dates and changes of modality, treatment centre, date and cause of death, and information concerning transfer from or to other renal registries.

Data processing

The data sets were received at the AMC in Open-Data-Base-Connectivity (ODBC) compatible file-formats. Most of them had been sent in an encrypted form. After performing consistency checks the data were converted to the desired format in order to make storage in our relational and event-driven database (Microsoft® SQL Server™) possible. The core database consists of a patient and a transaction table and can be extended according to future needs.

Data analysis

We analysed data from 1980 to 1999. An exception was made for French-Belgium, because suitable data were not available before 1985.

The date of onset of ESRD was defined as the date of start of RRT. We excluded patients with a diagnosis of acute renal failure, patients not residing in the area of a contributing registry, and patients with a missing start date. The incidence of RRT was defined as the number of new cases per year. The prevalence was defined as the number of patients alive and on RRT on 31 December. For both parameters, the mid-year population was used as denominator. Renal disease and causes of death were defined according to the ERA–EDTA coding systems (appendices 1 and 2). We classified the primary renal diseases into eight and the causes of death into 11 groups.

Differences between groups were analysed with *t*-tests for continuous variables and chi-square tests for categorical variables. A two-sided *P*-value less than 0.05 was considered statistically significant. Statistical analysis of mortality and technique failure was performed by the Kaplan–Meier method and by Cox proportional hazards regression. The first day on dialysis was taken as the starting point for the analysis of patient survival on dialysis. The small number of patients whose first mode of treatment was transplantation ($n = 1669$) have been excluded from this analysis. The death of the patient was the event studied. Transplantation and recovery of renal function were censored observations. For the analysis of patient survival after transplantation, we took the date of the first renal transplant as the first day of follow-up. Death was the event, whereas the follow-up time was censored at loss of follow-up. In the analysis of technique survival on dialysis, the first dialysis modality was defined as the treatment the patient received 90 days after the start of dialysis. This was done to address the fact that some patients receive haemodialysis for a very short period, while preparations are made for peritoneal dialysis. Technique failure was defined as transfer to the other dialysis modality; follow-up time was censored at death, transplantation, recovery of renal function, and at loss of follow-up. For first renal allograft recipients, both the start of dialysis and death were defined as graft failure. The follow-up time of patients alive and on RRT as of 31 December 1999 was censored at that date. To study the change of mortality and technique failure survival over time, we classified the patients according to start of dialysis or first renal transplant.

Results

Data processing

All delivered data formats could be used without difficulty. The problems encountered during data processing concerned the use of different coding systems for ESRD treatment by the contributing registries and, to a smaller extent, the different coding systems for primary renal disease and causes of death (1994 and 1995 versions of the ERA–EDTA codes). Furthermore, the lack of formal data dictionaries complicated the merging process.

Any difficulties concerning interpretation of the data were solved in consultation with the contributing registries. The problems of the different coding systems were addressed by grouping different codes. In total, the data processing was completed in 6 weeks.

Patients

We received data on 66 607 patients, some of whom started RRT as far back as the late 1960s. Table 1 shows the number of patients starting RRT from 1980 to 1999 according to registry of origin.

The incidence and prevalence of RRT per million population (p.m.p.) are shown in the Figures 1 and 2 respectively. As expected, both increased over this period of 20 years in all countries. In 1999, the incidence of RRT in French-Belgium was twice that of Norway and also the prevalence showed a marked variation between countries. The mean age of incident patients increased by 14 years. In 1999, it varied from 57 years in Finland to 63 years in French Belgium. In patients with adult type polycystic kidney disease, the increase in age was only 4 years.

Figure 3 shows that in relative terms the contribution of glomerulonephritis/sclerosis and pyelonephritis

to incident RRT declined between 1980 and 1999. However, the incidence of these diseases remained relatively stable, varying between 11 and 16 p.m.p. for glomerulonephritis/sclerosis and between 6 and 9 p.m.p. for pyelonephritis.

Events

After a median follow-up time of 2.7 years (range 0–20 years) there had been 31 106 deaths, 790 patients had recovered renal function, and 396 were lost to follow-up. At 31 December 1999 there were 25 070 patients alive and on RRT. During the observation period there were 19 804 first transplants (2621 living, 14 027 cadaveric, and 3156 with donor type unknown).

Cause of death

Data on the cause of death were missing for 22% of the deceased patients, which was primarily due to the very high percentage of missing values in the 1980s. We therefore decided to limit the analysis of the causes of death to those years in which the data were complete for more than 85%. This criterion was satisfied from 1991 to 1999 (mean of missing values 12%) and during this time there were 19 851 deaths, 17 924 of which were in dialysis patients and 1927 in patients with a functioning transplant. Over this 9-year period the distribution of causes of death did not change. The most common cause of death was cardiac, accounting for 36% of deaths in dialysis patients and 35% in the transplant group (Figure 4). However, when cardiac deaths were subdivided, myocardial ischaemia and infarction were more common in transplant recipients, while heart failure and cardiac arrest occurred more frequently in the dialysis patients. Death from a cerebrovascular accident and from malignancy occurred more often in transplant recipients than in patients on dialysis, but in contrast cachexia, withdrawal from treatment, and suicide occurred much less frequently.

Table 1. Data according to registry of origin

	Millions of inhabitants (1999)	No of new patients (1980–1999)*
Austria	8.2	13 313
French-Belgium	4.3	6430
Finland	5.2	5742
Netherlands	15.7	20 191
Norway	4.4	5215
Scotland	5.2	6480
Total	43	57 371

*Data from French-Belgium relate to the period 1985–1999

Mortality

Dialysis. For the entire cohort 2-, 5-, and 10-year patient survival on dialysis was 67, 35, and 11%. After adjustment for age, gender, and diabetes mellitus, the survival of patients starting dialysis was slightly better for the 1990–1994 cohort (RR 0.94, 95% CI 0.90–0.98) and the 1995–1999 cohort (RR 0.88, 95% CI 0.84–0.92) compared to the 1980–1984 cohort (Figure 5).

Transplantation. Patient survival in first renal allograft recipients was 90, 81, and 64% at 2, 5 and 10 years after the transplant. After adjustment for

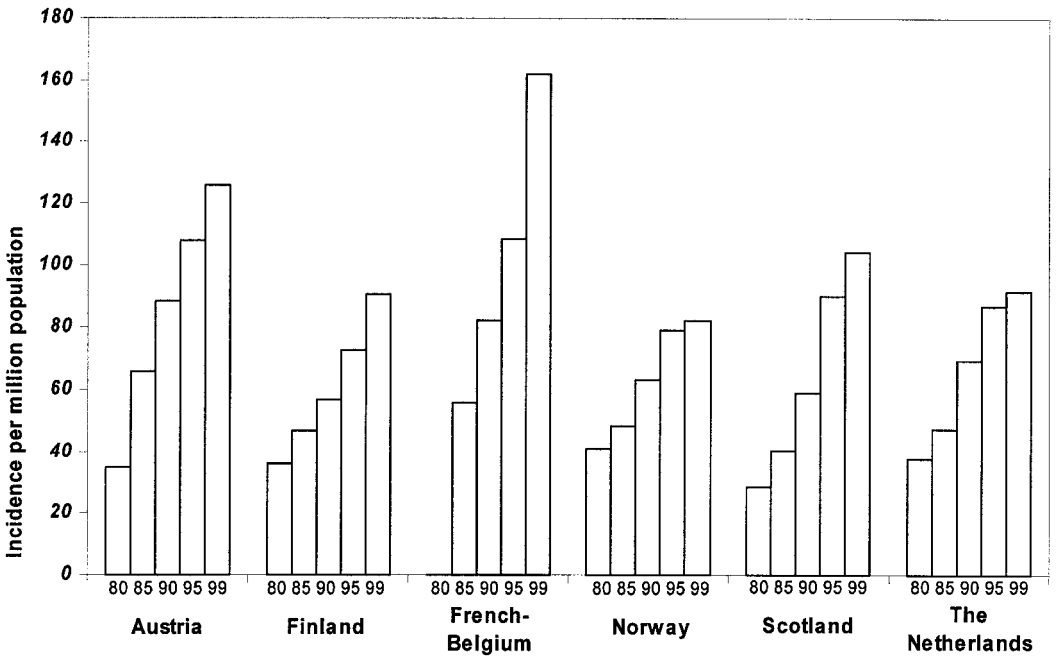

Fig. 1. Incidence of RRT per million population by registry 1980–1999.

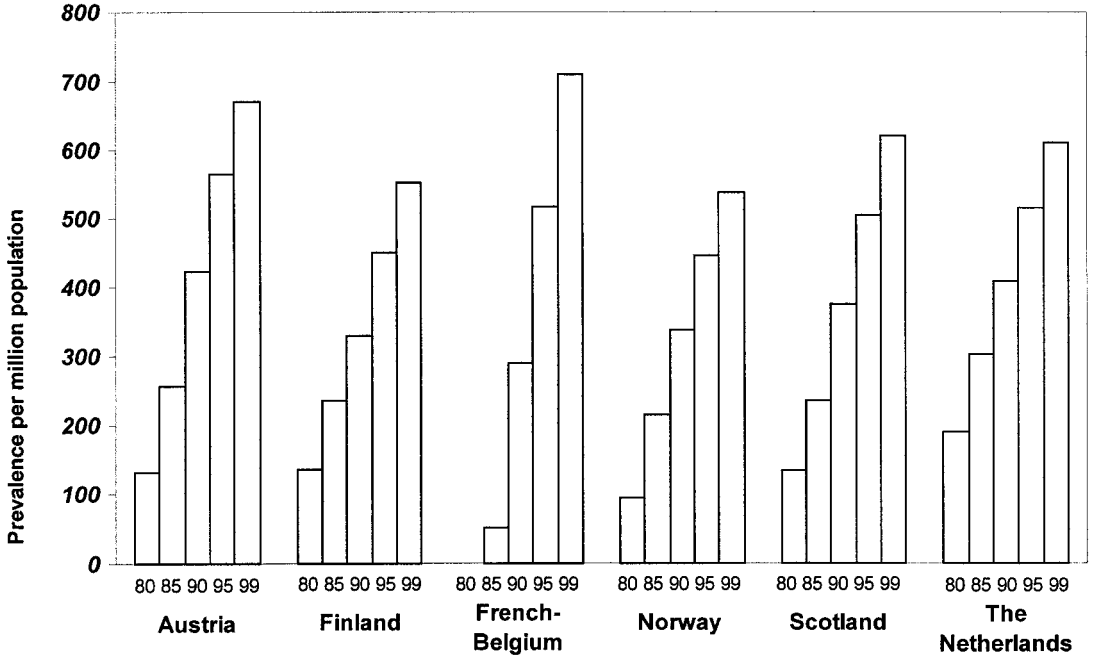

Fig. 2. Prevalence of RRT per million population by registry 1980–1999.

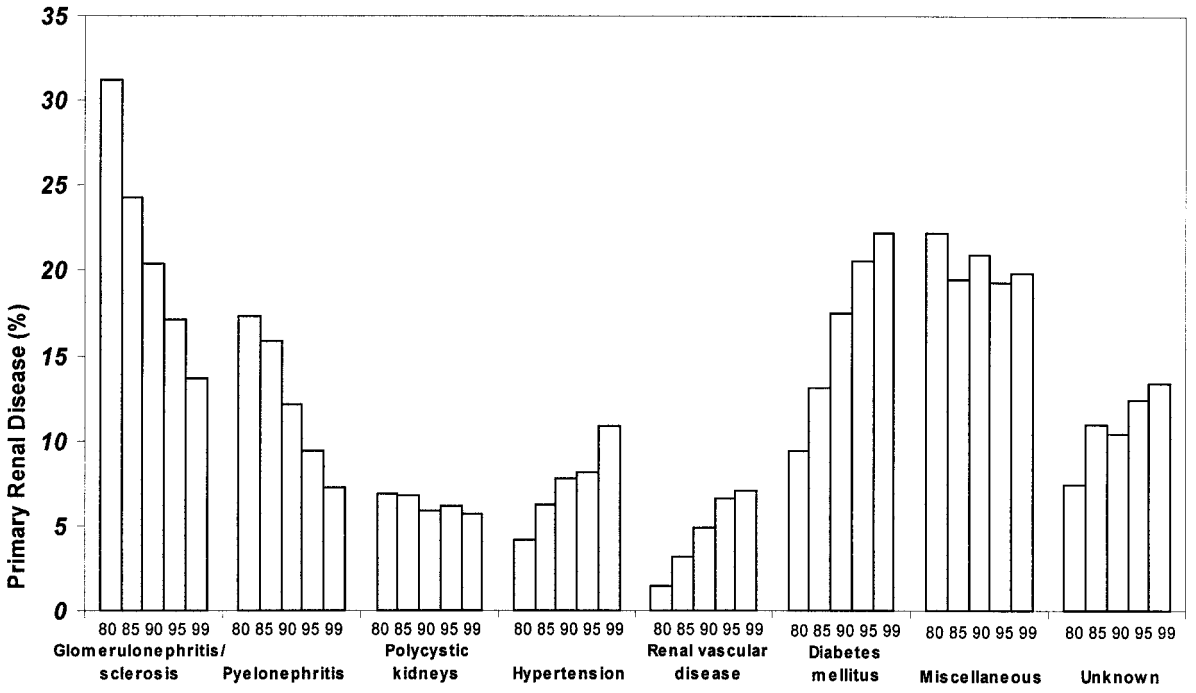

Fig. 3. Distribution of primary renal disease (%) in incident patients 1980–1999.

age, gender, diabetes mellitus, and graft source (living or cadaveric donor), there was a marked improvement in the survival of first renal allograft recipients. Compared to the 1980–1984 cohort, the subsequent cohorts showed an increasing reduction in the risk of death of 19, 32, and 56% respectively (1985–1989 cohort, RR 0.81, 95% CI 0.75–0.88; 1990–1994 cohort, RR 0.68, 95% CI 0.62–0.74; 1995–1999 cohort, RR 0.44, 95% CI 0.39–0.50). Figure 6 suggests that this improvement relates to both short- and long-term survival.

Technique failure

Dialysis. Two-, 5-, and 10-year technique survival was 96, 93, and 89% in haemodialysis patients and 76,

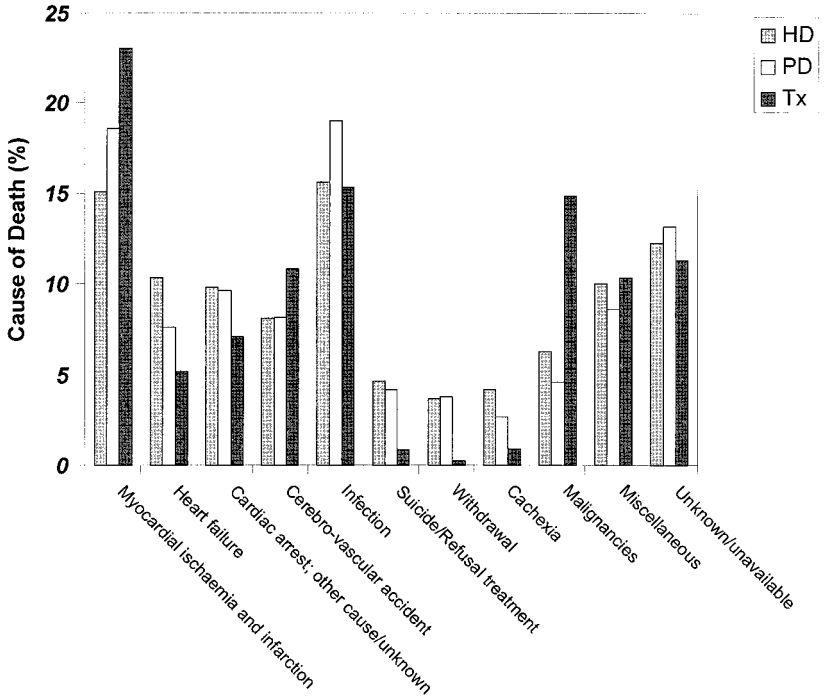

Fig. 4. Causes of death by treatment modality at the time of death.

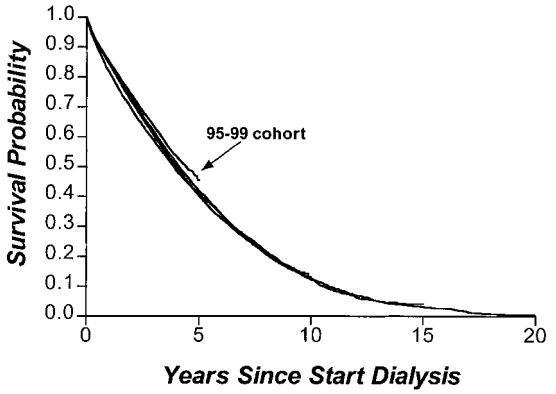

Fig. 5. Patient survival on dialysis for patients starting dialysis in different time periods (adjusted for age, gender, and diabetes mellitus).

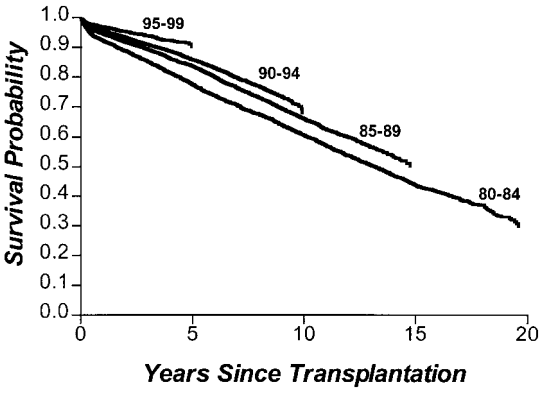

Fig. 6. Patient survival in first renal allograft recipients in different time periods (adjusted for age, gender, diabetes mellitus, and donor type).

49, and 22% in those on peritoneal dialysis. For both modalities the crude technique survival remained unchanged over time, but after correction for age, gender, and diabetes mellitus, there was a slight reduction in haemodialysis technique survival in the most recent cohort (RR 1.24, 95% CI 1.06–1.45). The peritoneal dialysis technique failure was lower in the 1985–1989 cohort (RR 0.76, 95% CI 0.66–0.88) compared to the 1980–1984 cohort, but increased again in subsequent years.

Transplantation. Graft survival was 78, 65, and 47% at 2, 5, and 10 years for the entire cohort. There was a steady decline in graft failure over the four periods and this is shown in Figure 7.

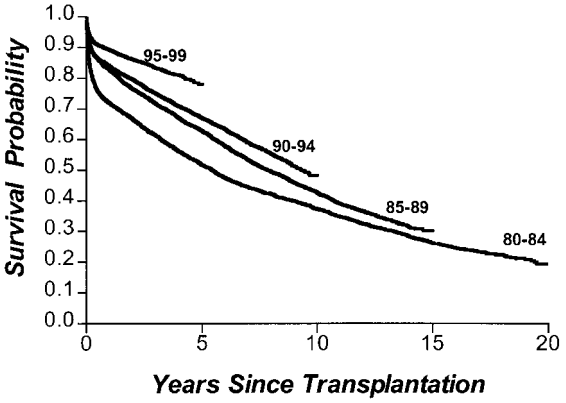

Fig. 7. Graft survival in first renal allograft recipients in different time periods (adjusted for age, gender, diabetes mellitus, and donor type).

Discussion

This project has shown that it is feasible to combine data from different renal registries and to generate basic renal epidemiology data. After receipt of the data, the data processing was completed within 6 weeks. The addition of data from more registries in the future may, however, increase the complexity of the process. For this and other reasons, the ERA–EDTA Registry and the national and regional renal registries within Europe should make a joint effort to standardize their definitions and to achieve cross-mapping between current coding systems. Furthermore, the use of formal data dictionaries is needed.

The continuous increase in incidence and prevalence of RRT is a world-wide phenomenon, although the rates in Europe are still much lower than in the US [2–4]. The increase in rates applies especially to patients with diabetes mellitus [2,5] and renal vascular disease [2]. The increased incidence of RRT has also been attributed to increased acceptance to therapy, improved survival from other diseases (survival from competing risk), and/or an increase in the true incidence of renal disease [6]. In addition, renal disease may be more often detected and reported. Contrary to some predictions, there are no signs yet of a halt to the increasing incidence of RRT, and although this increase is universal, the numbers p.m.p. differ substantially between countries as can be seen from our data. It is not well understood why this is the case. The acceptance for RRT or the referral patterns may differ among countries, but also general population characteristics and the prevalence of diseases leading to ESRD may vary. Both the increased incidence of RRT and the improved survival of transplant recipients will contribute to the increasing prevalence. The reasons for the differences in incidence between countries will be the subject of further study within our registry.

With respect to the causes of death, a comparison with US data is hampered by the use of different coding systems. Nevertheless, a broad comparison with those data [7] reveals no major differences in the distribution of the causes of death, except that our data suggest a lower percentage of cardiac deaths in dialysis patients. Due to the large numbers of patients in all our death categories, relatively small differences between dialysis and transplant patients reached statistical significance. These modality differences are most probably confounded by patient characteristics and therefore need further study.

The most important finding of this analysis is that there was a slight improvement in the more recent cohorts in the survival of dialysis patients, whereas the survival of renal transplant recipients has improved substantially. Our results show less improvement in survival of dialysis patients than a previous ERA–EDTA Registry report, which demonstrated a 4% increase by each calendar year of starting RRT between 1975 and 1992 [8]. There are, however, some differences between our studies. Elinder *et al.* [8] studied data from an earlier period, and their patient groups differed with respect to diagnosis and age. There are also differences in analytical methods, as we censored the follow-up times of patients at the time of transplant, whereas Elinder *et al.* included those patients who have a more favourable outcome. Registries in Canada and the US have shown improved case-mix adjusted survival in dialysis patients in recent years [9–12], but this is in the context of previous reports of higher mortality rates on dialysis in the US than in European countries. Unlike the American registries, we are not able to correct for important prognostic factors, other than for the presence of diabetes mellitus as a cause of ESRD, as European registries do not usually collect this information.

In contrast, there has been a considerable improvement in the survival of first renal allograft recipients and this has also been shown in other registry publications [13]. In this analysis of the UNOS database, the risk of death with a functioning graft was 67% less in patients who received transplants in 1997 compared with those transplanted in 1988.

As expected, the haemodialysis technique survival was greater than that of peritoneal dialysis. It is disappointing that there has only been a temporary improvement of peritoneal dialysis technique survival, despite increasing experience with the technique and decreasing peritonitis rates. This will be subject of further study.

As with patient survival following renal transplantation, the survival of the grafts has also improved substantially over the past 10–20 years both in the US [2,14] and in Europe [15]. Multiple factors have probably contributed to the increasing success of renal transplantation, especially the availability of more potent immunosuppressive drugs [16]. Our current data set does not permit a more extensive investigation of the determinants of patient and allograft survival.

Conclusion

This project provides support for the feasibility of a 'new style' ERA–EDTA Registry based on collaboration between the ERA–EDTA and the national and regional registries. During this pilot project it became evident that registry practice varies, even within this group of well-established contributing registries. The results of this pilot study strengthen the case for the establishment of a common terminology within the ERA–EDTA area and, if feasible, around the world. The International Federation of Renal Registries has recently taken a first step in this process. With the addition of other registries and the start of new research projects, the work of our European registry will become more complex. It will also become more interesting, creating the possibility of studying to what extent apparent differences in outcome are caused by variations in patient care protocols and registry practice across countries.

The data collected have confirmed a further growth of RRT incidence and prevalence over the last decade. They have also shown a slight improvement in patient survival on dialysis over the last 20 years. Others had already shown an improvement in patient survival on RRT. This analysis suggests the latter is primarily an effect of the improvement of transplantation results.

The first test database will now be expanded by adding the data of other registries. We hope that the new ERA–EDTA registry can make a meaningful contribution to research in the field of RRT. We intend to do this not only by providing basic data on RRT in Europe, but also by initiating focused studies and by assisting in the development of national registries in countries which at present lack one.

Acknowledgements. We would like to thank the patients and the staff of dialysis and transplant units for contributing the data *via* their national and regional renal registries.

Appendix 1

Primary renal disease (PRD)	1994	1995	PRD group
Glomerulonephritis; histologically NOT examined	10	10	I
Focal segmental glomerulosclerosis with nephrotic syndrome in children	11	11	I
IgA nephropathy (proven by immunofluorescence, not code 76 and not 85)	12	12	I
Dense deposit disease; membranoproliferative GN; type II (proven by immunofluorescence and/or electron microscopy)	13	13	I
Membranous nephropathy	14	14	I
Membranoproliferative GN; type I (proven by immunofluorescence and/or electron microscopy, not code 84 or 89)	15	15	I
Crescentic (extracapillary) glomerulonephritis (type I, II, III)	16	16	I
Focal segmental glomerulosclerosis with nephrotic syndrome in adults	17	17	I
Glomerulonephritis; histologically examined, not given above	19	19	I
Pyelonephritis, cause not specified	20	20	II
Pyelonephritis associated with neurogenic bladder	21	21	II
Pyelonephritis due to congenital obstructive uropathy with/without vesico-ureteric reflux	22	22	II
Pyelonephritis due to acquired obstructive uropathy	23	23	II
Pyelonephritis due to vesico-ureteric reflux without obstruction	24	24	II
Pyelonephritis due to urolithiasis	25	25	II
Pyelonephritis due to other cause	29	29	II
Interstitial nephritis (not pyelonephritis) due to other cause, or unspecified (not mentioned above)	30	30	VII
Nephropathy (interstitial) due to analgesic drugs	31	31	VII
Nephropathy (interstitial) due to cis-platinum	32	32	VII
Nephropathy (interstitial) due to cyclosporin A	33	33	VII
Lead-induced nephropathy (interstitial)		34	VII
Drug-induced nephropathy (interstitial) not mentioned above	39	39	VII
Cystic kidney disease, type unspecified	40	40	VII
Polycystic kidneys; adult type (dominant)	41	41	III
Polycystic kidneys; infantile (recessive)	42	42	VII
Medullary cystic disease; including nephronophthisis	43	43	VII
Cystic kidney disease, other specified type	49	49	VII
Hereditary/familial nephropathy, type unspecified	50	50	VII
Hereditary nephritis with nerve deafness (Alport's syndrome)	51	51	VII
Cystinosis	52	52	VII
Primary oxalosis	53	53	VII
Fabry's disease	54	54	VII
Hereditary nephropathy, other specified type	59	59	VII
Renal hypoplasia (congenital), type unspecified	60	60	VII
Oligomeganephronic hypoplasia	61	61	VII
Congenital renal dysplasia with or without urinary tract malformation	63	63	VII
Syndrome of agenesis of abdominal muscles (Prune belly)	66	66	VII

Primary renal disease (PRD)	1994	1995	PRD group
Renal vascular disease, type unspecified	70	70	V
Renal vascular disease due to malignant hypertension	71	71	IV
Renal vascular disease due to hypertension	72	72	IV
Renal vascular disease due to polyarteritis	73	73	VII
Wegener's granulomatosis	74	74	VII
Glomerulonephritis related to liver cirrhosis	76	76	VII
Cryoglobulinaemic glomerulonephritis		78	VII
Renal vascular disease, due to other cause (not given above and not code 84–88)	79	79	V
Diabetes glomerulosclerosis or diabetic nephropathy, type I	80	80	VI
Diabetes glomerulosclerosis or diabetic nephropathy, type II	81	80	VI
Myelomatosis/light-chain deposit disease	82	82	VII
Amyloid	83	83	VII
Lupus erythematosus	84	84	VII
Henoch–Schönlein purpura	85	85	VII
Goodpasture's syndrome	86	86	VII
Systemic sclerosis (scleroderma)	87	87	VII
Haemolytic uraemic syndrome (including Moschcowitz syndrome)	88	88	VII
Multi-system disease, other (not mentioned above)	89	89	VII
Tubular necrosis (irreversible) or cortical necrosis (different from 88)	90	90	VII
Tuberculosis	91	91	VII
Gout	92	92	VII
Nephrocalcinosis and hypercalcaemic nephropathy	93	93	VII
Balkan nephropathy	94	94	VII
Kidney tumour	95	95	VII
Traumatic or surgical loss of kidney	96	96	VII
Other identified renal disorders	99	99	VII
Chronic renal failure; aetiology uncertain	0	0	VIII

I, Glomerulonephritis/sclerosis; II, pyelonephritis; III, polycystic kidneys, adult type; IV, hypertension; V, renal vascular disease; VI, diabetes mellitus; VII, miscellaneous; VIII, unknown.

Appendix 2

Cause of death (COD)	1994	1995	COD group
Myocardial ischaemia and infarction	11	11	I
Hyperkalaemia	12	12	X
Haemorrhagic pericarditis	13	13	X
Other causes of cardiac failure	14	14	II
Cardiac arrest/sudden death; other cause or unknown	15	15	III
Hypertensive cardiac failure	16	16	II
Hypokalaemia	17	17	X
Fluid overload/pulmonary oedema	18	18	II
Pulmonary embolus	21	21	X
Cerebrovascular accident, other cause or unspecified	22	22	IV
Gastrointestinal haemorrhage	23	23	X
Haemorrhage from graft site	24	24	X
Haemorrhage from vascular access or dialysis circuit	25	25	X
Haemorrhage from ruptured vascular aneurysm (not codes 22 or 23)	26	26	X
Haemorrhage from surgery (not codes 23, 24 or 26)	27	27	X
Other haemorrhage (not codes 23–27)	28	28	X

Cause of death (COD)	1994	1995	COD group
Mesenteric infarction	29	29	X
Pulmonary infection (bacterial, not code 73)	31	31	V
Pulmonary infection (viral)	32	32	V
Pulmonary infection (fungal or protozoal; parasitic)	33	33	V
Infections elsewhere except virus hepatitis	34		V
Septicaemia	35	35	V
Tuberculosis (lung)	36	36	V
Tuberculosis (elsewhere)	37	37	V
Generalized viral infection	38	38	V
Peritonitis (all causes except for peritoneal dialysis)	39	39	V
Liver disease due to hepatitis B virus	41	41	X
Liver disease due to other viral hepatitis	42	42	X
Liver disease due to drug toxicity	43	43	X
Cirrhosis, not viral	44	44	X
Cystic liver disease	45	45	X
Liver failure, cause unknown	46	46	X
Patient refused further treatment for ESRD	51	51	VI
Suicide	52	52	VI
ESRF treatment ceased for any other reason	53	53	VII
ESRF treatment withdrawn for medical reasons		54	VII
Uraemia caused by graft failure	61		X
Pancreatitis	62	62	X
Bone marrow depression	63	63	X
Cachexia	64	64	VIII
Malignant disease, possibly induced by immunosuppressive therapy	66	66	IX
Malignant disease: solid tumours except those of 66	67	67	IX
Malignant disease: lymphoproliferative disorders except those of 66		68	IX
Dementia	69	69	X
Peritonitis (sclerosing, with peritoneal dialysis)	70	70	V
Perforation of peptic ulcer	71	71	X
Perforation of colon	72	72	X
Chronic obstructive airways disease	73	73	X
Accident related to ESRF treatment (not 25)	81	81	X
Accident unrelated to ESRF treatment	82	82	X
Other identified cause of death	99	99	XI
Peritonitis (bacterial, with peritoneal dialysis)		100	V
Peritonitis (fungal, with peritoneal dialysis)		101	V
Peritonitis (due to other cause, with peritoneal dialysis)		102	V
Cause of death uncertain/not determined	0	0	XI

I, myocardial ischaemia and infarction; II, heart failure; III, cardiac arrest, other cause/unknown; IV, cerebrovascular accident; V, infection; VI, suicide/refusal of treatment; VII, withdrawal from treatment; VIII, cachexia; IX, malignancies; X, miscellaneous; XI, unknown/unavailable.

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