

The Slovenian Society of Nephrology

Slovenian Renal Replacement Therapy Registry



2006 ANNUAL REPORT

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Ljubljana, September 2008

SLOVENIAN RENAL REPLACEMENT THERAPY REGISTRY: 2006 ANNUAL REPORT

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Introduction

The present report provides an update of epidemiology and treatment practices in end-stage renal disease (ESRD) patients treated with renal replacement therapy (RRT) in Slovenia in 2006. The report is based on individual and center questionnaires prepared by the Slovenian Renal Replacement Therapy Registry Group. The response rate to the questionnaires was 100%. Pediatric data has also been included.

The expert group for dialysis initiated annual RRT reports in 1999. These reports were initially based on data from renal center questionnaires, with each questionnaire tapping the aggregate data for patients at one center. In 2002, we began collecting individual patient data as well, and by 2004, a response rate of 100% was achieved for individual patients. With these data, the Slovenian RRT registry joined the ERA/EDTA (European Renal Association-European Dialysis and Transplant Association) registry (Section B, aggregated data), and the Slovenian RRT Registry Group was founded, sponsored by the Slovenian Society of Nephrology. The registry is voluntary.

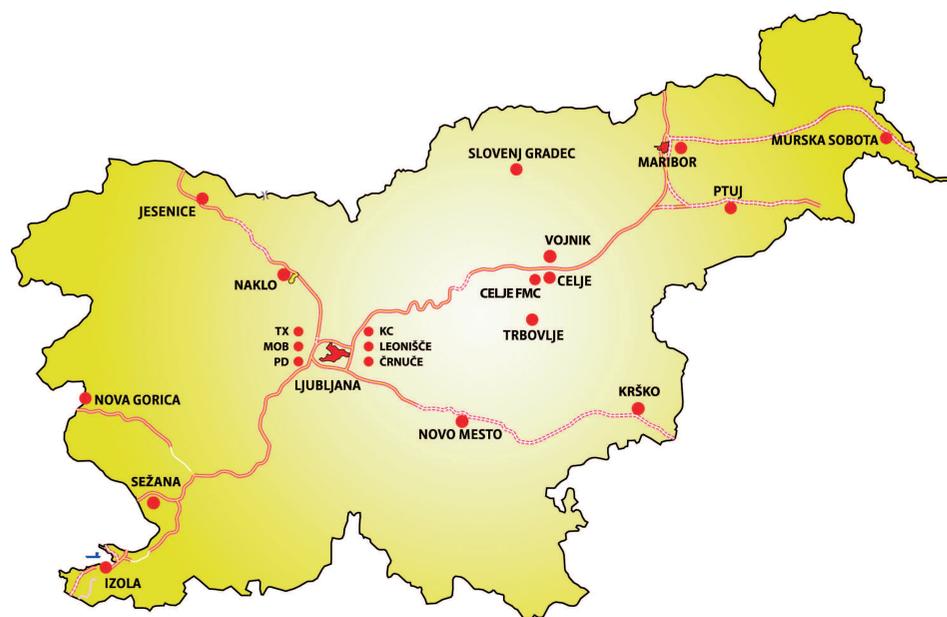
The aims of the registry, which collects data on individual RRT patients as well as data on renal center characteristics, are: 1) to be informed on the number of patients and their characteristics, 2) to monitor and improve the quality of RRT care, 3) to compare Slovenian RRT care with that of other countries, 4) to use registry data for the planning of health care facilities and personnel.

The general population of Slovenia is about 2 million (in 2006: 2,010,000; 1,023,000 women and 987,000 men).

Renal centers

On December 31, 2006, there were 21 renal centers in Slovenia (the same as in 2005): 15 in-hospital dialysis centers, 5 private, out-patient hemodialysis centers (4 of them Fresenius Medical Care centers), and 1 transplant center (Fig. 1). One of the 15 in-hospital centers is the Center for Pediatric Dialysis and Transplantation, and another is the Center for Peritoneal Dialysis at the University Medical Center Ljubljana. 11 out of the 15 in-hospital centers perform hemodialysis procedures for patients with acute renal failure. In addition to the specialized Center for Peritoneal Dialysis and the University Medical Center Ljubljana, peritoneal dialysis is performed at 8 in-hospital dialysis centers in Slovenia.

Fig. 1. Renal centers in Slovenia on December 31, 2006



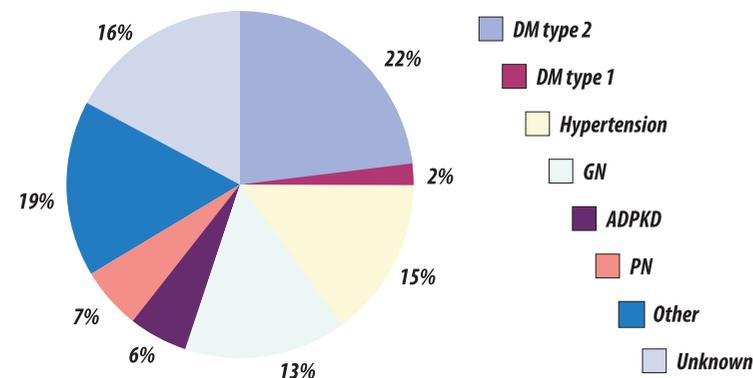
Incident patients

a) Incident patients at day 1

There were 249 incident patients (day 1) in 2006, with an incident rate of 123.9 pmp (per million of population). Of these 249 patients, 150 were men (152 pmp) and 99 were women (96.8 pmp). Men represented 60.2% of the incident patients. The mean age of incident patients was 63.1 ± 15.6 years, the median age was 66 years. The mean age of incident men was 62.7 ± 14.3 years (median 64.5 years). The mean age of incident women was 63.7 ± 17.4 years (median 69 years). 4 patients starting RRT in 2006 were 20 years old or younger.

The adjusted incidence rate pmp (with a general population of EU25 of year 2000 used for the adjustment calculation) was 117.5 pmp, men 148.6 pmp and women 89.6 pmp.

Fig. 2. Primary renal disease in incident patients (at day 1) in Slovenia in 2006 (abbreviations: DM: diabetic nephropathy; HT: hypertension (hypertensive nephrosclerosis (+ischemic nephropathy)); GN: glomerulonephritis; PKD: polycystic kidney disease; PN: pyelonephritis).



The primary renal diseases in incident patients at day 1 were: diabetic nephropathy: type 1: 1.6%, type 2: 23.3%, both 24.9%; hypertension 14.1%; renovascular disease 0.8%; glomerulonephritis 13.3%; polycystic kidney disease 5.6%; pyelonephritis 6.8%; miscellaneous (other) 18.9%; unknown: 15.7%. Diabetes was present in 77/249 (30.5 %) of incident dialysis patients (information on the presence of diabetes is collected separately as comorbidity data).

b) Incident patients at day 91 (only patients that survived 90 days on RRT)

There were 228 incident patients (day 91) in 2006, with an incident rate of 113.4 pmp, 137 men (138.8 pmp) and 91 women (89.0 pmp). Men represented 60.1% of the incident (day 91) patients. The mean age of incident (day 91) patients was 62.2 ± 15.7 years (median 66 years). The mean age of incident (day 91) men was 61.6 ± 14.2 years (median 63 years). The mean age of incident (day 91) women was 63.1 ± 17.6 years (median 68.5 years).

The adjusted incidence rate pmp (with a general population of EU25 of year 2000 used for the adjustment calculation) was 107.2 pmp, men 134.4 pmp and women 82.1 pmp.

The primary renal diseases in incident patients at day 91 were almost the same as in incident patients at day 1: diabetic nephropathy: type 1: 1.8%, type 2: 23.7%, both 25.4%; hypertension 14.0%; renovascular disease 0.9%; glomerulonephritis 14.0%; polycystic kidney disease 6.1%; pyelonephritis 5.3%; miscellaneous (other) 18.9%; unknown: 15.4%. Diabetes was present in 66/228 (28.9 %) of incident day 91 dialysis patients (information on the presence of diabetes is collected separately as comorbidity data).

Prevalent patients

Data relating to prevalent ESRD patients on different forms of RRT are presented in Table 1 and Fig. 3. The annual increase in 2006, as compared to 2005, was 1.8%. After two years of slight increase, a decrease in the number of patients treated with peritoneal dialysis was observed.

Fig. 3. Number of patients on different forms of renal replacement therapy from 1998-2006 (HD: hemodialysis; PD: peritoneal dialysis; Tx: kidney transplantation).

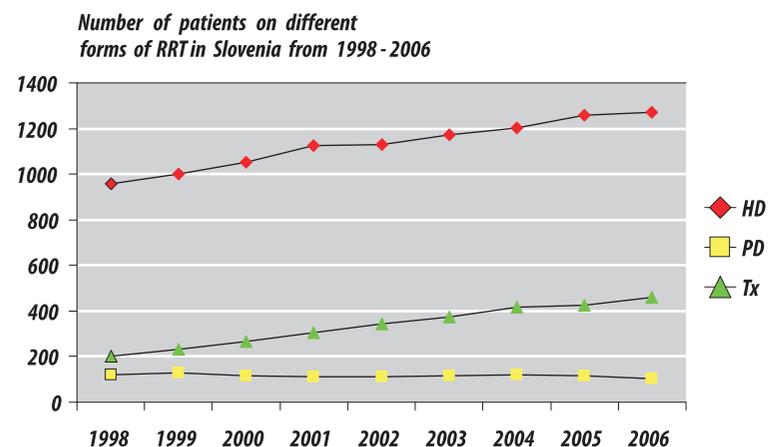


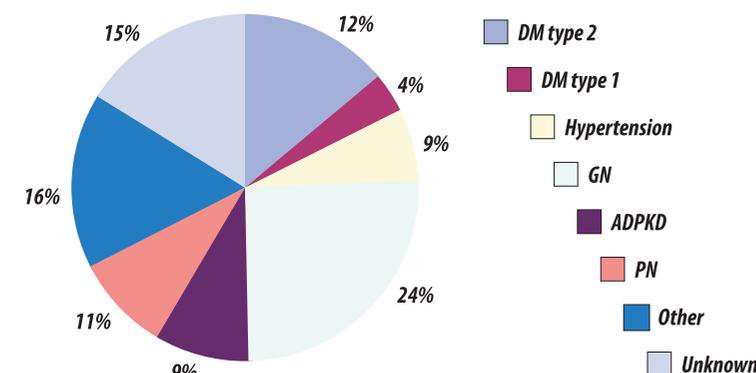
Table 1. Prevalence of end-stage renal disease patients on different forms of renal replacement therapy on December 31 in the period from 1998-2006 (residents only).

December 31	Hemodialysis	Peritoneal dialysis	Functioning graft	All
1998 (n)	957	121	201	1279
1999 (n)	1000	129	230	1359
2000 (n)	1051	117	267	1435
2001 (n)	1125	113	304	1542
2002 (n)	1131	110	343	1584
2003 (n)	1171	116	374	1661
2004* (n)	1202	119	415	1736
2005* (n)	1260	115	427	1802
2006* (n)	1271	103	461	1835
Increase 1999 (n/%)	43 / 4.5 %	8 / 6.6 %	29 / 14.4 %	80 / 6.3 %
Increase 2000 (n/%)	51 / 5.1 %	- 12 / - 9.3 %	37 / 16.1 %	76 / 5.6 %
Increase 2001 (n/%)	74 / 7.04 %	- 4 / - 3.4 %	37 / 13.9 %	107 / 7.5 %
Increase 2002 (n/%)	6 / 0.5 %	- 3 / - 2.7 %	39 / 12.8 %	42 / 2.7 %
Increase 2003 (n/%)	40 / 3.5 %	6 / 5.5 %	31 / 9.0 %	77 / 4.9 %
Increase 2004* (n/%)	31 / 2.6 %	3 / 2.6 %	41 / 11.0 %	75 / 4.9 %
Increase 2005* (n/%)	58 / 4.8 %	- 4 / - 3.4 %	12 / 2.9 %	66 / 3.8 %
Increase 2006* (n/%)	11 / 0.9 %	- 12 / - 10.5 %	34 / 8.0 %	33 / 1.8 %

*Based on individual patient data

On December 31, 2006, there were 1835 prevalent RRT patients in Slovenia with a prevalent rate of 912.9 pmp, 1028 men (1041.5 pmp) and 807 women (788.9 pmp). Men represented 56% of the prevalent RRT patients. The mean age of prevalent patients was 58.4±14.9 years, the median age was 59 years. The mean age of prevalent men was 57.6±14.2 years, median age 59 years. The mean age of prevalent women was 59.4±15.7 years, median age 60 years. 17 patients were ≤ 20 years of age.

Fig. 4. Primary renal diseases in prevalent patients in Slovenia in 2006 (abbreviations: DM: diabetic nephropathy; Hypertension: hypertensive nephrosclerosis and/or ischemic nephropathy; GN: glomerulonephritis; PKD: polycystic kidney disease; PN: pyelonephritis).



The primary renal diseases in prevalent RRT patients were: diabetic nephropathy: type 1: 3.7%, type 2: 11.83%, both 15.4%; hypertension 7.8%, renovascular disease 0.8%; glomerulonephritis 24.6%; polycystic kidney disease 8.7%; pyelonephritis 11.3%; miscellaneous (other) 16.2%; unknown: 15.1%.

The distribution of RRT modalities is presented in Table 2. The majority of prevalent RRT patients are treated with chronic hemodialysis. These patients are older and have a higher percentage of diabetics than patients treated with peritoneal dialysis or kidney transplantation.

Table 2. Patients treated with different forms of renal replacement therapy (RRT) in Slovenia on December 31, 2006.

	No. of patients (% of all RRT)	% men	Median age (range) – years	Diabetic nephropathy/ diabetes (%)**	Crude death rate in 2006***
Hemodialysis	1271 (70%)	55%	65 (17-93)	19.2/24.2	15.56%
Peritoneal dialysis	103 (6%)	59%	53 (2-76)	17.4/21.3	4.58%
Transplantation*	461 (24%)	57%	52 (14-76)	4.0/14.3	1.35%
All*	1835 (100%)	56%	59 (2-93)	15.4/21.6	11.43%

*Residents only;

**The presence of diabetes is collected separately as comorbidity data.

*** Incident day 1 included.

Table 3. Number of prevalent and incident patients per million of the population (pmp) from 1998-2006.

December 31	1998	1999	2000	2001	2002	2003	2004*	2005*	2006*
Prevalence pmp	651	692	723	771	807	846	869	901	913
Incidence pmp	-	115	109	144	115	131	125	125	124

*Based on individual patient data.

Pediatric RRT patients in Slovenia

There were 17 prevalent patients aged 20 years or younger in Slovenia on December 31, 2006. Four of them started RRT in 2006 (one with preemptive kidney transplantation, 3 with chronic hemodialysis). 6 pediatric patients had a functioning kidney graft (5 from cadaveric donors and one from a living related donor), 6 were treated with peritoneal dialysis (all of them with automated peritoneal dialysis), and 5 with chronic hemodialysis. The median age of prevalent pediatric RRT patients was 17 years (range 2-20 years). The primary renal diseases in prevalent pediatric RRT patients were: focal segmental glomerular sclerosis in one, IgA nephropathy in one, cistinosis in one, systemic lupus erythematosus in one, cortical necrosis (hypoxia at birth) in one, autosomal recessive polycystic kidney disease in one, nephronophthisis in one, nonspecific cystic disease in one, renal hypoplasia in one, interstitial nephritis in two, pyelonephritis with vesicourethral reflux in three, and pyelonephritis with congenital obstructive disease in three patients.

One child aged 3 years, treated with automated peritoneal dialysis, died in 2006 from respiratory insufficiency as the consequence of pulmonary hypoplasia.

Crude death rate of RRT patients

208 RRT patients died in 2006. Of these, 202 were dialysis patients (197 hemodialysis and 5 peritoneal dialysis, incident day 1 patients were included) and 6 were kidney graft recipients.

The crude death rate was calculated by dividing the number of patients who died with the average number of prevalent RRT patients at the end of 2005 and 2006 (Table 4). The crude death rate for dialysis patients in 2006 was 14.7% (15.56% for HD patients and 4.58% for PD patients), 1.35% for transplanted patients, and 11.43% for all RRT patients. The most common cause of death in dialysis patients was cardiovascular disease (42%), followed by sepsis (17%), malignoma (14%), and cerebrovascular disease (6%) (Fig. 5). There were three suicides among hemodialysis patients in 2006. In two patients, renal replacement therapy was stopped for medical reasons. The cause of death in 6 kidney graft recipients was: sepsis in 3, acute myocardial infarction in one, and sudden death (probably due to cardiac disease) in two. Two of the 5 PD patients died because of sclerosing peritonitis. The mortality rate of hemodialysis patients increased slightly in the period from 1999-2005, and continued to rise in 2006. (Table 4, Fig. 6).

Fig. 5. Causes of death of dialysis patients in 2006 (n=202).

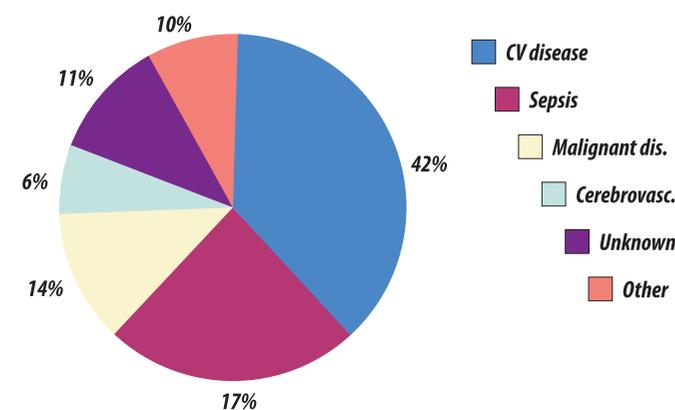


Table 4. Crude death rate of dialysis patients in the period from 1999-2005 (for 2005 and 2006: individual patient data, incident patients at day 1 included).

	1999	2000	2001	2002	2003	2004	2005	2006
All dialysis (†HD+‡PD)	10.9%	10.4%	10.4%	12.9%	11.8%	12.6%	12.8%	14.7%
HD	11.3%	10.8%	10.5%	13.2%	12.0%	13.1%	13.4%	15.56%
PD	8.8%	7.3%	9.6%	9.8%	9.8%	8.3%	6.8%	4.58%
Tx							0.90%	1.35%*
All RRT							10.0%	11.43%

† HD: Hemodialysis

‡ PD: Peritoneal dialysis

** 3 kidney graft recipients requiring hemodialysis 2, 14 and 36 days before death were counted as transplant deaths.

Long-term (≥30 years) RRT survivors in Slovenia

The patients who had started RRT in 1978 or earlier were identified from the Slovenian RRT Registry. As of March 2008, 33 patients were alive, treated with RRT for 32±2.0 yrs (30-36), 18 men and 15 women aged 61±8 yrs (46-84); primary renal diseases: glomerulonephritis - 20, pyelonephritis - 4, unknown nephropathy - 6, analgesic - 1, lupus - 1, Alport - 1. None had diabetes.

Group 1. Chronic HD ≥30 yrs: 16 patients, 7 men and 9 women aged 62±12 years (46-84), duration of RRT 31.6±1.5 years (30-35). The primary renal diseases were glomerulonephritis in 8, pyelonephritis in 3, analgesic nephropathy in one, lupus nephritis in one, and unknown nephropathy in 3. None had diabetes. One had an 18-month period of functioning cadaveric kidney graft, another had an unsuccessful transplantation (Tx) with a graft that never functioned, and one had a 12-year period of peritoneal dialysis. The vascular accesses are: AV fistula in 10 patients, PTFE graft in 3 patients, and a single-lumen, noncuffed catheter locked with citrate and used as permanent vascular access (for years) in 3 patients. Three of the 16 patients are treated with a 4-times-weekly schedule and the remainder (13 patients) with 3-times-weekly hemodialysis; 4/16 are treated with HDF and the rest with BHD. The weekly duration of hemodialysis is 14.0 ±2.0 hours (12-16.5), dry body weight 52.4±9.6 kg (32.5-65 kg), mean blood flow 264±52 ml/min. Two patients with a catheter are dialyzed by the single-needle technique, while in a third patient the catheter is used as an artery and blood is returned interchangeably via the leg peripheral veins. 6/16 patients do not receive erythropoiesis stimulating agents (ESA) therapy, the mean weekly ESA dose in 10 patients who do receive it is 4300 international units intravenously. As concerns kidney transplantation status, 8/16 patients refused to be transplanted during chronic hemodialysis treatment, 3 are not candidates because of their age (and comorbidity), and 5 patients showed medical contraindications for kidney transplantation.

Group 2. Kidney graft in function ≥30 years: 2 men, aged 76 and 69 years, both received a full-matched kidney from a living related donor in 1976 (after 2 months, and 2 years on hemodialysis, respectively), which still functions today. Current immunosuppression consists of low-dose steroids.

Group 3. Current HD, with prolonged Tx period: 3 patients, 2 men, aged 63 years (24 years Tx and 12 years HD) and 53 years (11 years Tx, 19 years HD), and a woman aged 53 years (25 years Tx, 8 years HD).

Group 4. Current Tx, with prolonged HD period. 12 patients, 7 men and 5 women, aged 58±5 years (50-71), duration of RRT 31.7±1.4 years (30-35). HD period was 14.8±7 years (6-28).

HD contributed to 734 years (68.7%) and Tx to 335 years (31.3%) of cumulative 1069 years of life on RRT in these long-term survivors. The longest duration of RRT treatment is 36 years (24 years of Tx, 12 years of HD). The longest duration of HD is 35 years, 2 months. The longest functioning of a kidney graft is 32 years. One patient who had been treated with RRT for 37 years (22 years of Tx, LRD, 15 years of HD) died in August 2007 and is not included in the analysis.

29/33 long-term (≥30 years) RRT survivors (15 hemodialysis patients and 14 patients with a functioning kidney graft) were treated at the Department of Nephrology, University Medical Center Ljubljana, in March 2008. Two patients were treated at the Dialysis Center Izola, one at the Dialysis Center Nova Gorica, and one at the Dialysis Center Krško (transferred from the Department of Nephrology in Ljubljana).

Hemodialysis in prevalent patients

1271/1835 (69.3 %) of prevalent RRT patients were treated with chronic HD (55.2% men, median age 65 yrs, range 17-93, mean 62.1± 14.3, 19.2 % were classified as having diabetic nephropathy as the primary renal disease, and 24.2 % of HD patients were reported as having diabetes).

The majority of Slovenian hemodialysis patients were treated in in-hospital centers (77% at the end of 2006). The percentage of patients treated in private, out-patient hemodialysis centers shows a slight increase over the 2002-2006 period, amounting to 23% of all hemodialysis patients at the end of 2006. Four out of 5 private centers (that served 220 patients in 2004, 253 patients in 2005, and 270 patients in 2006) are owned by Fresenius Medical Care.

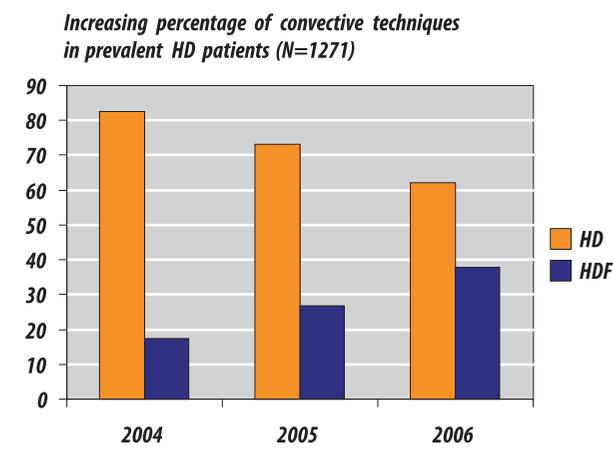
Table 5. Number and percentage of hemodialysis patients treated in private, out-patient hemodialysis centers on December 31, 1999-2006.

December 31	1999	2000	2001	2002	2003	2004*	2005*	2006*
private/all HD patients (n)	131/1000	157/1051	177/1125	223/1131	246/1171	243/1202	269/1260	292/1271
% of private HD patients	13.1%	14.9%	15.7%	19.7%	21.0%	20.2%	21.3%	23%

*Individual patient data.

The percentage of patients treated with convective techniques (hemodiafiltration/hemofiltration) is increasing: 17.5% in 2004, 26.9% of all hemodialysis patients (n=339) in 2005 and 37.8% in 2006 (n=480, on-line HDF: 448 patients; on-line hemofiltration: 7 patients; acetate free biofiltration: 25 patients). At the end of 2006, the majority of the patients (62.2%, n=791) were treated with bicarbonate hemodialysis. In the majority of hemodialysis patients (76.4%, 971/1271), ultrapure dialysis fluid was used (including patients treated with convective techniques).

Fig. 6. Increasing percentage of convective techniques in prevalent hemodialysis patients in the period from 2004-2006.



Prescription of hemodialysis: a minority of patients (5.1%, 65/1271) are treated with twice-weekly hemodialysis, 3 patients with once-weekly hemodialysis, 9 patients (0.7%) with 4-times-weekly hemodialysis, and the vast majority, 93.9% (1194/1271), are treated with 3-times-weekly hemodialysis. The average weekly time on dialysis is 13.1±2.0 hours (3-24 hours, including patients treated with once- or twice-weekly dialysis), the median weekly time on hemodialysis

is 13.5 hours. Regular night-shift in-hospital hemodialysis is offered at the Dialysis Center Zaloška to employed patients, students and pupils. The mean dry body weight of hemodialysis patients was 68.1 ± 15.3 kg (32-140 kg, median body weight 67 kg). The mean blood flow was 284 ± 44 ml/min (140-400), and 108 patients (8.5%) were dialyzed in the single-needle dialysis mode. Anticoagulation was performed using low molecular weight heparin in 18.5% (235/1271) of hemodialysis patients, while unfractionated heparin was used in the majority (81.5%) of hemodialysis patients. The mean heparin dose was 5542 ± 2328 iu per hemodialysis, median 5500 iu (ranging from 2000-19.500 units, including a dose of low molecular weight heparin expressed in antiXa units).

Acute hemodialysis

Hemodialysis in intensive care units is performed in 11 hospitals, in 9 of them together with continuous renal replacement therapy (CRRT). CRRT in newborns and small children is performed by the nephrologists and nurses of the Dialysis Center Zaloška, University Medical Center Ljubljana.

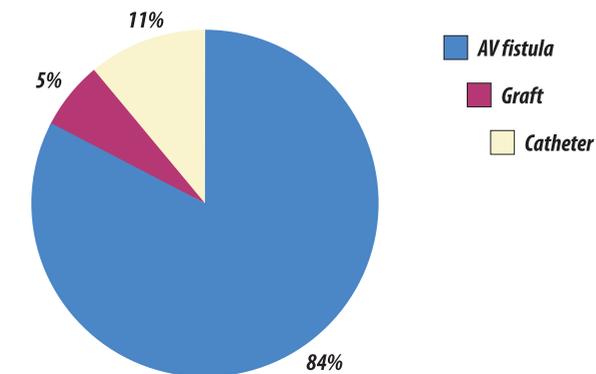
Acute dialysis (usually meaning dialysis in intensive care units) is reimbursed separately. In the case of CRRT, it is reimbursed as acute hemodialysis for every 8 hours of treatment.

5065 hemodialysis procedures were reported to have been reimbursed as acute hemodialysis in 2006 (all centers included), with 588 patients reported (one hospital center did not report its number of patients) to have been treated, 445 by intermittent hemodialysis (75.7%), 21 by CRRT only (3.6%), and 122 by a combination of CRRT and intermittent hemodialysis (20.7%).

Vascular access in hemodialysis patients

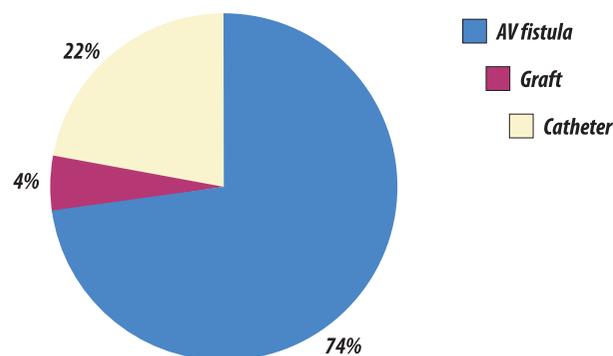
Prevalent hemodialysis patients. On December 31, 2006 there were 1271 prevalent chronic hemodialysis patients (55.2% men, median age 65 years, range 17-93, mean 62 ± 14 , 24.2% diabetics). The vascular accesses were: native arteriovenous fistula (AV) in 84.3% (n=1071), PTFE graft in 4.7% (n=60), and HD catheter in 11% (n=140) (Fig. 7). In patients with AV fistula and graft, the location of fistula/anastomosis was on the forearm in 66% (n=745) of patients, on the elbow/arm in 32.6% (n=369), and on the thigh in 1.5% (n=17) of patients. AV fistula or graft were on the left side in 67.6% (n=764) of patients and on the right side in 32.4% (n=367) of cases. Hemodialysis catheters (n=140) were: temporary (noncuffed) in 92.9% (n=130) and permanent silastic in 7.1% (n=10) of patients; precurved jugular in 83.6% (n=117), subclavian in 15% (n=21), and femoral in 1.4% (n=2) of patients; placed on the right side in 92.9% (n=130) and on the left in 7.1% (n=10) of patients; single-lumen in 79.3% (n=111) and double-lumen in 20.7% (n=29) of patients. The catheters were locked with citrate (4% or 30%) during the interdialysis period in the majority of patients. The most common type of catheter used (also as permanent access) was the precurved, noncuffed, single-lumen jugular catheter (Medcomp, Harleysville, PA, USA). In some patients, this type of catheter has been used for years.

Fig. 7. Vascular access in prevalent hemodialysis patients on December 31, 2006 (n=1271).



Incident hemodialysis patients: On December 31, 2006, there were 207 new hemodialysis patients (58% men, median age 64.5 years, range 17-93 years, 29.5% diabetics) who were alive and on hemodialysis (patients on PD and incident HD patients who died soon after starting dialysis are excluded), with the following vascular accesses (on December 31, 2006): native arteriovenous fistula in 73.4% (n=152), PTFE graft in 4.3% (n=9), and HD catheter in 22.2% (n=46) of patients. In patients with AV fistula and graft, the location of fistula/anastomosis was on the forearm in 68.3% (n=110), on the elbow/arm in 31.1% (n=50), and in the thigh in 1 patient – 0.5% of cases. An AV fistula or graft was on the left side in 67.7% (n=109) and on the right side in 32.3% (n=52) of these patients. The hemodialysis catheters (n=46, 22.2%) were: temporary (noncuffed) in all patients; precurved jugular in 76.1% (n=35), subclavian in 21.7% (n=10) and femoral in 2% (n=1) of patients; placed on the right side in 89% (n=41) and on the left in 11% (n=5) of patients; single-lumen in 76% (n=35) and double-lumen in 24% (n=11) of all cases.

Fig. 8. Vascular access in incident hemodialysis patients on December 31, 2006 (n=207).



Vascular access activities at the Dialysis Center Zaloška, Department of Nephrology. Two dedicated nephrologists (M. M. and R. P.) from the Department of Nephrology perform vascular access surgery for approximately half of all Slovenian hemodialysis patients, including children. This includes vascular access surgery for all private hemodialysis centers in Slovenia. In the rest of the country, vascular access surgery is performed by a dedicated surgeon at each hospital, with complicated cases being referred to nephrologists at the Dialysis Center Zaloška. These cases include the salvage of suddenly thrombosed AV fistulas and grafts. Surgical procedures are performed in the operative theatre of the Dialysis Center Zaloška under local anesthesia and as outpatient procedures in the vast majority of patients. In a few patients (mainly pediatric), an AV fistula is created under general anesthesia, again by nephrologists.

In 2006, 273 surgical procedures were performed, 61 of which were salvage procedures for thrombosed AV fistulas or grafts. In 2006, 843 hemodialysis catheters – mainly temporary (noncuffed) – were inserted. In addition, 445 ultrasonography examinations of AV fistulas or grafts (preoperative mapping, ultrasonography of dysfunctional or failed fistula) were performed.

In 2007, 243 surgical procedures were performed, 62 of which were surgical salvage procedures for thrombosed native AV fistula (29 procedures) and Gore-tex AV fistula (33 procedures). In addition to salvage procedures, 181 surgical constructions of AV fistula (145 native, 34 PTFE grafts, 2 brachiobasilic fistulas with superficialization) were performed. In the same year, 883 hemodialysis catheters were inserted, of which 327 jugular single lumen, 6 jugular double lumen, 420 femoral single lumen and 130 femoral double lumen, all noncuffed and locked with 30% citrate. In addition, 395 ultrasonography examinations of AV fistula or graft (preoperative mapping, ultrasonography of dysfunctional or failed fistula) were performed.

A total of 4777 AVF/graft construction/salvage procedures and 18826 hemodialysis catheter insertions had been performed at the Dialysis Center Zaloška at the end of 2007.

Hemodialysis monitors in Slovenia

On December 31, 2006, there were 485 hemodialysis monitors and 392 hemodialysis stations in Slovenia, 19 of which were dedicated to patients with transmissible diseases (hepatitis B and C and MRSA-positive patients). The hemodialysis monitors used were from Fresenius (40%), Gambro (36.1%), Braun (14%), and from Hospal-Gambro (Integra) (7%). There were 14 monitors for continuous renal replacement therapy, 12 of which were from Prisma-Hospal and two were from Braun (Table 6). In addition to hemodialysis monitors (485), there are 3 apheresis monitors at the Dialysis Center Zaloška – 2 for plasma exchange and protein A immunoadsorption (Citem 10, Excorim, Fresenius) and 1 for LDL apheresis (Kaneka).

Table 6. Number and manufacturers of hemodialysis monitors used in Slovenia on 31 December, 2001-2006

HD monitors (n)	2001	2002	2003	2004	2005	2006
All	351	400	413	429	465	485
Gambro	160	163	164	154	163	175
Fresenius	147	173	176	187	195	194
Hospal Integra	25	28	27	32	34	34
Braun	14	29	35	45	61	68
CRRT†	5	7	11 (Prisma 10)	11 (Prisma 9)	12 (Prisma 10)	14 (Prisma 12, Braun 2)

†CRRT: continuous renal replacement therapy.

Transmissible diseases in dialysis patients

3.2% (n=44) of dialysis patients had the hepatitis B or C virus infection in 2006 (2 patients had both hepatitis B and C virus infections), whose number and percentage has been low over the years (Table 7). The number of methicillin-resistant *Staphylococcus aureus* (MRSA)-positive dialysis patients has been decreasing in the last four years. All positive patients (including MRSA) have been isolated. The main dialysis unit for patients with transmissible diseases is in the Dialysis Center Zaloška, with 5 dialysis stations (in a separate room) dedicated to hepatitis B and C virus-positive patients and additional 2 dialysis stations (in a separate room) dedicated to MRSA-positive patients. MRSA-positive patients are also dialysed in two out of four FMC dialysis centers, separately in a dedicated room, with dedicated dialysis monitors.

There were no HIV-positive patients on chronic renal replacement therapy through the end of the year 2006.

Table 7. Number and percentage of dialysis patients positive for hepatitis B or C virus and MRSA (methicillin-resistant *Staphylococcus aureus*).

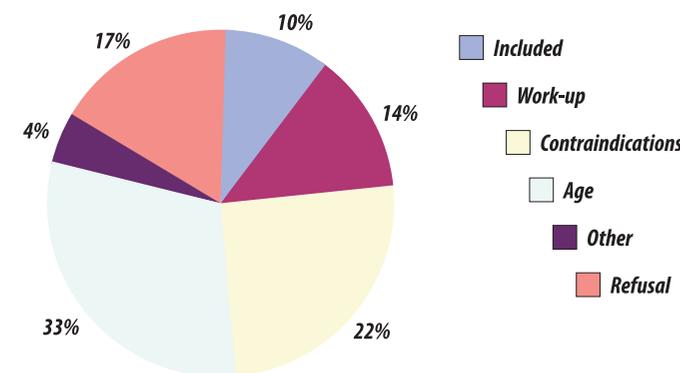
	1999	2000	2001	2002	2003	2004	2005	2006
†HBV (n)	13	14	20	20	20	20	18	22 (+2)
‡HCV (n)	22	22	21	22	20	15	12	20 (+2)
HBV+HCV (%)	3.1	3.1	3.3	3.4	3.1	2.7	2.2	3.2
†‡MRSA(n) (##HD/‡‡PD)	-	14/5	32/4	36/4	34/2	26/4	24/2	20/0
MRSA HD+PD (%)		1.6	2.9	3.2	2.8	2.3	1.9	1.5

† HBV: hepatitis B virus
 ‡ HCV: hepatitis C virus
 †‡MRSA: methicillin-resistant *Staphylococcus aureus*
 ## HD: hemodialysis
 ‡‡ PD: peritoneal dialysis

Dialysis patients and waiting list for cadaveric kidney transplantation

According to the referrals from the Kidney Transplant Center, 10% of dialysis patients (137/1374) were on the waiting list for cadaveric kidney transplantation at December 31, 2006, with an additional 186 patients (13.5%) under work-up for inclusion. 32.2% (442/1374) of the patients were not included because of their age (and associated comorbidities), 22.5% (309/1374) because of medical contraindications, 4.4% (61/1374) for other reasons, and 17.4% (239/1374) of dialysis patients reportedly refused to be transplanted. Some of these patients have significant comorbidities. The patients referred as refusing kidney transplantation and being >65 years of age were counted as not referred to the waiting list because of age (although there is no upper age limit for inclusion in the waiting list for kidney transplantation). All patients refusing kidney transplantation are usually thoroughly informed on kidney transplantation and on studies showing the survival benefits of transplantation compared to dialysis, and are continuously being informed on new drugs, improvements in immunosuppressive protocols, and other approaches that are expected to improve the results and decrease the side effects of immunosuppressive therapy after transplantation. Their decision to refuse kidney transplantation were discussed during their regular visits to nephrologists.

Fig. 9. Dialysis patients and waiting list for cadaveric kidney transplantation on December 31, 2006.



Kidney transplantation

There is one transplant center in Slovenia, located at the University Medical Center Ljubljana. Slovenia has been a member of Eurotransplant since January 1, 2000.

In 2006, 48 cadaveric kidney transplantations were performed, which was an increase compared to 28 cadaveric kidney transplantations in 2005. This was the first graft in 39 patients and the second graft in 9 patients. Six transplant recipients were older than 60 years, four transplant recipients were diabetics, and one recipient was younger than 18 (15) years. Three (out of 461) kidney graft recipients died in 2006 with functioning kidney grafts, and 12 started chronic dialysis because of end-stage kidney graft failure. Three of these 12 patients died soon after starting hemodialysis (2, 14 and 36 days afterwards, respectively). Thus, the total number of kidney graft recipients who died either with functioning grafts or soon after graft failure was 6.

The total number of renal transplantations in Slovenia from 1970 to December 31, 2006 was 684, of which 124 involved a living related donor and 560 a cadaveric donor. The total number of patients with functioning kidney grafts (residents only) was 461 on December 31, 2006. Of these patients, 438 (95%) received grafts from deceased and 23 (5%) from living related donors.

A survival analysis shows better patient and graft survival in Slovenia compared to Eurotransplant data, and better graft survival compared to Collaborative Transplant Study data.

Fig. 10. Kidney-only transplant graft survival rates stratified by Center (Slovenia) and ET transplants (Jan 1, 2000 to Dec 12, 2007).

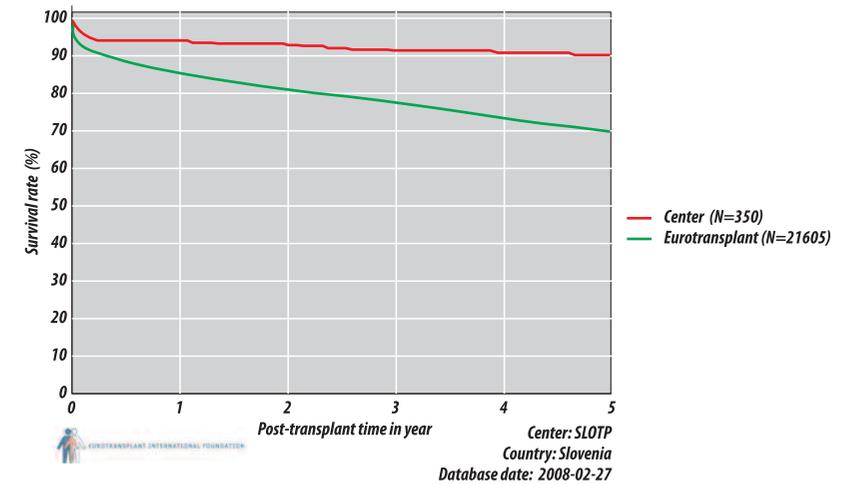
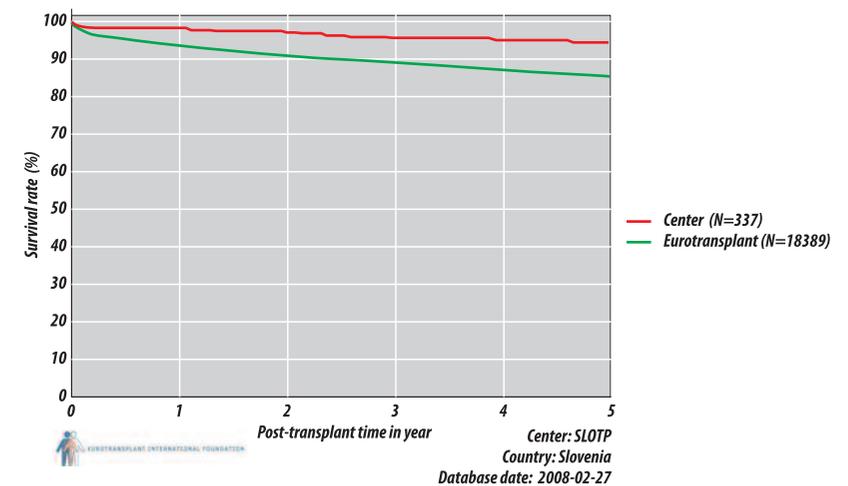
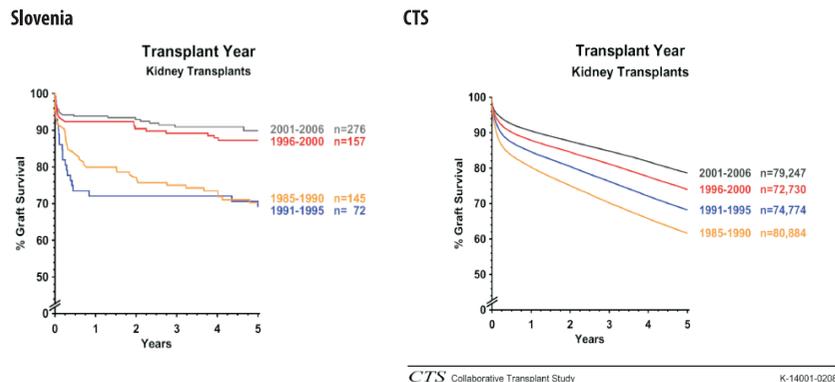


Fig. 11. Kidney-only transplant patient survival rates stratified by Center (Slovenia) and ET transplants (Jan 1, 2000 to Dec 12, 2007).



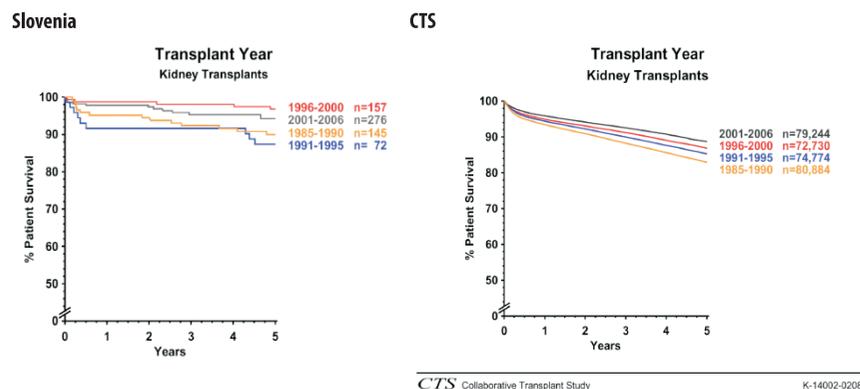
Figs. 12-13. Comparison of graft and patient survival in different periods between Slovenian kidney graft recipients and data from the Collaborative Transplant Study (CTS).

Graft survival (deceased donors)



Selection	Kaplan-Meier Estimates ± Standard Error in %									
	Year 1		Year 2		Year 3		Year 4		Year 5	
2001-2006	93.8	±1.4	93.0	±1.6	90.9	±1.8	90.9	±1.8	89.9	±2.1
1996-2000	92.4	±2.1	90.4	±2.3	89.2	±2.5	87.9	±2.6	87.3	±2.7
1991-1995	72.1	±5.3	72.1	±5.3	72.1	±5.3	72.1	±5.3	69.2	±5.5
1985-1990	80.0	±3.3	77.2	±3.5	75.0	±3.6	73.5	±3.7	70.2	±3.9

Patient survival



Selection	Kaplan-Meier Estimates ± Standard Error in %									
	Year 1		Year 2		Year 3		Year 4		Year 5	
2001-2006	97.8	±0.9	97.4	±1.0	95.3	±1.4	95.3	±1.4	94.2	±1.8
1996-2000	98.7	±0.9	98.7	±0.9	98.1	±1.1	98.1	±1.1	96.8	±1.4
1991-1995	91.6	±3.3	91.6	±3.3	91.6	±3.3	91.6	±3.3	87.4	±3.9
1985-1990	95.2	±1.8	94.5	±1.9	92.3	±2.2	91.6	±2.3	90.0	±2.5

Department of Nephrology, University Medical Center Ljubljana

The Department of Nephrology is the largest nephrological institution in the country. It is also one of the largest departments of the University Medical Center Ljubljana (one of two university medical centers in the country with over 7000 employees).

The Department of Nephrology has 180 employees (27 physicians, 143 nurses and technicians, 10 administrative workers) and is organized in seven units:

1. a hospital ward (30 beds);
2. an outpatient unit for general nephrology and hypertension (about 5000 patient visits per year);
3. the Center for Kidney Transplantation, which takes care of all renal transplant recipients in Slovenia and keeps a waiting list for renal transplantation;
4. Dialysis Center Zaloška (Center for Acute and Complicated Dialysis): 41 dialysis stations operating in 4 shifts, 24 hours/day, ≈36,000 dialysis procedures per year; intensive-care dialysis is performed in >20 dislocated intensive care units, including pediatric intensive care units (where adult nephrologists and nurses perform hemodialysis and plasma exchange of newborns and infants), offering dialysis and plasma exchange procedures 24 hours a day, both at the Center as well as in intensive care units; various types of vascular access surgery performed by specially trained nephrologists (temporary and permanent hemodialysis catheters, native and graft arteriovenous fistula);
5. Center for Hemodialysis Leonišče: 18 dialysis stations, ≈10,000 dialysis procedures per year;
6. Center for Peritoneal Dialysis: ≈40-50 patients on peritoneal dialysis;
7. Ultrasound Unit: biopsies of native and transplanted kidneys, ultrasonography/Doppler of kidneys and renal arteries, ultrasonography/Doppler related to vascular access for hemodialysis: preoperative mapping, ultrasonography/Doppler of dysfunctional and failed AV fistula, ultrasonography-guided hemodialysis catheter insertion, echocardiography, all performed by dedicated nephrologists.

766/1835 (41.7%) of all RRT patients in Slovenia had been treated at the Department of Nephrology (as their primary center) at the end of 2006. Among these, 265 were chronic hemodialysis patients, 40 patients were on peritoneal dialysis, and 461 patients had a functioning kidney graft. In 2006, ≈46,000 hemodialysis procedures were performed, 1966 in intensive care units. The Department of Nephrology is also a tertiary referral center for all complicated cases in the areas of nephrology and dialysis for the whole country.

Apheresis procedures at the Department of Nephrology, University Medical Center Ljubljana

Apheresis procedures (membrane plasma exchange, LDL apheresis with dextrane-sulphate columns - Kaneka and protein A immunoadsorption) are performed at the Dialysis Center Zaloška, Department of Nephrology, University Medical Center Ljubljana. An increase in the number of plasma exchange procedures was observed in the period from 1997-2006, while the number of immunoadsorption procedures was comparatively stable in the last 3 years (Table 8).

Table 8. Number of apheresis (membrane plasma exchange, LDL apheresis and protein A immunoadsorption) procedures performed in the period from 1997-2005

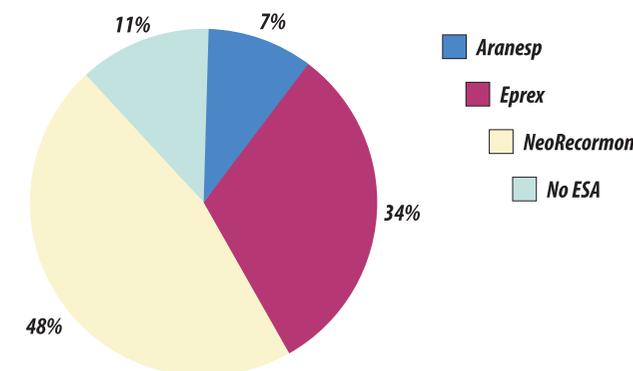
	All apheresis procedures	Membrane plasma exchange	LDL apheresis	Immunoadsorption (protein A)
1997	183	113	27	43
1998	251	136	17	98
1999	296	180	64	52
2000	452	293	65	94
2001	443	231	61	151
2002	480	235	54	191
2003	572	242	80	250 (24 new*)
2004	569	246	78	245 (22 new)
2005	673	410	34	229 (21 new)
2006	609	416	19	174 (17 new)
2007	674	426	18	230 (18 new)

*new refers to the first use of Fresenius (Excorim) protein A Immunosorba columns

Erythropoiesis stimulating agents (ESA) therapy in prevalent RRT patients

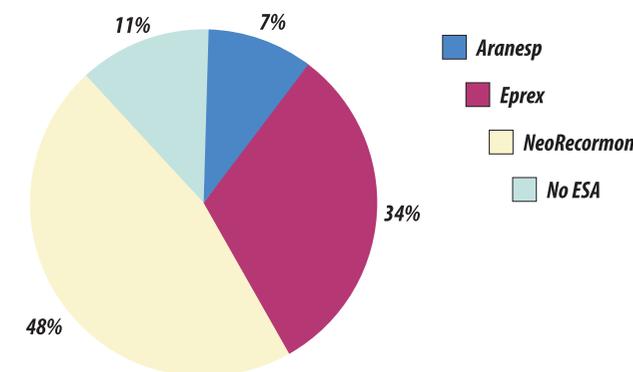
Hemodialysis patients (n=1271, median age 65 yrs (13-92), 55% men, 24.2% diabetics): 88.7% (1128/1271) have received ESA, almost all of them intravenously. The median weekly dose in the last week of December 2006 was 6000 units (mean 6690±5795, range 500-60000 units); the patients who received Aranesp were not counted (the dosing schedule was missing for a significant portion of Aranesp-treated patients). 11% (n=143) of patients did not receive epoetin, while 48% (n=604) have received NeoRecormon, 34% (N=433) Eprex and 7% (n=91) Aranesp.

Fig 14. ESA therapy (last week in December 2006) in prevalent hemodialysis patients (N=1271).



Peritoneal dialysis patients (n=103, median age 53 yrs, range 2-76, mean 51±16 years, 59% men, 21.4% diabetics): 80.6% (83/103) have received ESA subcutaneously. The median weekly dose in the last week of December 2006 was approximately 4000 units (mean 4927±4645 units, with all patients counted).

Fig 15. ESA therapy (last week in December 2006) in prevalent peritoneal dialysis patients (N=103).



Transplant patients (n=461, median age 52 yrs, range 14-76, 57% men, 14.3% diabetics): 13.9% (64/461) have received ESA subcutaneously. The median weekly dose in the last week of December 2006 was 4000 units (mean 4747±3426, range 500-18000 units, only those patients who received ESA were counted).

Fig 16. ESA therapy (last week in December 2006) in patients with functioning kidney grafts (N=461).

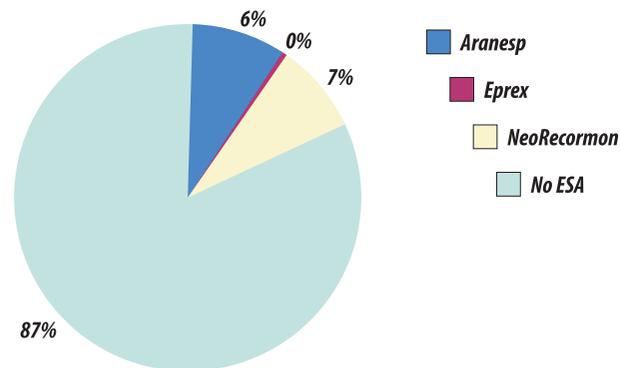
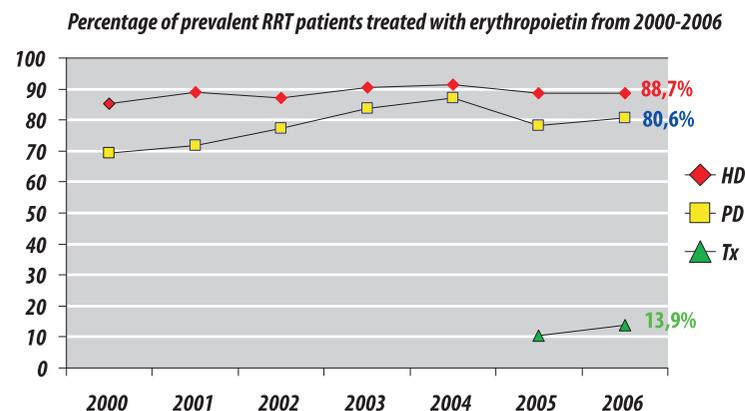


Fig 17. Percentage of prevalent RRT patients treated with erythropoiesis stimulating-agents (ESA) from 2000-2006.



International comparison

Table 9. Some data from other countries selected from the ERA-EDTA registry, Annual Report 2006

Country	General population in thousands*	Incidence at day 1 (N)	Incidence pmp	Incident diabetics pmp	Prevalence (N)	Prevalence pmp	Tx pmp**
Austria	8268	1306	158	52	7544	912	430
Bosnia and Herzegovina	3832	398	104	31	2012	604	34
Denmark	5437	640	118	29	4307	792	315
Finland	5266	441	84	30	3807	723	413
Germany	82315	17548	204	73	91718	1114	306
Greece	11148	2185	196	58	10968	984	188
Norway	4661	464	100	17	3508	753	549
Poland	38117	4650	122	36	21765	571	210
Romania	21566	1617	75	16	6573	305	19
Russia	142221	3934	28	4	18486	130	29
Slovenia	2010	248	124	31	1835	913	229
Sweden	9081	1156	127	33	7677	845	441
The Netherlands	16346	1828	112	18	12617	772	411
UK, England	46144	5103	111	22	32335	701	280
UK, Scotland	5117	586	115	25	3966	775	354
Turkey	70490	12979	184	53	42196	599	59

*general population covered by the registry

** number of patients with functioning kidney grafts pmp

In the United States, the prevalence rate of RRT patients in 2005 was 1585 pmp (485,012 patients), the incidence rate 351 pmp, and the number of patients with functioning kidney grafts was 485 pmp. In Japan, there were 257,765 dialysis patients in 2005 with a prevalence rate of 2018 pmp, almost all RRT patients being treated with dialysis.

Summary – Renal Replacement Therapy in Slovenia in 2006

- 21 renal centers (the same as in 2005), 20 dialysis and 1 kidney transplant center;
- Prevalence rate 913 pmp (+1.8%), incidence rate 124 pmp, median age of incident patients 66 years, 55% men;
- RRT modality of prevalent patients: 70% HD, 24% functioning graft, 6% PD;
- Hemodialysis: 77% of patients are dialyzed in hospital dialysis centers and 23% in 5 private, free-standing dialysis centers (4 are owned by Fresenius Medical Care);
- HDF in 37.8% of HD patients, automated PD in 26% of PD patients, cadaveric graft in 95% of patients with a functioning kidney graft;
- Crude death rate of dialysis patients 14.7%, of transplant patients 1.35%, and of all RRT 11.4% ((incident day 1 included);
- 33 patients alive in March 2008, ≥ 30 years on RRT (1.8% of all prevalent patients);
- Vascular access - prevalent HD patients: 84% native AV fistula, 5% PTFE graft and 11% catheter; incident HD patients: 74% native AV fistula, 4% PTFE graft and 22% catheter;
- Average epoetin weekly dose: HD 6700 units (iv, all HD patients counted), PD 5000 units (sc, all PD patients counted), Tx 4800 units (sc, only patients receiving EPO were counted).

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Date: _____

RENAL REPLACEMENT THERAPY QUESTIONNAIRE FOR 2006 – DIALYSIS AND KIDNEY TRANSPLANTATION – INDIVIDUAL PATIENT

Renal center: _____

Questionnaire is provided for:

- All patients treated with renal replacement therapy in your renal center for **end-stage renal failure on December 31, 2006**
- All patients treated with renal replacement therapy who died during 2006 in your renal center (even if they were dialyzed for ESRD only once):

Name: _____ Sex: _____ Date of birth: _____

Type of RRT on December 31, 2006: **HD** **CAPD** **Automated** **PD** **Tx**

Primary renal disease: _____ EDTA code: _____

Date and type of first RRT in life ever: **HD** **PD** **Tx** **Date:** _____

Comorbidity at the end of 2006 : _____ Comorbidity at the start of RRT: _____

- | | |
|-------------------------------------|--------------------------------|
| a) Diabetes mellitus Type 1 2 | a) Diabetes Type 1 2 |
| b) Ischemic heart disease | b) Ischemic heart disease |
| c) Peripheral art. occlusive dis. | c) Periph. art. occlusive dis. |
| d) Cerebrovascular dis. | d) Cerebrovascular dis. |
| e) Malignant dis. _____ | e) Malignant dis. _____ |

Dates of changes in RRT, chronologically (e.g. HD from, 1. Tx date Donor cadaveric or living related, restarted HD from, 2. Tx date Donor cadaveric or living related, PD from, Not requiring dialysis from),

Transfer of the patient from another renal center in 2006 (vacation dialysis not counting):

The patient came from: _____ Date: _____

Positive for transmissible diseases (mark): hepatitis B hepatitis C MRSA other: _____

Patient on RRT who died in 2006 in your renal center:

Date of death: _____ Cause of death: _____ EDTA code: _____

Epoetin dose (per week) in the last week of December 2006: Dose: _____ No. of applications/week: _____

EPO (mark): Eprex NeoRecormon Aranesp Route of application: i.v. s.c.

Is the **dialysis patient** treated in your renal center on 31 December 2006 included in the **waiting list for cadaveric kidney transplantation**?

yes no

If not, please explain why:

a) medical contraindications _____

b) refusal _____

c) diagnostic workup (preparing for inclusion) _____

d) age _____

e) other _____

Remarks: _____

Signature: _____

ADDITIONAL QUESTIONNAIRE FOR HEMODIALYSIS PATIENTS TREATED AT YOUR DIALYSIS CENTER (FOR ESRD) ON DECEMBER 31, 2006

Name: _____

If »positive« for transmissible disease, mark the isolation policy:

A) isolated room
 B) isolated HD monitor
 C) last in the dialysis shift
 D) not isolated

Type of hemodialysis procedure in the last week of December 2006:

BHD
 Online HDF
 Online HF
 AFBF

Ultrapure dialysis fluid: yes no

Number of HD procedures per week in the last week of December 2006: _____

Number of hours of HD per week in the last week of December 2006 (e.g. 12; 13,5; 15...): _____

If HF/HDF, the amount of fluid exchanged per procedure: _____

If HF/HDF (mark) predilutional postdilutional combination

Dialyzer in the last week of December 2006: _____

Dry body weight in the last week of December 2006: _____

Blood flow in the last week of December 2006 (ml/min) : _____

Single-needle procedure: yes no

Anticoagulation (last week of December 2006): Unfractionated heparin: Dose per HD: _____

Low molecular weight heparin (original name): dose per HD: _____

Vascular access on December 31, 2006:

Type
 Position of anastomosis
 Side

AV FISTULA (mark)

native	Gore-tex		
forearm	elbow	arm	thigh
right	left		

CATHETER

jugular	subclavian	femoral
right	left	
temporary (noncuffed)		silastic
single-lumen		double-lumen

Remarks: _____

Signature: _____

Date: _____

RENAL REPLACEMENT THERAPY QUESTIONNAIRE FOR 2006 – DIALYSIS CENTER

Renal center: _____

Number of RRT patients on December 31, 2006

All: _____ HD: _____ PD: _____

Number of hemodialysis stations on December 31, 2006:

Number of »positive« dialysis patients on December 31, 2006:

Hepatitis B _____ Hepatitis C _____ HBV+HCV _____ HIV: _____

MRSA: _____ Other: _____

The isolation policy of »positive« patients (mark):

HBV pos. A) Dedicated rooms B) Dedicated monitors C) Last in shift D) No isolation

HCV pos. A) Dedicated rooms B) Dedicated monitors C) Last in shift D) No isolation

MRSA pos. A) Dedicated rooms B) Dedicated monitors C) Last in shift D) No isolation

Remarks: _____

Number of employed physicians in renal center: _____

Number of employed graduate renal nurses: _____

Number of employed medical technicians: _____

Number of employed administrative personnel: _____

Number of employed technicians for hemodialysis monitor maintenance: _____

Additional personnel employed in renal center: _____

Remarks: _____

Number of HD procedures performed in 2006 (data for state insurance):

All: _____ Type I: _____ Type III: _____

Number of acute HD procedures performed in 2006 (data for state insurance):

Acute renal failure treated with dialysis – number of patients in 2006:

Of these, the number of patients treated: a) only with intermittent HD: _____ patients
 b) only with CRRT: _____ patients
 c) with combined HD and CRRT: _____ patients

Number of dialysis patients treated with epoetins on December 31, 2006:

All: _____ HD: _____ PD: _____

Number of predialysis patients treated with epoetin on December 31, 2006 (approximations according to available data, assuming that predominantly nephrologists from dialysis centers prescribe epoetins to predialysis patients):

New patients starting chronic dialysis in 2006:

All: _____ HD: _____ PD: _____

Number of dialysis patients who died in 2006 (even if they were dialyzed for ESRD only once):

All: _____ HD: _____ PD: _____

Number of dialysis patients included in waiting list for cadaveric renal transplantation on December 31, 2006:

All: _____ HD: _____ PD: _____

Number of hemodialysis monitors on December 31, 2006:

Types of hemodialysis monitors on December 31, 2006: Fresenius:

Gambro: _____ Integra: _____ Prisma: _____ Other: _____

Remarks: _____

Signature: _____ E-mail: _____

