

ANNUAL REPORT 2001

The Norwegian Renal Registry

(Norsk Nefrologiregister)

This report will also be available on:

<http://152.94.12.230/Nyreforening/Uremiregisteret/esdr.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 1997, 1998, 1999 and 2000 (in English) have been distributed; the latter four have also been made available on Internet.

National organisation and policy

Norway has 4.51 mill. inhabitants (Jul. 2001) and 19 counties with populations ranging from 74000 to 512000. 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 Jul. 2001, 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 2001

During 2001 a total of 425 new patients (in 2000: 401) entered renal replacement therapy (RRT), i.e. 94.2 per mill. inhabitants.

A majority of 63.5% were males and 36.5% females. Median age at start was 64.0 years, mean 60.5 years, ranging from 3 weeks to 87 years.

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

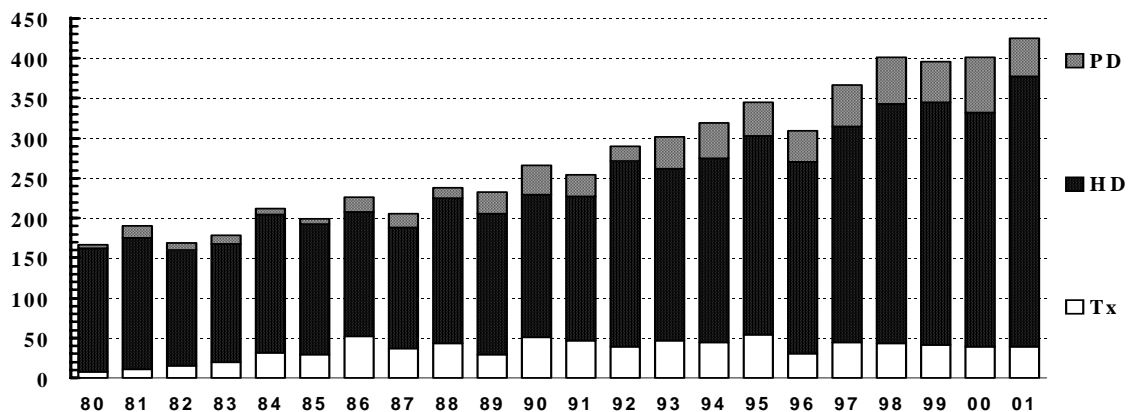
	< 15	15-24	25-34	35-44	45-54	55-64	65-74	75+	Total	in %
HD	2	4	23	29	47	58	88	87	338	79.5
PD	1	1	3	5	8	10	9	11	48	11.3
TX	2	2	5	7	11	4	6	2	39	9.2
Total	5	7	31	41	66	72	103	100	425	100
in %	1.2	1.6	7.3	9.6	15.5	16.9	24.2	23.5	100	

At start of treatment, 298 (70.1%) were considered by their nephrologist to be a potential candidate for transplantation, while 127 (29.9%) were accepted for life-long dialysis (constituting 35% of those starting with HD and 19% of those starting PD).

Among patients starting dialysis in 2001, 25% were previously unknown to the renal unit when they presented with terminal renal failure, 52% were known and started RRT as planned, while 24% were known but had a hastened RRT-start.

Incidence data: Changes 1980-2001

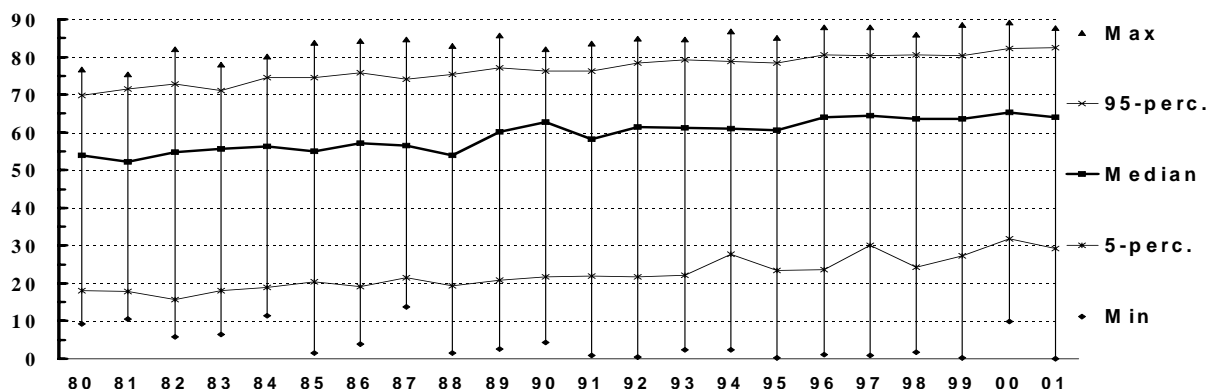
New patients in RRT by year of start, and first mode of treatment



TL 07 /02

Incidence data: Age at start

Age of new patients in RRT Percentiles and range, by year of start



TL 07 /02

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 2001

at age 26 days. The number of children below 15 years has not changed during the period - it has ranged from two to eight per year.

Incidence data: Primary renal disease

	1980-84	1985-89	1990-94	1995-99	2000	2001
Glomerulonephritis	34%	36%	31%	24%	19%	19%
Pyelo/interstitial nephr.	16%	14%	11%	12%	11%	14%
Polycystic diseases	10%	9%	9%	9%	8%	8%
Diabetic nephropathy	13%	12%	12%	11%	15%	14%
Amyloidosis	7%	6%	6%	4%	4%	4%
Vascular/hypertensive	5%	8%	18%	24%	26%	28%
Immune/systemic	4%	5%	4%	6%	4%	3%
Kidney tumour	1%	1%	1%	1%	2%	1%
Myelomatosis	3%	2%	1%	2%	4%	3%
Other defined	4%	4%	4%	3%	2%	3%
Unknown	3%	3%	3%	4%	6%	3%
N:	912	1106	1419	1817	401	425

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 2001, 34 were registered as having Type I, 27 as Type II diabetes. In addition 44 patients with other types of primary renal disease were recorded having diabetes as a co-morbid factor (two were Type I and 42 Type II), thus 25% of new patients were diabetics.

Cardiovascular disease is often present at start of RRT. Symptomatic heart disease was reported in 142; two out of these had a previous heart transplant. Cerebrovascular disease was reported in 50 and peripheral arteriosclerotic disease in 87 patients.

Prevalence data: Status by 31.dec. 2001.

By the end of 2001, 2756 patients in Norway received renal replacement therapy, i.e. 611.1 per million inhabitants. This represents an increase of 150 patients or 5.8 % since 2000.

Gender: 63.8% males and 36.2% females.

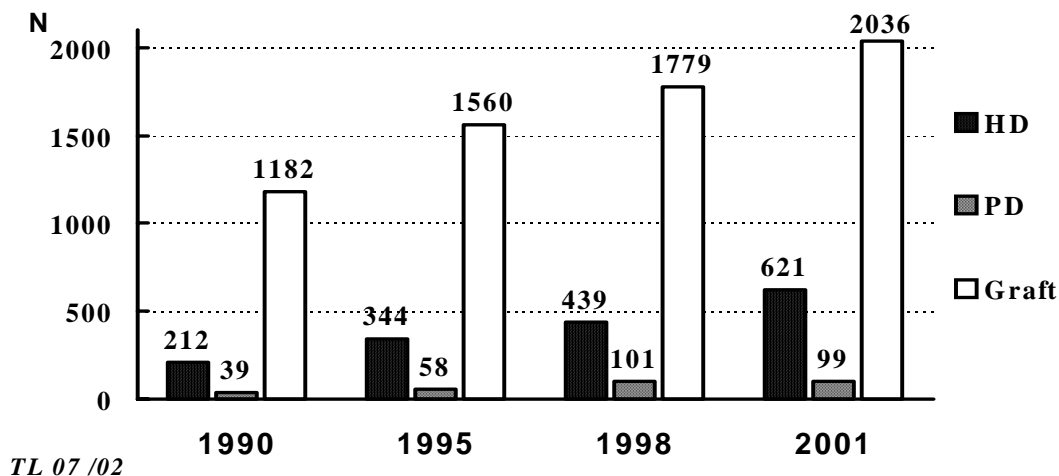
Median age by the end of the year was 55.2 years, mean 54.7 years and range 0.3-89.3 years.

Tabulated by last mode of treatment, and age by end of 2001:

	< 15	15-24	25-34	35-44	45-54	55-64	65-74	75+	Total	in %
HD	1	6	34	50	73	121	153	183	621	22.5
PD	1	0	6	9	18	15	22	28	99	3.6
TX	26	70	214	353	500	438	327	108	2036	73.9
Total	28	76	254	412	591	574	502	319	2756	100
In %	1.0	2.8	9.2	14.9	21.4	20.8	18.2	11.6	100	

Renal replacement therapy in Norway

Prevalence of treatment modes in 1990, -95, -98 and 2001.

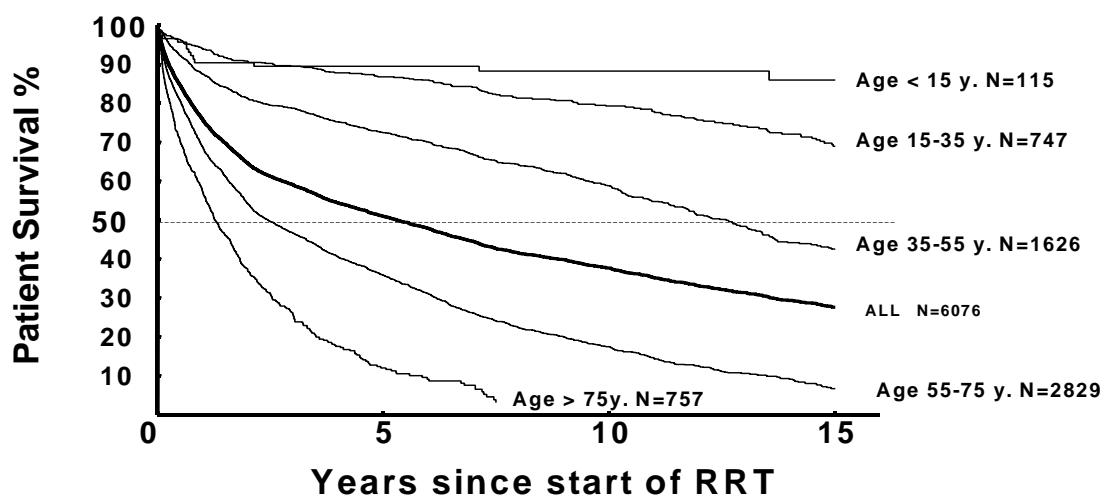


Patient survival on RRT:

Several factors influence the patient survival on RRT. Last years report illustrated epoch differences and the influence of primary renal diagnosis, as well as the initial evaluation done by the nephrologist. The following Kaplan-Meier plot illustrates patient survival in different age groups as of Aug. 2002 for all patients starting RRT in the period 1980-2001.

Age-related survival on RRT.

All new pats. 1980-2001, by age at start of RRT.



Death in RRT in 2001:

A total of 278 patients in renal replacement therapy died during 2001, i.e. 9.2% out of the 3031 persons at risk. Among these, 64% were males and 36% females. Median age at death was 71 years, mean 67.8 years, and the range 13-90 years. Median time from start of RRT until death was 24 months, with a range spanning from day one to more than 23 years. The final mode of treatment was HD for 179 patients and PD for 21, while 78 died with a more or less well-functioning graft. Eight died within two months after graft loss; thus 86 deaths were termed 'TX-related'. 25 patients died following termination of treatment, five of those because the patient refused further treatment.

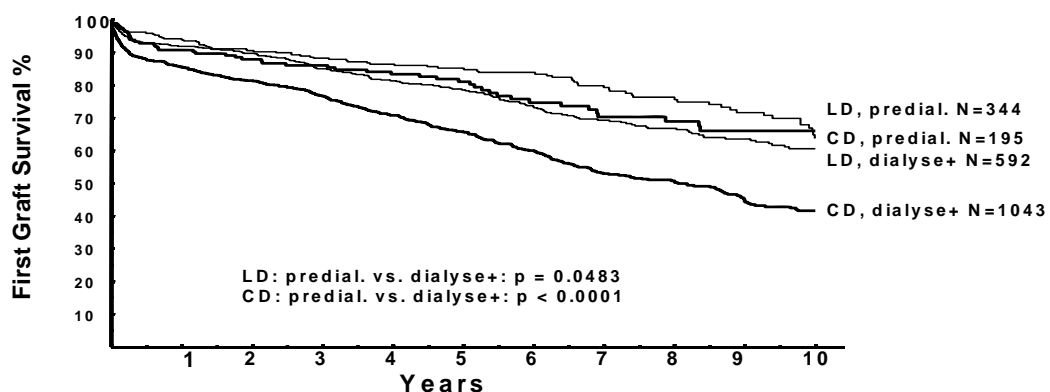
As in previous years, cardiac (33%) complications were the most frequent causes of death, followed by vascular complications (20%), infections (23%), and malignant tumours (12%).

Transplantation and waiting lists:

A total of 211 renal transplants were performed at Rikshospitalet University Hospital in 2001, i.e. 46.8 per million inhabitants. In 86 (40.8%) the graft came from a living related or spouse donor, 20 of the LD-graft recipients were grafted pre-emptively and 2 received a second graft after rejection of the first without new dialysis. 125 patients received a cadaveric graft, 18 were pre-emptively transplanted, while 2 had a second or third graft without entering dialysis. There were 193 first grafts (81 LD and 112 CD), 16 were second grafts (4 LD, 12 CD) and 2 third grafts (1 LD, 1 CD). Simultaneous kidney + pancreas transplantation was performed in 12, one patient with a functioning kidney graft received isolated Langerhans Islets.

As appears from the following analysis, graft survival is better among pre-emptively transplanted recipients.

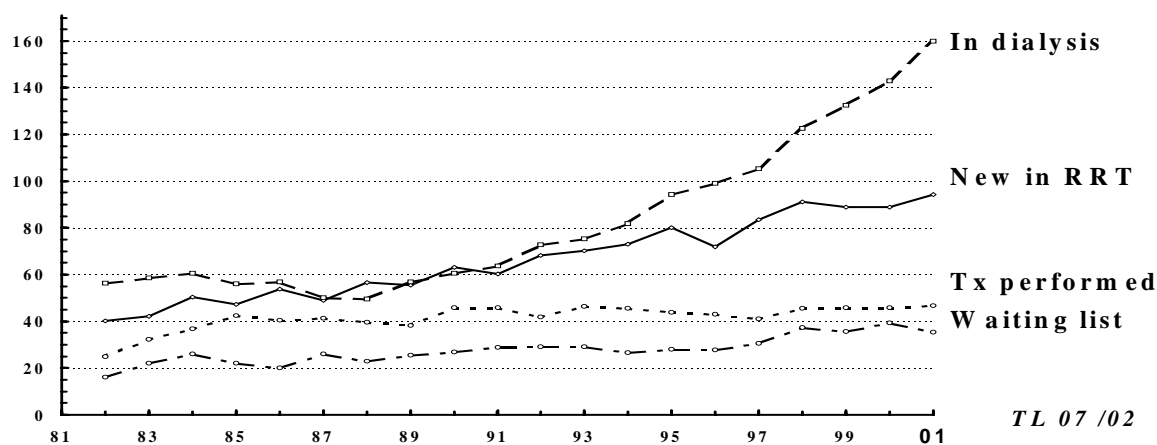
Survival of first renal grafts, effect of preemptive transplantation Norway 1989-2001



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 112 first cadaveric graft recipients in 2001 ranged from 14 to almost 80 years, with a mean age of 57.6 y. Out of these, 35 % were above the age of 65 and 8% were 75 or older. The 81 recipients of a first living donor graft were from 1.4 to 75 years, mean 43.1 y. Re-graft recipients were younger, ranging from 20 to 55 years, mean 42.1 y.

Renal replacement therapy in Norway

Status by end of year - pats. pr mill. inhabitants



By end 2001, 160 patients (39.3 per mill.) were on the active waiting list for a necro-kidney. This represented a reduction of 17 patients (10%) since 2000. Among those waiting by Dec.31, median time on the list was 9 months. 39% had waited less than 6 months, 59% less than one year and 16% more than two years. The 125 recipients given a necro-kidney in 2001 had a median waiting time of 10 months and a maximum of 46 months at the time of grafting. Among the 720 patients in dialysis treatment by Dec.31, 291 (40%) 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 now, the response rate for dialysis patients is > 99% and for transplanted patients 98.4%.

Rehabilitation status: Five main groups have been defined:

	Working	Able to work	Self-caring	Need of assist	Need for care
Dialysis	9%	33%	37%	14%	6%
Transplant	48%	20%	26%	4%	2%

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	53%	28%
BP >130/80 and ≤ 140/90	20%	38%
BP ≤ 130/80	27%	34%
Beta-blocker	49%	33%
Calcium-channel-blocker	42%	46%
ACE-inhib./AT-blocker	28%	37%

75% of dialysis patients and 76% of the transplanted use one or more antihypertensive drugs (diuretics not included). Among those not using antihypertensive drugs, 14% of the transplanted and 73% of the dialysis patients had BP > 140/90.

Erythropoietin (EPO): 88% of dialysis patients and 4% of transplanted patients use EPO.

D-vitamin: 75% of dialysis patients and 13% of transplanted use active vitamin D₃.

Statins:

38% of dialysis patients and 50% of transplanted patients either use a statin or participate in a double blind study (“Alert”).

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 2001-reports, 82% use ciclosporine, 9% use tacrolimus, 55% use azathioprine, 20% mycophenolate and 1% rapamycin. 97% of transplanted patient use prednisolone. Among those using a calcineurin-inhibitor only 62% 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, 21% have a value $\leq 100\mu\text{mol/L}$, 49% in the range 101-150, 20% 151-200, 6% 201-250 and 4% above 250. Serum creatinine below 125 (upper normal male value) was found in 49% of calcineurin-inhibitor users and in 67% 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 7% of patients a diagnosis of chronic rejection has been made, in 72% 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 39 (6%). Most patients (67%) receive 3 treatment sessions per week, 30% receive 1-2 sessions and 3% receive 4 or more. 21% are treated for 15 or more hours/week, and 29% for less than 10 hours. KT/V would be a better indicator of dialysis adequacy; collection of this awaits a better standardisation.

Among PD patients, 28% use APD, none use IPD. A few get additional HD, but are categorised as PD-patients. 35% of PD-patients are noted to have had one or more peritonitis episodes during 2001, a further 14 of the HD patients had PD-peritonitis during 2001.

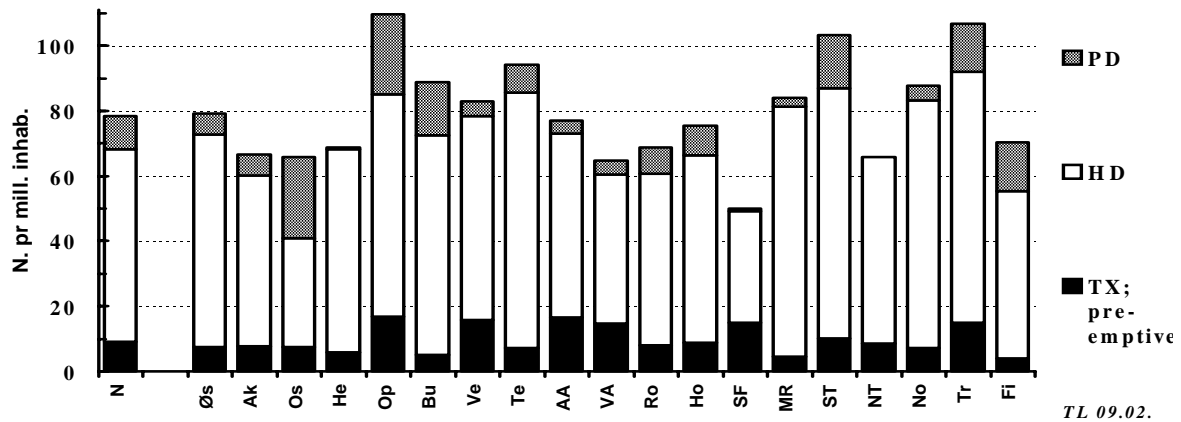
Regional differences within Norway

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 varies considerably. In the following figure, patients were grouped by county of domicile at RRT-start and incidence calculated as a yearly mean for the ten-year period 1992-2001:

RRT in Norway 1992-2001

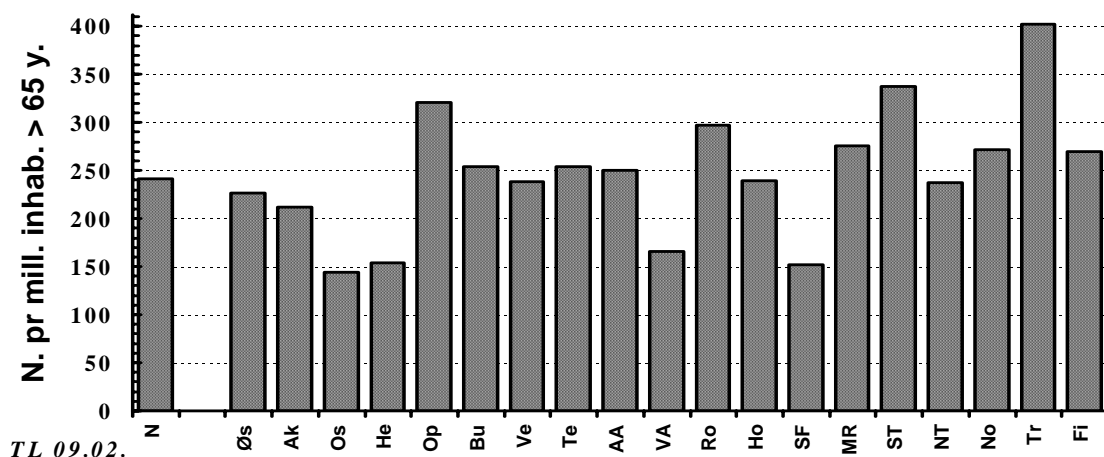
Mean yearly incidence, by first treatment and county



As appears, the mean yearly incidence of RRT-start varied from 50 to 110 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 12%; in the individual counties this figure ranged from 5 to 30%. In some counties PD is rarely used, in others up to 38% of new patients have this as first treatment mode. Close to 75% received HD as first treatment mode, in the counties this ranged from 50 to 91%.

RRT in Norway 1992-2001

Mean yearly incidence among age 65+, by county



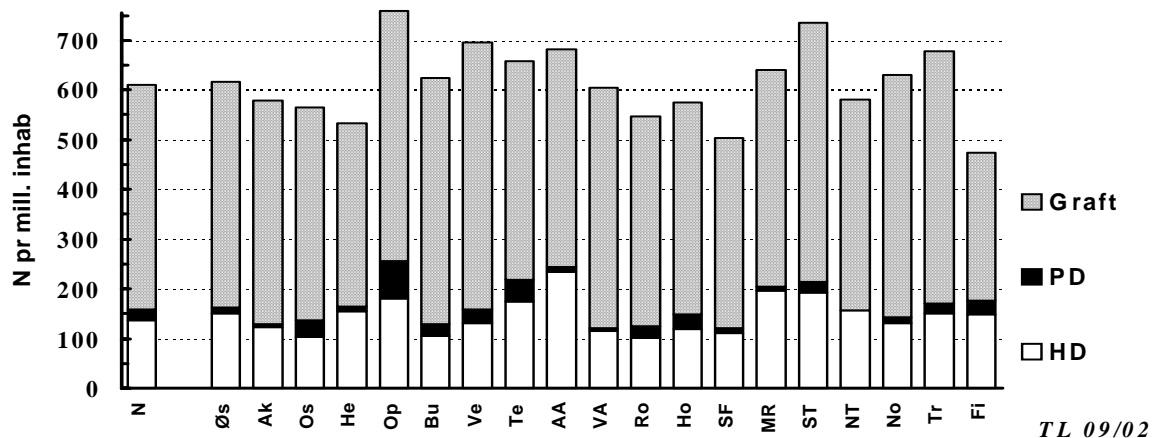
A considerable variation in age distribution of incident patients in the counties is apparent, in 2001 mean age of new patients ranged from 52.5 to 70.7 years. When calculating the yearly take-on rate of patients above 65 years in relation to the number of inhabitants above 65, even more striking differences between the counties could be observed. While the national mean was 242 patients pr. mill. pr. year, this figure varied from a low 144 to a high 402 among the counties.

The proportion of the new patients in 2001 who first presented in the renal unit with a terminal renal failure also varied considerably between counties – from 8% and up to 50%. In the majority of these cases the diagnosis implies that renal failure has developed gradually over years. Thus, in most counties there must be a need for improved co-operation within the primary health service in order to achieve early referrals.

Prevalence:

Again, the data demonstrate great differences between the counties. In all counties the majority of patients have a functioning graft, constituting from 63% to 80% of the total RRT-population. The dialysis prevalence ranges from 120 to 256 per mill. inhabitants in the counties, indicating great 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.

RRT in Norway by end of 2001
Prevalence, by treatment mode and county



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. Unless a corresponding rise in kidney donation (both living and necro-donors!) is achieved, the number of patients in dialysis will rise and they will constitute an increasing proportion of the RRT-population.

Compared to the Swedish RRT-incidence (124 per million in 2001) and prevalence (735 per million), Norwegian numbers still are low. There are no clear reasons for such a difference between our two 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 near future.

*Report completed 20.09.2002
Torbjørn Leivestad M.D.*