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The
Norwegian Renal Registry

(Norsk Nefrologiregister)

This report will also be available on:
http://www.nephro.no/registry.html

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Preface

The Norwegian Renal Registry (Norsk Nefrologiregister) was formally constituted in 1994 as collaboration between The Norwegian Renal Association (Norsk Nyremedisinsk Forening) and Rikshospitalet University Hospital, with the latter as the formal owner. National data on renal replacement therapy (RRT) had been collected within The Renal Association since 1980 in a less formalised manner, and the transplant centre had stored data on transplanted patients since the sixties. Further, Norwegian renal units had reported to the ERA-EDTA-registry since the late sixties.

According to its statutes, The Norwegian Renal Registry shall combine the handling of data for all these purposes. It shall present national statistical reports and form a basis for research. Reports for 1995 and 1996 in Norwegian, and since 1997 in English, have been distributed; the latter five have also been made available on Internet.

National organisation and policy

Norway has 4.565 mill. inhabitants (July 2003) and 19 counties with populations ranging from 73300 to 520000. Each county, except one, has a central renal unit and some have additional unit(s) run in close contact with the central unit. There is only one transplant centre (two during 1963-83). Pre-transplant work-up, as well as post-transplant follow-up beyond 3 months, is handled by the county-centres.

The county-centres are responsible for reporting data from day 1 on all patients receiving renal replacement therapy (RRT) for chronic renal failure within their area. Treatment of acute renal failure is not reported unless the failure is irreversible, in which case the whole treatment period is included. Minor changes of treatment modality, e.g. from HD to HDF or between CAPD and APD, are not reported. Similarly, temporary changes to HD for PD-patients are not reported. At intervals, cross-checking for unreported deaths is performed against official census data.

Transplantation has always been considered the treatment of choice, if possible with a living related donor. Since 1984, also spouse donors have been used. Acceptance criteria for transplantation have been wide, strict age limits have not been applied. Over time, an increasing number of non-transplantable patients have also been offered life-long dialysis.

Incidence and prevalence calculations in this report are based on the national population data from July 2003, although this in some instances may be slightly misleading since population changes have not been uniform in all counties during the period.

Incidence figures for 2003

During 2003 a total of 436 new patients (in 2002: 419) entered renal replacement therapy (RRT), i.e. 95.5 per mill. inhabitants.

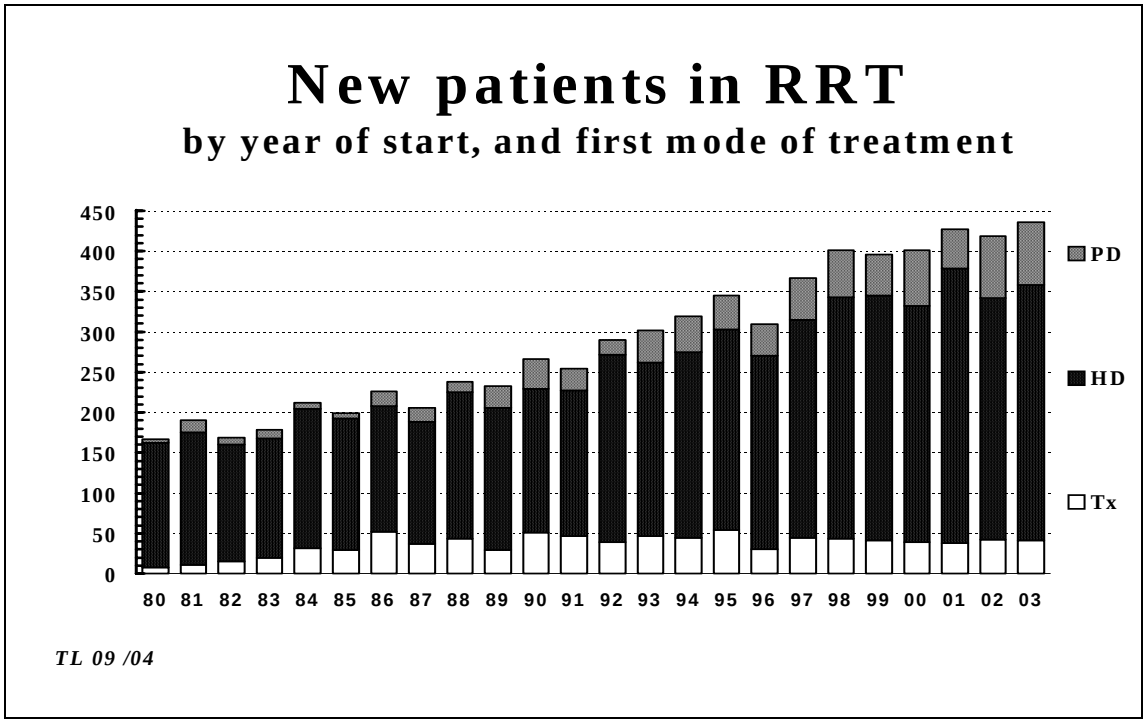
A majority of 68.3% were males and 31.7% females. Median age at start was 63.2 years, mean 60.2 years, ranging from 8 months to 90 years.

Tabulated by first mode of treatment, and age at start of treatment:

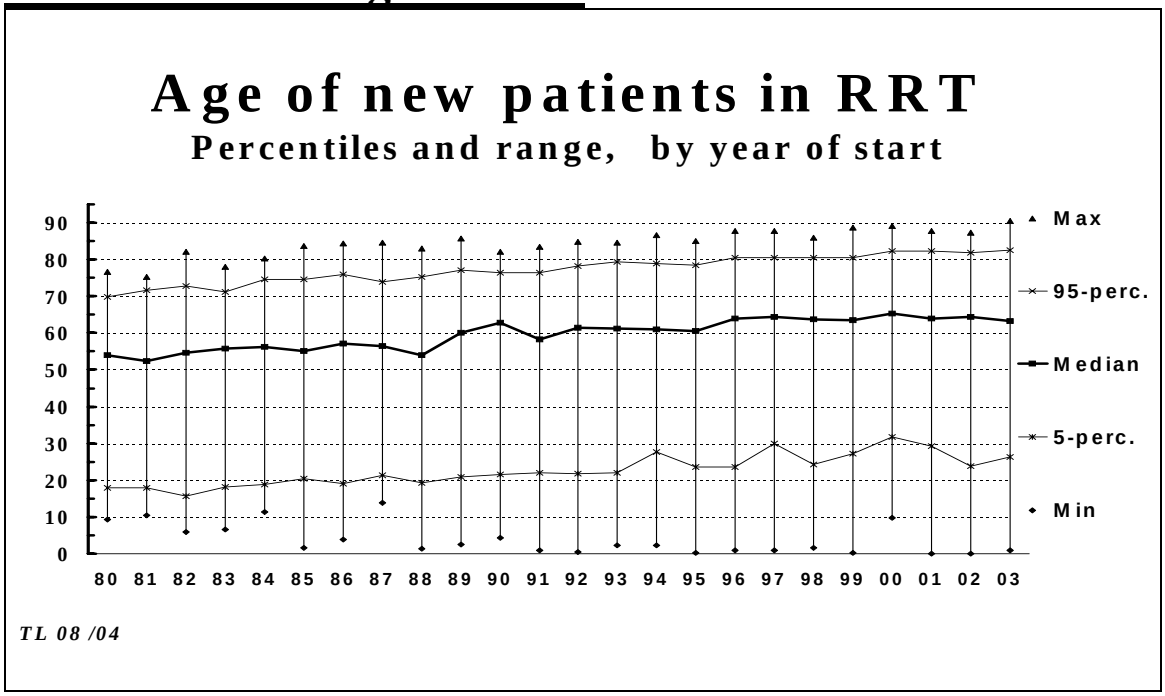
	< 15	15-24	25-34	35-44	45-54	55-64	65-74	75+	Total	in %
HD	1	7	24	22	38	67	70	88	317	72.7
PD	3	0	4	5	11	13	19	23	78	17.9
TX	6	4	4	6	11	8	0	2	41	9.4
Total	10	11	32	33	60	88	89	113	436	100
in %	2.3	2.5	7.3	7.6	13.8	20.2	20.4	25.9	100	

At start of treatment, 289 (66.3%) were considered by their nephrologist to be a potential candidate for transplantation, while 147 (33.7%) were accepted for life-long dialysis (constituting 38% of those starting with HD and 36% of those starting PD).
Among patients starting dialysis in 2003, 21% were previously unknown to the renal unit when they presented with terminal renal failure, 54% were known and started RRT as planned, while 25% were known but had a hastened RRT-start.

Incidence data: Changes 1980-2003



Incidence data: Age at start



Since registration started in 1980 there has been a continuous shift in patient age. Both the maximum and the median age at start of RRT have increased. Also the 5-percentile and 95-percentile values (i.e. including the majority of patients) have increased with a similar number of years. But also smaller children have been accepted, the youngest ever started PD in 2002 at age 13 days. The number of children below 15 years has not changed during the period - it has ranged from two to ten per year.

Incidence data: Primary renal disease

	1980-84	1985-89	1990-94	1995-99	2000-02	2003
Glomerulonephritis	34%	36%	31%	24%	18%	19%
Pyelo/interstitial nephr.	16%	14%	11%	12%	12%	8%
Polycystic diseases	10%	9%	9%	9%	8%	10%
Diabetic nephropathy	13%	12%	12%	11%	14%	16%
Amyloidosis	7%	6%	6%	4%	4%	2%
Vascular/hypertensive	5%	8%	18%	24%	28%	28%
Immune/systemic	4%	5%	4%	6%	4%	4%
Kidney tumour	1%	1%	1%	1%	1%	2%
Myelomatosis	3%	2%	1%	2%	3%	3%
Other defined	4%	4%	4%	3%	3%	4%
Unknown	3%	3%	3%	4%	4%	5%
N:	912	1106	1419	1817	1249	436

The main change over time has been an increase of vascular/hypertensive nephropathy and a relative reduction of glomerulonephritis. Whether this only reflects changed coding practice or a true shift is not known.

Diabetic nephropathy has contributed 10-15% per year. Until 1995 sub-classification was not reliably registered. In 2003, 25 were registered as having Type I and 43 as Type II diabetes. In addition 51 patients with other types of primary renal disease were recorded having diabetes as a co-morbid factor (all were Type II), thus 27% of new patients were diabetics.
The time from onset of diabetes to start of RRT differed considerably. For the 25 with Type I diabetes the mean time was 30.8 years, for the 43 with Type II diabetic nephropathy the mean time was 13.1 years. Type II diabetics judged to have a primary renal disease other than diabetic nephropathy in mean had 8.3 years of diabetes duration.

Cardiovascular disease is often present at start of RRT. Symptomatic heart disease was reported in 151 (35%); two out of these had a previous heart transplant. Cerebrovascular disease was reported in 48 (11%) and peripheral arteriosclerotic disease in 73 patients (17%).

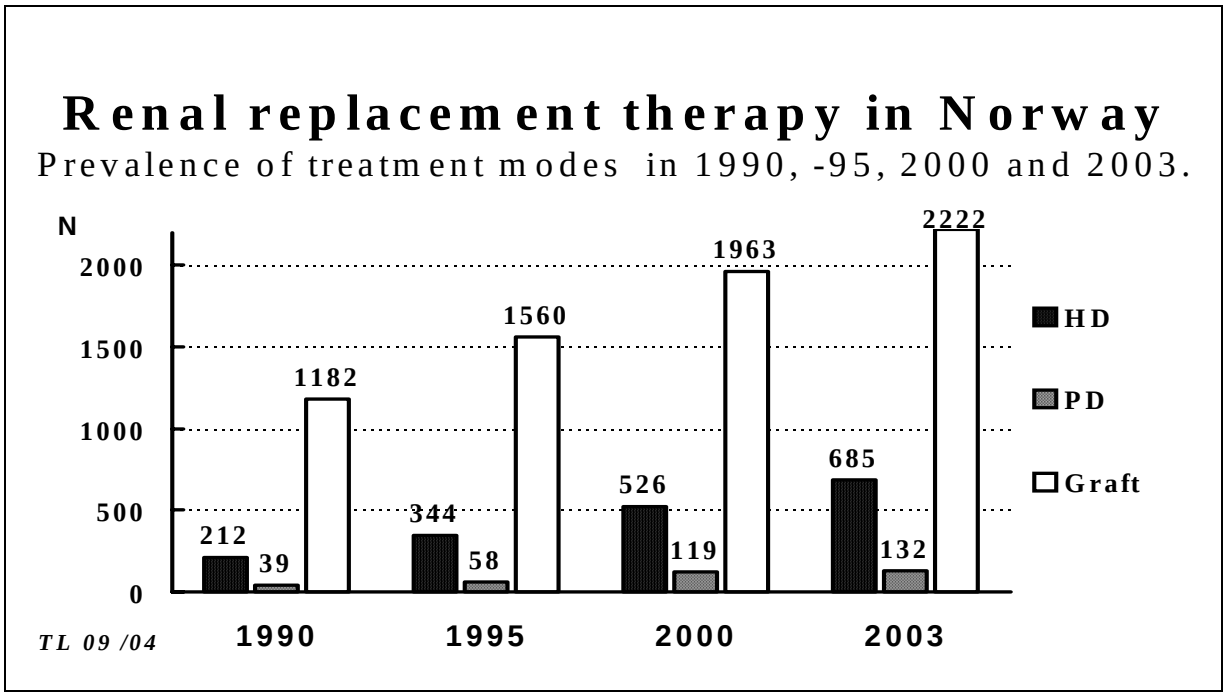
Prevalence data: Status by 31.dec. 2003.

By the end of 2003, 3039 patients in Norway received renal replacement therapy, i.e. 665.7 per million inhabitants. This represents an increase of 129 patients or 4.4 % since 2002.
Gender: 64.2% males and 35.8% females.

Median age by the end of the year was 56.2 years, mean 55.3 years and range 1.2-91.2 years.

Tabulated by last mode of treatment, and age by end of 2003:

	< 15	15-24	25-34	35-44	45-54	55-64	65-74	75+	Total	in %
HD	2	12	35	53	88	129	148	218	685	22.5
PD	1	0	7	8	15	26	36	39	132	4.3
TX	33	79	204	378	500	545	348	135	2222	73.1
Total	36	91	246	439	603	700	532	392	3039	100
In %	1.2	3.0	8.1	14.4	19.8	23.0	17.5	12.9	100	



Death in RRT in 2003:

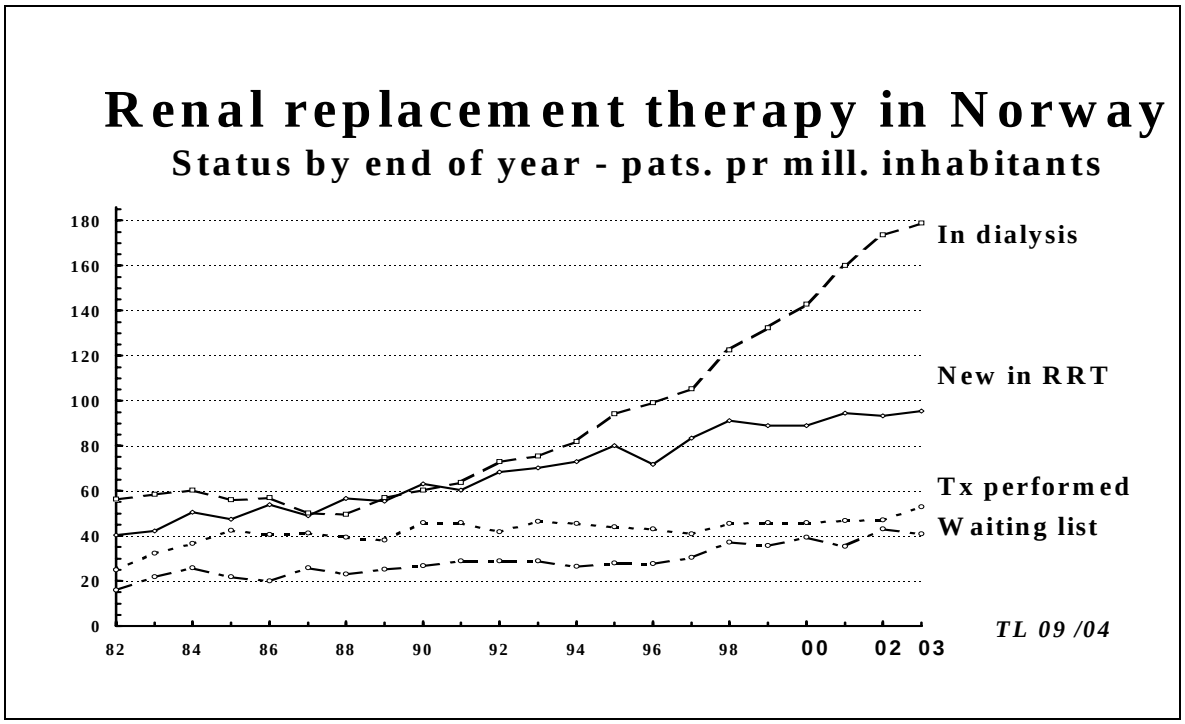
A total of 286 patients in renal replacement therapy died during 2003, i.e. 8.5 % out of the 3346 persons at risk. Among these, 69% were males and 31% females. Median age at death was 71 years, mean 69.1 years, and the range 23-89 years. Median time from start of RRT until death was 36 months, with a range spanning from day one to more than 28 years.
The final mode of treatment was HD for 169 patients and PD for 30, while 87 died with a more or less well-functioning graft. Two died within two months after graft loss; thus 89 deaths were termed 'TX-related'. 29 patients died following termination of treatment, 5 of those because the patient refused further treatment.
As in previous years, cardiac (33%) complications were the most frequent causes of death, followed by infections (17%), vascular complications (16%), and malignant tumours (16%).

Transplantation and waiting lists:

A total of 241 renal transplants were performed at Rikshospitalet University Hospital in 2003, i.e. 52.9 per million inhabitants. In 87 (36.1%) the graft came from a living donor (LD), 16 of those were biologically unrelated to the recipient (mainly spouses). Among the LD-graft recipients 29 were grafted pre-emptively. 154 patients received a cadaveric donor graft (CD), 12 were pre-emptively transplanted, while four had a re-graft without entering dialysis. There were 208 first grafts (79 LD and 129 CD), 29 were second grafts (7 LD, 22 CD), 2 third grafts (CD), one fourth (CD), and one sixth graft (LD). Simultaneous kidney + pancreas

transplantation was performed in 11. Among patients with a functioning kidney graft four received isolated Langerhans Islet cells and one received a whole pancreas ("dyssynchroneous").

In principle, transplantation is offered to all patients considered to profit from it, with no strict upper or lower age limit. The age of the 129 first cadaveric graft recipients in 2003 ranged from 7 to 81 years, with a mean age of 55.7 y. Out of these, 28 % were above the age of 65 and 9 % were 75 or older. The 79 recipients of a first living donor graft were from 0.8 to 76 years, mean 44.0 y. Regraft recipients (n=33) were from 20 to 74 years, mean 47.0 y.



By end 2003, 187 patients (41.1 per mill.) were on the active waiting list for a CD renal graft. This represented a reduction of 8 patients (4%) since 2002. Among those waiting by Dec.31, median time on the list was 10 months. 34% had waited less than 6 months, 55% less than one year and 15% more than two years. The 154 recipients given a CD-graft in 2003 had a median waiting time of 10 months and a maximum of 66 months at the time of grafting.
Among the 816 patients in dialysis treatment by Dec.31, 361 (44%) were for various reasons not considered candidates for a new renal graft.

Patient status and treatment.

By the end of each year the registry distributes a patient questionnaire asking for patient status and actual treatment as well as complications during the treatment year. Data are requested for all dialysis patients starting RRT before Dec.1 and for all transplanted patients with more than 4 months observation since their latest transplant.
By end of Sept. 2004, the 2003-response rate for dialysis patients is 96.8% and for transplanted patients 96.0%. The following calculations are based on received reports only.

Rehabilitation status: Five main groups have been defined:

	Working	Able to work	Self-caring	Need of assist	Need for care
Dialysis	9%	35%	35%	15%	6%
Transplant	46%	23%	25%	4%	1%

Blood pressure: Hypertension is a problem, both in dialysis and after transplantation. The table shows blood pressure (BP) groups and the most widely used drugs:

	Dialysis	Transplanted
BP > 140/90	48%	23%
BP >130/80 and ≤ 140/90	5%	12%
BP ≤ 130/80	47%	66%
Beta-blocker	51%	36%
Calcium-channel-blocker	42%	46%
ACE-inhib./AT-blocker	32%	39%

74% of dialysis patients and 73% of the transplanted use one or more antihypertensive drugs (diuretics not included). Nearly half (48%) of tx-patients not receiving calcineurin inhibitors were not taking antihypertensives, this applied only to 25% of those using calcineurin inhibitors. Among those not using antihypertensive drugs, 14% of the transplanted and 18% of the dialysis patients had BP > 140/90.

Erythropoietin (EPO): 90% of all dialysis (HD+PD) patients and 5% of transplanted patients use EPO.
Among the HD/HDF patients, the 93% using EPO had a mean haemoglobin value of 11.7g/dL, the 7% without EPO had a mean of 12.0g/dL. Corresponding figures among PD-patients was: 76% using EPO, mean Hb 12.5g/dL, 24% without EPO, mean Hb 12.9g/dL.

D-vitamin: 65% of dialysis patients and 12% of transplanted use active vitamin D_3.

Statins:
48% of dialysis patients and 53% of transplanted patients either use a statin or participate in a double blind study ("Alert") comparing fluvastatin with placebo.

Immunosuppressive drugs:
Until 1983 azathioprine with prednisolone was standard therapy after transplantation. Since then, ciclosporine and prednisolone, most often combined with azathioprine, has been standard. During the later years mycophenolate and tacrolimus and also rapamycin have been used. Based on the received 2003-reports, 77% use ciclosporine, 13% use tacrolimus, 42% use azathioprine, 33% mycophenolate and 2% rapamycin. 97% of transplanted patient use prednisolone. Among those using a calcineurin-inhibitor 77% have reached the daily prednisolone-dose of 5mg (or less) recommended for patients with stable function. In some few it has been deliberately withdrawn.

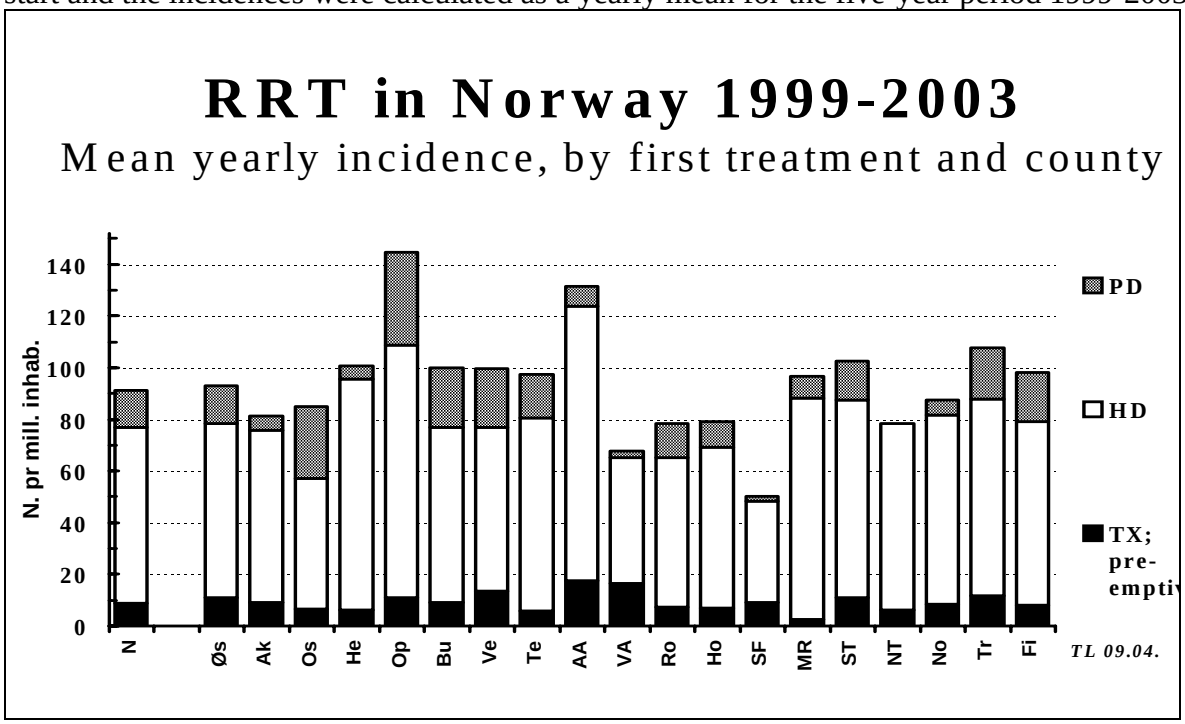
Graft function:
Grouped by serum creatinine concentration, 25% have a value ≤ 100μmol/L, 46% in the range 101-150, 18% 151-200, 6% 201-250 and 5% above 250. Serum creatinine below 125 was found in 50% of calcineurin-inhibitor users and in 69% of those without. The latter group mainly consists of patients transplanted before ciclosporine, and with a high proportion of HLA-identical sibling graft recipients.
For 8% of patients a diagnosis of chronic rejection has been made, in 67% of these this diagnosis has been verified by biopsy.

Dialysis treatment:
Among HD/HDF patients, only two were on home dialysis. HDF was reported in 82 (13%). Most patients (71%) receive 3 treatment sessions per week, 23% receive 1-2 sessions and 5% receive 4 or more. 19% are treated for 15 or more hours/week, and 25% for less than 10

hours. KT/V would be a better indicator of dialysis adequacy; collection of this still awaits a better standardisation.
Among PD patients, 37% use APD, none use IPD. A few (3) get additional HD, but are categorised as PD-patients. 27% of PD-patients are noted to have had one or more peritonitis episodes during 2003, a further 15 of the HD patients had PD-peritonitis during 2003.

Regional differences within Norway

Incidence:
During all the years since data collection was started, the number of patients reported has differed substantially between centres, also after correction for population size. Further the first mode of treatment (HD, PD or pre-emptive transplant) for new patients differs considerably. In the following figure, patients were grouped by county of domicile at RRT-start and the incidences were calculated as a yearly mean for the five-year period 1999-2003:

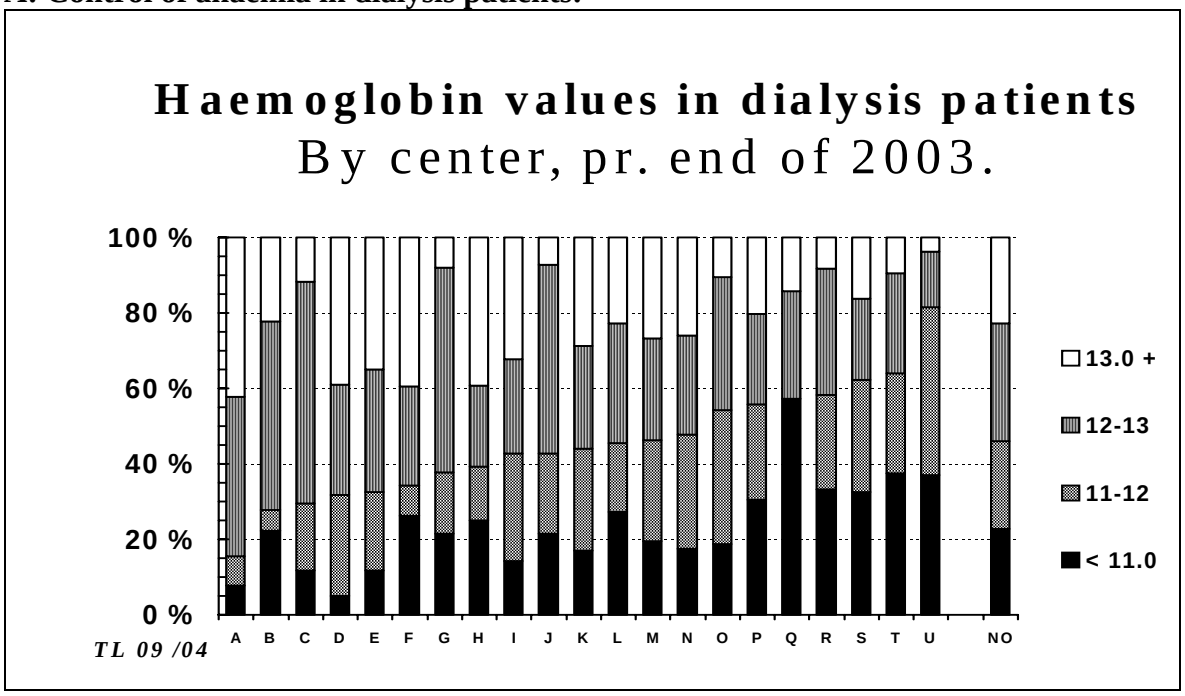


As appears, the mean yearly incidence of RRT-start varied from 50 to 145 pr. million. Noticeably, the county having the lowest incidence (Sogn og Fjordane) is also known to be where people live the longest and have the lowest general morbidity.
Although there is national consensus that pre-emptive transplantation is preferable, this was only achieved in 10%; in the individual counties this figure ranged from 3% to 23%.
In some counties PD is rarely used, in others up to 31% of new patients have this as first treatment mode. 75% received HD as first treatment mode, in the counties this ranged from 60% to 92%.

The proportion of the new patients in 2003 who first presented in the renal unit with a terminal renal failure was lower than in 2002 (19% vs. 25%) with wide variations between centres – from 0% in three centres and up to 38% at highest. In the majority of these cases the diagnosis would imply that renal failure has developed gradually over years. Although the figures may seem to have improved, in most counties there still seems to be a need for improved co-operation within the primary health service in order to achieve early referrals.
Quality parameters:

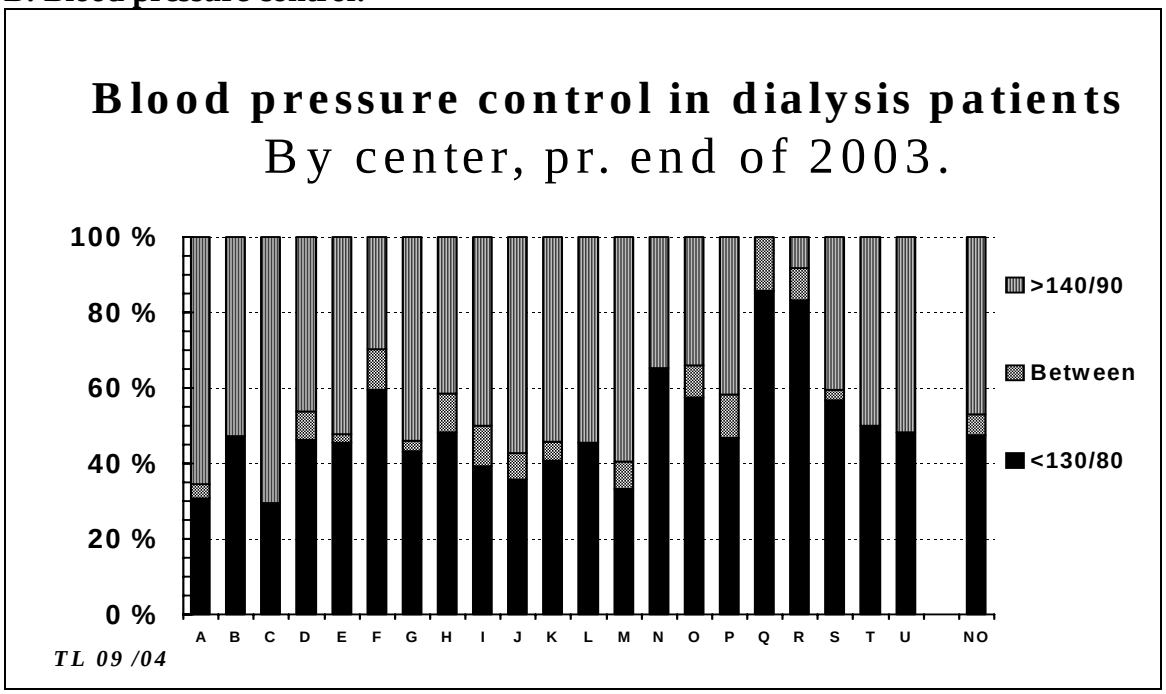
Based on received patient questionnaires, the fulfilment rate per centre can be calculated for a few quality parameters. In the following figures, the centre identities are given by a code that will be disclosed only to the key person at the individual centre.

A: Control of anaemia in dialysis patients:

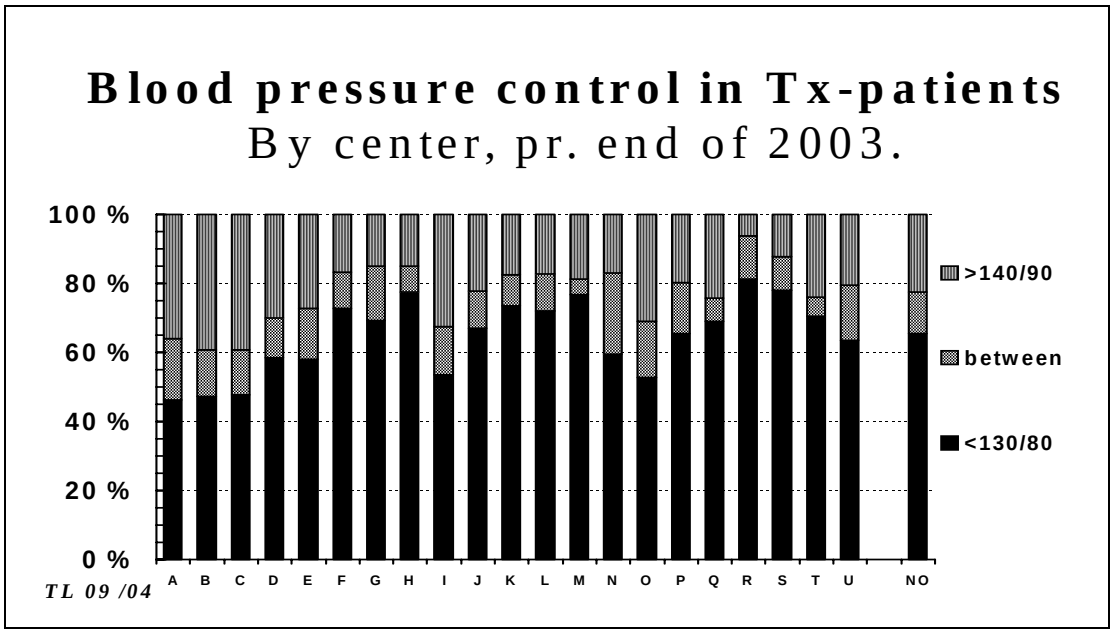


As appears, 77% of Norwegian dialysis patients had a haemoglobin value above the 11.0g/dL low limit recommended in European Best Practice Guidelines. In the individual centres this rate varied from 43% to 95%. Data have not been corrected for gender.

B: Blood pressure control:



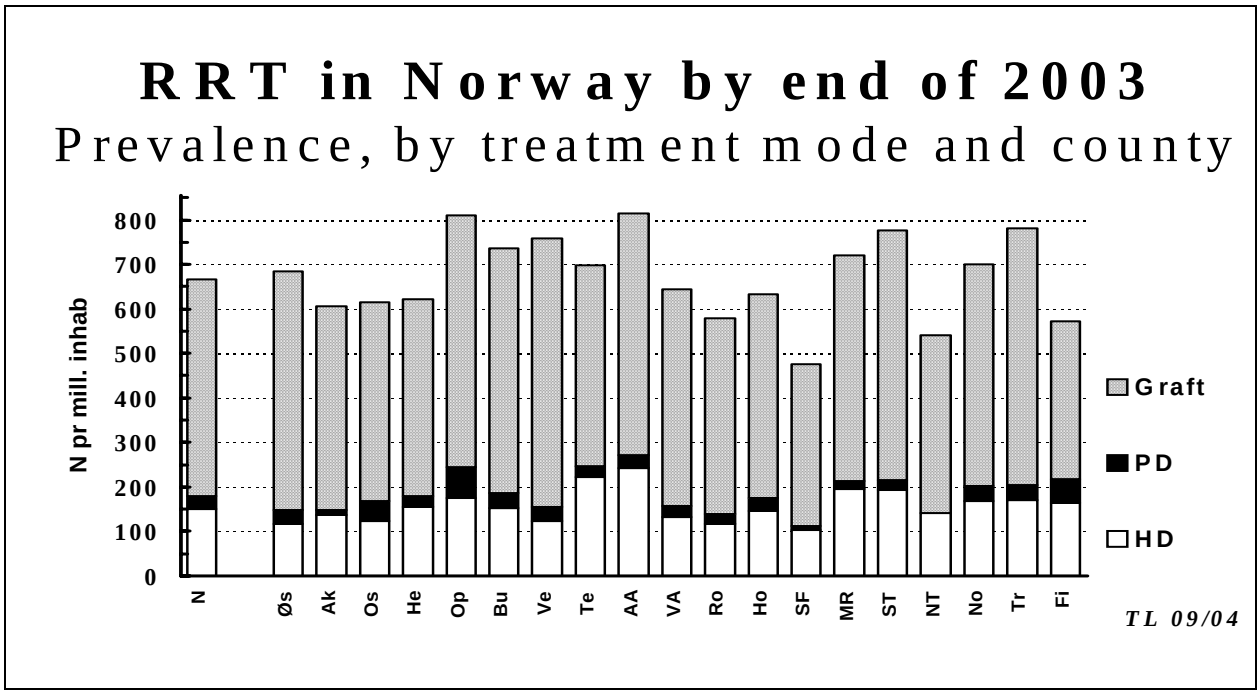
While 48% of dialysis patients had blood pressure of 130/80 or below, this proportion ranged from 29 to 86% in the individual centres. The fraction having blood pressure values of 130/80 or lower was somewhat higher among PD patients than among HD/HDF patients.



The degree of blood pressure control has been shown important both for graft and patient survival. 65% of transplanted patients had values of 130/80 or below, again we see a considerable variation among centres; from 46 to 81%, could be demonstrated. The data have not been corrected for possible age differences.

Prevalence:

Again, the data demonstrate great differences between the counties. In all counties the majority of patients have a functioning graft, constituting from 60% to 80% of the total RRT-population. The dialysis prevalence ranges from 112 to 271 per mill. inhabitants in the counties, indicating considerable differences in workloads and costs. In some counties, two out of three dialysis patients are not considered candidates for a new graft, in others this applies only to 10-15%. But counties with high dialysis prevalence do not necessarily have a high prevalence of 'non-transplantable' patients.



Concluding remarks:

Even if it may seem that the incidence increase during the latest years has levelled off, the prevalence of RRT-patients will continue to increase in the coming years. The marked county differences may indicate that we still can expect further increased national incidence. The high transplantation rates achieved in 2002 and 2003 (and up to now also in 2004) may seem to have retarded the yearly increase in dialysis prevalence somewhat. Whether this tendency will last remains to be seen. But in spite of a higher transplantation rate in Norway than in most other countries, the number of patients in dialysis will still rise and they will constitute an increasing proportion of the RRT-population.

Compared to the Swedish RRT-incidence (121 per million in 2003) and prevalence (774 per million), and the Danish figures (129 and 733 respectively), Norwegian numbers still are low. There are no obvious reasons for such a difference between our nations that are so similar in most respects. Therefore, the Norwegian health service needs to prepare for accommodating a significantly increased number of RRT-patients in the coming years.

Report completed 19.10.2004
Torbjørn Leivestad M.D.

Appendix: