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June 25-28, 2010
Munich, Germany



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Selected Abstracts of the
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1. Progression of Chronic Kidney Disease

The Cockcroft-Gault, MDRD and CKD-EPI Equations: Which one is the Best for the Prediction of Renal Function in Patients Hospitalized due to Emergency?

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Introduction and Aims: The current staging system for chronic kidney disease is based primarily on estimated glomerular filtration rate (eGFR). It is known that the lower eGFR the higher risk of adverse outcomes is to be expected. Recent results show differences in glomerular filtration rate (GFR) estimated with the use of different equations. The aim of the study was to compare the values of eGFR calculated using the Cockcroft-Gault (CG), Modification of Diet in Renal Diseases (MDRD) and Chronic Kidney Disease Epi-

demiology Collaboration (CKD-EPI) equations in the cohort of patients hospitalized due to emergency.

Methods: The study involved 469 patients: 228 females (F) and 241 males (M) aged 64.9±14.3 (21-96) years. Among them, 44.6% of subjects were ≤65 years of age, whereas 55.4% were older. The main causes of hospitalization were acute coronary syndrome (28.8%), heart failure (17.7%) and pneumonia (11.3%). Hypertension (HA) was stated in 69.5% of subjects (73.3% of F and 66% of M). Diabetes mellitus (DM) was diagnosed in 44.4% of both F and M. The results of eGFR were expressed in ml/min/1.73 mm².

Results: We obtained a strong positive correlation between eGFR calculated with CG and MDRD ($r=0.917$; $p<0.0001$), MDRD and CKD-EPI ($r=0.974$; $p<0.0001$), as well as between CG and CKD-EPI ($r=0.947$; $p<0.0001$). Mean values of eGFR calculated according to CG, MDRD and CKD-EPI were: 61.32 ± 27.4 , 62.82 ± 26.9 and 60.7 ± 25 . Depending on the equation used, values of eGFR < 60 ml/min/1.73m² were stated in 52.7% (CG), 45.3% (MDRD) and 49% (CKD-EPI) of subjects. In the group aged ≤65 years, they were stated, respectively, in 17%, 21.6% and 21.3% of patients. The mean values of eGFR obtained with the three equations were similar (78.27 ± 28.4 , 75.0 ± 27.9 and 73.9 ± 26). In contrast, in the group

older than 65 years, 83% (CG), 78.4% (MDRD) and 78.7% (CKD-EPI) of patients had eGFR < 60 ml/min/1.73mm². Compared to the younger group, the frequency of renal function impairment was highly significant for each equation ($p<0.0001$). Statistically significant were also differences between the mean eGFR calculated with CG (47.7 ± 17.0) and both MDRD (53.0 ± 21.6) and CKD-EPI (50.1 ± 19.7) ($p<0.01$). In addition, the mean values of eGFR in patients with HA were significantly lower than in those without HA (CG -55.9 ± 25.4 v. 73.6 ± 27.7 , MDRD -56.9 ± 24.8 v. 76.3 ± 26.8 , and CKD-EPI -54.7 ± 23.8 v. 74.5 ± 25 ; for each of them $p<0.0001$). The same concerned patients with DM (CG -55.3 ± 24.2 v. 66.1 ± 28.8 , MDRD -56.1 ± 25.3 v. 68.1 ± 27.0 , and CKD-EPI -54.0 ± 24.1 v. 66.1 ± 26.1 ; for all comparisons $p<0.0001$).

Conclusions: Our results showed that independently of the equation used age, HA and DM had an essential impact on kidney function in patients hospitalized due to emergency. However, in agreement with previous suggestions, also in this special cohort the use of CG for the calculation of eGFR in elderly may result in its underestimation.

Comparison of Estimating GFR Formulas in the Elderly Best Abstracts Presented by Young Authors

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Introduction and Aims: Despite current use, 24 hours creatinine clearance (CrCl_{24H}) is difficult to employ to estimate GFR in the elderly. Although many easy formulas are currently available to estimate GFR in adults, their use in the elderly is not validated. We conducted this study to better understand the relationship between estimating CrCl_{24H} and GFR formulas in the elderly.

Methods: Design: Cross-sectional study. We enrolled 72 patients aged 65-100 years who did not have polycystic kidney disease. Renal function was estimated by CrCl_{24H}, Cockcroft-Gault, MDRD and CKD-EPI formula. Renal dysfunction was considered as CrCl_{24H} < 60 ml/min. We classified estimated GFR (eGFR)

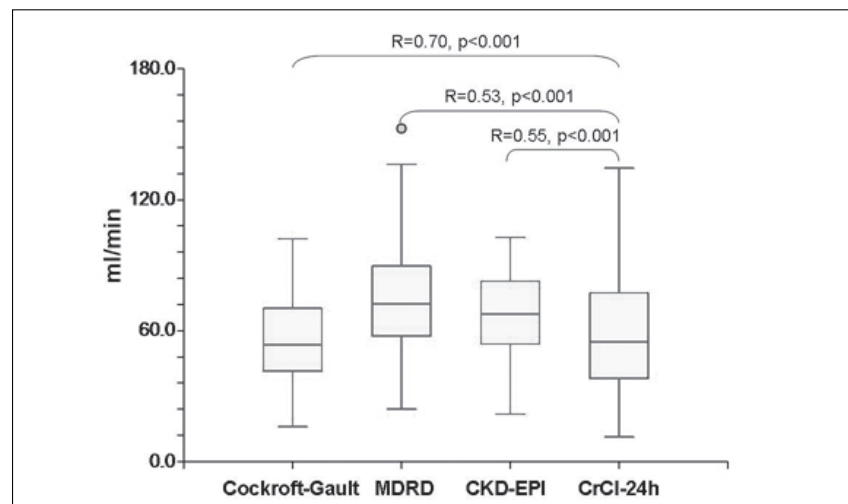
according to best cut-off. Spearman correlation was used to correlate estimating GFR formulas.

Results: The mean age was 79.9 ± 6.9 years, male sex 44.4%, diabetes 29.2%, hypertension 80.6%. Serum creatinine was 0.98 ± 0.42 mg/dl, CrCl 52.0 ± 28.0 ml/min, Cockcroft-Gault 56.2 ± 20.2 ml/min, MDRD 77.3 ± 29.4 ml/min, CKD-EPI 67.6 ± 19.8 ml/min, body surface area (BSA) 1.70 ± 0.22 m². Renal dysfunction was present in 41 patients (56.9%). The highest correlation was found between CrCl_{24H} and Cockcroft-Gault formulas (figure).

Sensitivity (Se), specificity (Sp), positive (PV+) and negative (PV-) predictive value of eGFR for renal dysfunction are reported in the table. ROC curve analysis show that discriminatory power of Cockcroft-Gault < 52.3 ml/min (AUC 0.86, p<0.001) was higher than discriminatory power of MDRD < 86.9 ml/min (AUC 0.71, p<0.001) and CKD-EPI < 64.9 ml/min (AUC 0.70, p<0.001).

Conclusions: In the elderly, Cockcroft-Gault formula is a stronger predictor of renal dysfunction than MDRD and CKD-EPI formulas.

Correlations between Different Estimating GFR Formulas



Diagnostic Tests of Three Estimating GFR Formulas for Renal Dysfunction

Patients with:	Sensibility (%)	Specificity (%)	Predictive Value + (%)	Predictive Value - (%)
Cockcroft-Gault < 52.3 ml/min (n=34)	78.0	93.5	94.1	76.3
MDRD < 86.9 ml/min (n=50)	87.8	54.8	72.0	77.3
CKD-EPI < 64.9 ml/min (n=26)	53.7	87.1	84.6	58.7

Simple Cystatin C Formula Compared to Sophisticated Creatinine and Cystatin C-Based Formulas (CKD-EPI) for Estimation of Glomerular Filtration Rate

Eight Best Abstracts and Eight Best Abstracts Presented by Young Authors

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Introduction and Aims: Serum creatinine concentration and serum creatinine-based formulas, like Modification of Diet in Renal Disease Study equation (MDRD) are the most commonly used markers to estimate glomerular filtration rate (GFR). Recently, serum cystatin C-based formulas, the newer creatinine formula (The Chronic Kidney Disease Epidemiology Collaboration formula (CKD-EPI creatinine formula) and equation that uses both serum creatinine and cystatin C (CKD-EPI creatinine & cystatin formula) were proposed as new GFR markers. The aim of our study was to compare MDRD, CKD-EPI creatinine, CKD-EPI creatinine & cystatin formulas and simple cystatin C formula (100/serum cystatin C) against ⁵¹CrEDTA clearance in patients with CKD.

Methods: In this study 800 adult Caucasian patients (339 women, 461 men; mean age 58±15.5 years) with established or suspected CKD were enrolled. In each patient serum creatinine and serum cystatin C (immunonephelometric method) were determined. GFR was calculated using the MDRD, CKD-EPI creatinine, CKD-EPI creatinine & cystatin formulas and simple cystatin C formula. GFR was also measured using ⁵¹CrEDTA clearance, and the correlation, accuracy, bias and precision of different equations were determined. Ability to correctly estimate patient's GFR with different equations compared to ⁵¹CrEDTA clearance below and above 60 ml/min/1.73 m² was analyzed.

Results: The mean ⁵¹CrEDTA clearance was 47.2 ± 33.6 ml/min/1.73 m², mean serum creatinine 257 ± 183.8 µmol/l and mean serum cystatin C 2.53 ± 1.53 mg/l. Statistically significant correlations between ⁵¹CrEDTA clearance and all formulas were found (P<0.0001 for all). The ROC curve analysis (cut-off for GFR 60 ml/min/1.73 m²) showed that CKD-EPI creatinine & cystatin formula had a higher diagnostic accuracy than MDRD (P<0.025) or CKD-EPI creatinine formulas (P<0.031) but not than simple cystatin C formula (P=0.057). Bland and Altman analysis for the same cut-off value showed that creatinine formulas

(MDRD bias: -27.9; CKD-EPI creatinine bias: -26.3 ml/min/1.73 m²) or CKD-EPI creatinine & cystatin formula (bias: -23.9 ml/min/1.73 m²) underestimated and simple cystatin C formula (bias: 5.3 ml/min/1.73 m²) overestimated measured GFR. All equations lacked precision. It was 16.8, 16.4, 15.6 ml/min/1.73 m² for MDRD, CKD-EPI creatinine, CKD-EPI creatinine & cystatin formulas and 22.6 ml/min/1.73 m² for simple cystatin C formula. Analysis of ability to correctly predict GFR below and above 60 ml/min/1.73 m² showed that simple cystatin C and CKD-EPI creatinine formulas but not CKD-EPI creatinine & cystatin formula had higher prediction than MDRD formula (89.1% vs. 85.3%: P<0.0289; 90.8% vs. 85.3%: P<0.009; 87.9% vs.85.3%: P=0.156).

Conclusions: Our results indicate that simple cystatin C formula which requires just one variable (serum cystatin C concentration) is reliable marker of GFR in patients with CKD and comparable to creatinine formulas including sophisticated CKD-EPI formulas.

A Survey of Inappropriate Referrals to Nephrology Services Based on CKD Guidelines

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Introduction and Aims: Following the introduction of CKD guidelines and routine reporting of estimated glomerular filtration rate (eGFR) by UK laboratories in May 2006, a substantial increase in referrals to nephrology services was observed. A considerable number of these were deemed inappropriate, because the renal impairment was either non-progressive or precipitated by renin angiotensin system (RAS) blockade. Written advice was given to ensure appropriate continued management in primary care with criteria for re-referral. The aim of the study was to evaluate the renal outcome of inappropriate referrals to this regional centre, and to identify the contributory role of RAS blockade.

Methods: The electronic patient administration system was searched for all rejected referrals from May 2006-October 2008. The relevant patients' laboratory results and clinical details were gathered, including demographics, serum creatinine (SCr) and eGFR at referral, a year prior and a year later; use of any RAS blocking medication, SCr values before and after stopping this; the reason for rejection of referral and any subsequent re-referrals.

Results: 204 rejected referrals were identified, 77 M and 127 F with an age range of 20-93, median age 72. eGFR ranged from 15 to >90 ml/min (median 43). By CKD classification, 6.4% were in stage 1; 20.1% in stage 2; 51.5% in stage 3 and 22% in stage 4. Reasons for referral were: renal impairment (68%), proteinuria/haematuria (13%), hypertension (12%) and miscellaneous (7%). Reasons for rejection were: stability of renal impairment (40%), impairment considered acceptable for age (21%) or impairment attributed to RAS blockade (10%), isolated microscopic haematuria (8%), minimal proteinuria (5%) or uncomplicated hypertension (12%). The remaining 4% included patients better suited for palliative treatment or urology.

At the time of referral, SCr values had already improved compared to a year prior in 39% of patients, and deteriorated <20% in 48%.

A year after referral, SCr levels had improved in 61% and deteriorated <20% in 31%. In the remaining 8%, contributing factors causing deterioration were left ventricular failure and infection.

Only 20 of 204 (10%) of patients were re-referred, of whom 7 were seen, investigated and discharged, 8 had progressive renal failure (4 diabetic, 4 other causes), 2 required treatment for renal anaemia, 2 developed acute on chronic renal failure due to sepsis and 1 was in urinary retention.

RAS blockade was stopped in 2 of 19 patients (10%) under the age of 70 and 23 of 48 (48%) over 70. This improved SCr values significantly (>15% in 65% of patients).

Conclusions: CKD guidelines and eGFR reporting have led to a large number of patients with relatively stable CKD being referred to nephrology, many being treated with RAS blockade. Inappropriate use of RAS blockade is an important cause of reversible renal impairment. These findings suggest that only a small proportion develop progression of CKD, and that the current guidelines warrant revision.

Late Referrals with Advanced Chronic Kidney Disease are Well-Known in General Practice and Non-Nephrology Departments

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Introduction and Aims: Late referral of patients with advanced chronic kidney disease (CKD) is a well-known major problem. To establish a strategy on earlier referral it is important to get information on late referred patients, including their previous contacts with the health care system. The aim of the present study was to study courses in hospital and general practice in a 2-year period before start of renal replacement therapy (RRT) and to characterise late referred patients according to sex, age, income, education and diagnosis.

Methods: All incident chronic RRT patients in the period 1999-2005 in Denmark were identified in the Danish National Registry on Regular Dialysis and Transplantation. Information on contacts to hospital before RRT start was obtained from the National Patient Registry, on courses in general practice from the National Health Insurance Service Registry and on income and education from Statistics Denmark. Because of non-specific classification of hospital department to the National Patient Registry in 5 of 15 nephrology departments, these patients (15%) were excluded. Late referral was defined as a course of less than 16 weeks in a nephrology outpatient clinic before RRT start. Logistic regression was used to compare age, sex, income, education and diagnosis of late referrals versus patients referred in time.

Results: In a total of 4132 incident RRT patients, 2014 (49% range 28-65%) were seen in a nephrology department less than 16 weeks before RRT start and 1351 (33% range 15-57%) within 1 week before RRT start. Among late referrals, 1465 (73%) had a course in a non-nephrology department between 17 weeks and 2 years before RRT start. These included departments of endocrinology (7%), cardiology (11%), internal medicine (54%), urology (7%) and any surgical department (52%). Previous admission to a department of nephrology was seen in 121 (6%).

A total of 1701 (84%) late referrals were seen in general practice and 998 (50%) had blood tests done in the calendar-year before RRT start. When controlling for differences in age and sex, odds ratio (OR) for late referral in patients with diabetic nephropathy was 0.60 ($p < 0.0001$), glomerulonephritis 0.47 ($p < 0.0001$), polycystic kidney disease 0.31 ($p < 0.0001$) and non-specific CKD 0.92 ($p = 0.31$) compared to the rest of the patients. In patients ≥ 70 years (36%) OR was 1.35 ($p < 0.0001$) for late referral compared to patients < 70 years. Education, income or sex did not have a significant effect on late referral alone.

Conclusions: The majority of late referred patients with advanced CKD had a course in a non-nephrology department or general practice before start of RRT. Patients above 70 years were most likely to be late referred. The reason for late referral needs to be clarified and the nephrology community has to develop a strategy on earlier referral in CKD patients.

Association of Blood Pressure with Decline in Renal Function and Time to Renal Replacement Therapy in Pre-Dialysis Patients

Best Abstracts Presented by Young Authors

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Introduction and Aims: High blood pressure is a known risk factor for decline in renal function in both the general population and in patients with CKD. However, in the dialysis population reverse epidemiology has been found, where both high and extreme low blood pressures are associated with higher mortality rates. The aim of this study was to investigate the association between systolic and diastolic blood pressure and time to RRT and rate of decline in renal function in pre-dialysis patients, to assess whether reverse epidemiology is already present in pre-dialysis patients.

Methods: In the retrospective PREPARE cohort 547 incident pre-dialysis patients were included when referred to pre-dialysis out-patient clinics between 1999 and 2001. The clinical status of the patients was followed through medical charts until start of RRT or mortality. Rate of decline in renal function was calculated with available eGFR measurements, calculated by the MDRD formula. All analyses were performed with 1 year follow-up after inclusion. Linear regression was used to assess the association between blood pressure and decline in renal function, and Cox regression for time to RRT.

Results: Every 10 mmHg increase in systolic or diastolic blood pressure resulted in a more rapid rate of decline, with a sex and age adjusted decline of 0.04 (0.02-0.07) and 0.05 (0.00-0.10) ml/min/month/1.73 m² respectively. Sex and age adjusted rate of decline in patients with systolic blood pressure <120 mmHg or ≥180 mmHg was 0.24 (-0.07-0.54) lower and 0.26 (0.03-0.50) ml/min/month/1.73 m² higher respectively, compared with patients between 120-139 mmHg (mean decline of 0.37 ml/min/month/1.73 m²). Further adjustment did not change these results.

The risk for starting RRT increased with every 10 mmHg increase in systolic or diastolic blood pressure, with a sex and age adjusted

HR of 1.10 (1.05-1.15) and 1.16 (1.05-1.27) respectively. The HR for starting RRT was 0.89 (0.48-1.67) for systolic blood pressure <120 mmHg and 2.30 (1.52-3.47) for ≥180 mmHg, with 120-139 mmHg used as reference. Further adjustment did not change these results.

Conclusions: Reverse epidemiology was not present in our pre-dialysis cohort, where only an increase in systolic or diastolic blood pressure is associated with a more rapid rate of decline in renal function and an earlier start of RRT. Patients with low blood pressure had less renal decline and a later start of RRT. Therefore, strict treatment of pre-dialysis patients with a low blood target goal, especially for systolic blood pressure, could be beneficial to postpone RRT and will lead to lower mortality rates.

Chronic Kidney Disease Progression and Mortality in Mild to Moderate Kidney Dysfunction According to Serum Phosphorous Levels

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Introduction and Aims: The impact of serum phosphate abnormalities on Chronic Kidney Disease (CKD) progression and mortality among patients with mild to moderate kidney failure is still far from being established.

Methods: We determined the association of baseline phosphatemia with the composite endpoint of dialysis inception or all-cause mortality. We utilized the patient's records from the "Prevenzione Insufficienza Renale Progressiva" (PIRP) (<http://www.antr.it/community/pirp.html>) database, a large project sponsored by the Emilia-Romagna Institute of Health aimed at optimizing CKD patients care. We identified all patients who underwent a glomerular filtration rate (GFR) and serum phospho-

rous assessment between 2004 and 2007. The patients were followed up to 4 years. Survival analyses estimated the relationship between serum phosphorous at baseline and outcomes.

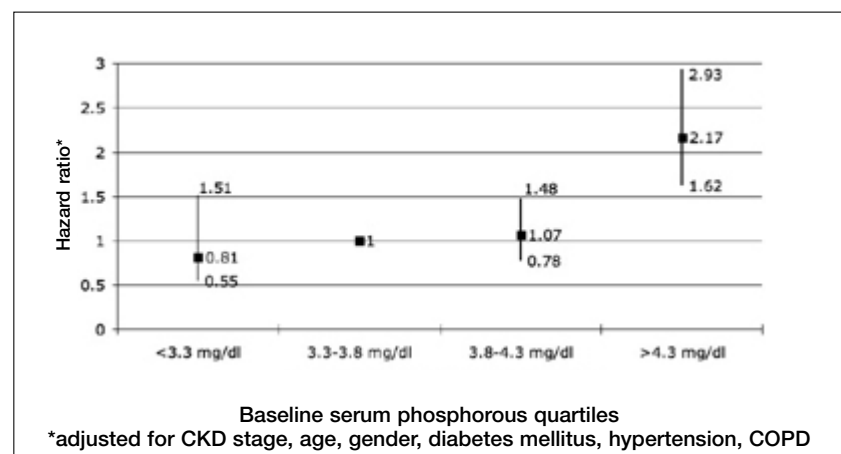
Results: A total of 1716 female and male subjects with CKD stage 3-5 were identified and classified according to quartiles of serum phosphorous at baseline. Elevated serum phosphorous was significantly associated with diabetes mellitus, but inversely associated with GFR, age and male sex (all p-trend values <0.001). A graded increase in the risk of commencing dialysis or dying was noted across quartiles of serum phosphorous (log-rank test p<0.001).

This association remained significant even after adjustment for traditional cardiovascular risk factors and CKD stage (Figure).

Indeed, patients in the highest serum phosphorous quartile (>4.3 mg/dl) experienced a 117% increase in the risk of the occurrence of the composite endpoint when compared to patients with serum levels of phosphorous of 3.3-3.8 mg/dl (Hazard Ratio 2.17; 95% Confidence Interval 1.62-2.93; p<0.001).

Conclusions: These analyses lend support to the hypothesis that serum phosphorous levels at baseline might accelerate residual renal function deterioration and increase the risk of death in patients with mild to moderate renal function impairment.

Risk of Dialysis Inception or All-Cause Mortality



2. Dialysis Modalities

Hemodiafiltration (HDF): Patterns of Use and Association with Outcomes in the Dialysis Outcomes and Practice Patterns Study (DOPPS)

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Introduction and Aims: HDF may provide greater clearance of middle molecules than standard hemodialysis (HD). In a prior DOPPS analysis HDF was associated with lower mortality compared to low-flux HD, and a clinical trial testing HDF vs. low-flux HD is ongoing. The current study provides updated data on patterns of HDF use in the international DOPPS cohort and describes the association of HDF with clinical outcomes in comparison to high-flux HD.

Methods: The study cohort comprised patients on thrice weekly maintenance dialysis for > 3 months in DOPPS I (1996-2001), II (2002-2004) and III (2006-2008).

HDF patients were classified as receiving “low” (5-15 L) or “high” (15-50 L) replacement fluid volume.

The association of HDF with inflammatory and nutritional measures was tested by logistic regression. Cox regression was used to estimate the associations of mortality with HDF use measured at the patient- and facility-level, using the case-mix adjusted % of facility patients on HDF as the predictor. Mortality risk associated with high- and low-volume HDF (vs. high flux HD) was assessed in two separate patient-level models.

Results: HDF was not used in the United States, Canada and Japan, but was used in Australia, New Zealand and all European countries, with highest use reported in Italy (18%) and Sweden (15%). HDF use varied widely across facilities within the same country. Use of both high-volume HDF (DOPPS I: 4.1%, II: 5.7%, III: 9.6%) and high-flux HD (DOPPS I: 17.5%, II: 33.7%, III: 43.9%) increased over time. On average, HDF patients were younger, had longer duration

of ESRD, and used fewer catheters. No difference in laboratory values and hospitalization risk was observed between HDF and HD patients. The associations of HDF with inflammatory markers and mortality risk are shown (Table). Similar results were found in models further adjusted for Kt/V and in analyses restricted to hospital-based and non-hospital based facilities.

Conclusions: Despite exposure to substantial amounts of an exogenous replacement fluid, HDF was not associated with an increase in inflammatory measures. Mortality risk was marginally lower for patients receiving high-volume HDF compared to high-flux HD (p=0.058) and significantly lower at facilities with a higher HDF use (p=0.0006). Larger volumes of replacement fluid may possibly lead to better outcomes among HDF patients due to increased convection. However, clinical trials are needed to definitely compare outcomes of high-volume HDF vs. high-flux HD.

Inflammatory and Nutritional Measures: Odds ratio (95% confidence interval)**

	Patient-level (vs. high-flux HD) [□]			Facility-level ^{□□}
	Low-volume HDF (5-15 L)	High-volume HDF (15-50 L)	Low-flux HD	HDF use: ≥ 15% vs. 1-14%*
Ferritin > 800 ng/ml	0.86 (0.62-1.19)	0.90 (0.68-1.19)	0.85 (0.70-1.03) ^c	0.72 (0.51-1.01) ^c
CRP > 10 mg/L	1.01 (0.66-1.55)	0.84 (0.60-1.17)	0.93 (0.75-1.16)	0.78 (0.57-1.07) ^d
WBC > 8000 mm ³	1.13 (0.84-1.52)	0.95 (0.76-1.17)	1.13 (0.99-1.30) ^c	0.95 (0.82-1.10)
Serum albumin < 3.5 g/dL	1.24 (0.93-1.66) ^a	1.38 (1.07-1.78) ^b	1.22 (1.03-1.45) ^b	1.03 (0.76-1.42)
Phosphorous > 5.5 mg/dL	1.00 (0.79-1.26)	1.03 (0.85-1.26)	1.03 (0.91-1.16)	0.83 (0.68-1.01) ^c

^a P<0.01; ^b P<0.05; ^c P=0.05-0.1; ^d P=0.1-0.15

* Mortality risk of patients treated at facilities where ≥15% patients are on HDF

** Adjusted for demographics, comorbidities, labs, catheter use, facility type, DOPPS phase and region

□ N=10,387

□□ N=13,671

One Year Observation of On-Line Hemodiafiltration (HDF) on Some Patterns in Uremics

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Introduction and Aims: On-line hemodiafiltration (OL-HDF) is for physiological reasons the most advanced form of extracorporeal renal replacement therapy. This approach gives the possibility to improve the still poor prognosis of hemodialysis (HD). However, the possible benefits of this therapy have not been well defined.

The purpose of study was to assess the influence of OL-HDF on dry weight, mean arterial pressure (MAP) and serum levels of total cholesterol (TCh) and triglycerides (Tg) in patients treated before by HD.

Methods: Thirty two uremics (25 non diabetic mellitus (NDM) and 7 diabetics type-2 (DM) participated in this study. The NDM group had a mean age 64 ± 14.56 and DM 56.67 ± 15.95 years, and average time of HD was 48.42 ± 41.64 months for both groups. Renal

disease was caused in NDM by chronic glomerulonephritis (9), hypertensive nephrosclerosis (10), polycystic disease (6), amyloidosis (4). NDM had been stable for 6.5 and DM 5.5 years on maintenance bicarbonate HD, scheduled thrice weekly 12 hrs/week, and achieved a mean single pool Kt/V_{urea} about 1.0 ± 0.2 , with low-flux membranes. Then they were switched to post-dilution OL-HDF. The OL-HDF was provided by 5008 Therapy System, using high-flux FX membrane, consisted of Q_b -300 ml/min., Q_d -500 ml/min, Kt/V_{urea} was 1.2 ± 0.3 , and time of OL-HDF was 240 min., with 10-17 L hemofiltrate exchanges of the replacement fluid. Both groups of patients during HD have been treated with 40 mg/day of simvastatins and ACE inhibitors/angiotensin II receptor antagonists. At the start of OL-HDF the dose of simvastatins was reduced to 20 mg. Predialysis blood samples were drawn twice, at the beginning and after 12 months of study. The measurements of dry weight (kg), MAP (mmHg) were estimated by conventional methods and TCh, Tg (mg/dl) by enzymatic assays. Means and standard deviations were calculated by conventional methods, and the statistical difference was determined by a paired Student's t-test.

Results: At the start of study the predialysis dry weight in NDM and DM was 67.4 ± 15.2 and 77.7 ± 14.7 Kg respectively, which was signifi-

cantly higher $p < 0.05$ in DM. After 12 months of study dry weight in NDM was 66.5 ± 14.7 Kg and in DM 78.8 ± 15 Kg which did not change significantly in comparison to the beginning. The MAP declined in NDM from 89.8 ± 10.8 to 84.0 ± 9.2 mmHg and in DM from 95.3 ± 8.3 to 86.2 ± 9.9 mmHg in studied patients. These values were significantly ($p < 0.05$) different between two groups and the periods of study. The mean levels of TCh, at the start were in NDM 198.9 ± 28.6 mg/dl, in DM 205.0 ± 30.4 mg/dl, showed a non-significant trend to decrease throughout the study in both groups: 185.7 ± 35.0 mg/dl, 183.6 ± 34.0 mg/dl respectively. The mean levels of Tg in NDM 165 ± 78.2 mg/dl declined to 157.2 ± 90 mg/dl, in contrast to DM which was 259.3 ± 161 mg/dl and decreased statistically ($p < 0.05$) to 182.3 ± 73 mg/dl.

Conclusions: The change from HD to OL-HDF was associated with better dialysis adequacy, stable dry weight and better blood pressure control, allowing for reduction the dose of antihypertensive drugs about 40%. The levels in serum of total TCh and Tg especially in diabetics declined, even with lower dose of simvastatins. These results showed beneficial effect of OL-HDF therapy, however further studies are needed.

Maintaining High-Efficiency On-Line Haemodiafiltration Performances while Reducing Dialysis Fluid Consumption by Automated Coupling Dialysate/Blood Flow Functions: A European Randomized Cross-Over Study

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Introduction and Aims: Quality improvement and limitation of costs of chronic haemodialysis therapy seemed to be a conflicting issue. But on-line haemodiafiltration (oHDF) with new automatic functions offers a cost-efficient improvement of therapy compared to standard haemodialysis (HD). In a prospective multicentre study both therapies were compared concerning dialysate consumption and delivered dialysis dose.

Methods: Seven dialysis centres from five European countries participated in a randomized clinical trial with cross-over design: 3 weeks standard HD *versus* 3 weeks post-dilutional oHDF with automatic functions coupling both dialysate flow rates and substitution flow rates to the effective blood flow rates in order to optimize solute exchange (by the Fresenius dialysis monitor 5008). For proper comparison the essential treatment factors (such as dialyzer,

treatment duration, ultrafiltration volume, and blood flow rate) were unchanged in HD and oHDF for the same patient. Treatment data were recorded during each treatment. Additionally, in two out of seven study centres it was possible to determine beta-2-microglobulin from pre- and post-dialytic blood samples at the end of each study phase.

Results: 54 patients from 7 dialysis centres were enrolled and 955 treatments were analyzed. The treatment factors were similar in HD and oHDF: polysulfone high-flux dialyzers (FX 800 in 78% and FX 1000 in 22% of the patients), mean treatment duration 4.11±0.21 h (HD) vs. 4.10±0.21 h (oHDF), mean ultrafiltration volume 2.60±1.15 L (HD) vs. 2.58±1.14 L (oHDF), mean volume of processed blood 79.9±10.1 L (HD) vs. 79.3±10.6 L (oHDF). Differ-

ences were observed only in dialysate flow rates (an essential investigational parameter of this study) and the substitution flow rates (an integral part of oHDF, but none in HD). Compared to HD, oHDF with automatic functions resulted in increased delivered dialysis doses (Kt/V: +3.5%, 54 patients, P<0.001, see fig. 1), increased middle molecule clearances (beta-2-microglobulin removal: +15.4%, 12 patients., P<0.001), and lower amounts of spent dialysate (-8.0%, 54 patients., P<0.001, see fig. 2).

Conclusions: Compared to standard HD, on-line haemodiafiltration with the investigated automatic functions offers a higher quality of dialysis concerning solute removal and dialysis dose, while enabling substantial savings in dialysate consumption.

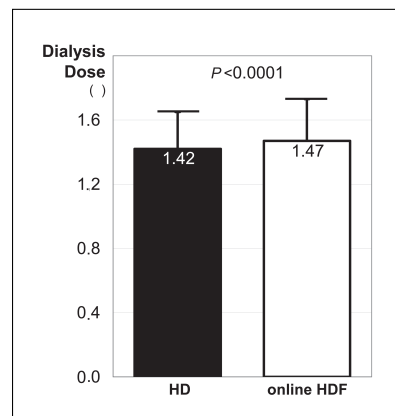


Fig. 1: Dialysis Dose in the Analysis Cohort (N=54); Data Expressed as Mean ± SD.

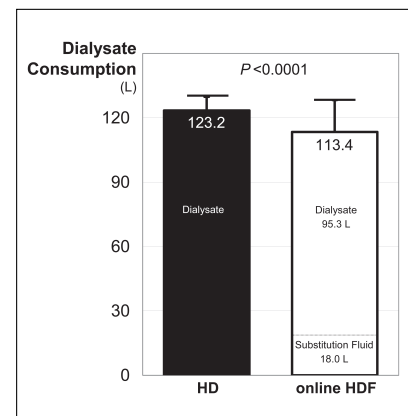


Fig. 2: Dialysate Consumption in the Analysis Cohort (N=54); Data Expressed as Mean ± SD.

Nocturnal Hemodialysis in Germany: A Case Control Study

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Introduction and Aims: Nocturnal in-center hemodialysis (NHD) is convenient to administer longer treatment hours. Data on long term outcome of NHD compared to standard hemodialysis (SHD) from controlled studies are lacking. We present data on treatment parameters and outcome from a large cohort of chronic NHD patients matched with controls for a similar risk profile.

Methods: NHD was defined as chronic in-center dialysis for > 90 days and treatment time > 7h. Controls were drawn from all associated renal units in Germany and matched 1:1 for age, gender and diabetic status. Demographic and treatment related parameters were extracted from the QiN and QuasyNet database, collecting mandatorily reported data on quality of care in chronic hemo-

dialysis in Germany. The observation period lasted from 1/1/2008 until 9/30/2009. All calculations were made with the “R” statistics program. A two-tailed $p < 0.05$ was considered significant.

Results: 688 patients met the criteria for NHD. The average age was 50.0 years, 24% of patients were women and 17 % were diabetic. There were fewer patients with a history of cerebro-vascular events (CVE) or chronic infections in the NHD group than in the SHD group (9.2 % vs. 14.2% for CVE and 8.3 vs. 14.5% for infection; $p < 0.05$). Other comorbidities were similar. The average time on dialysis before the observation period (dialysis burden) was longer in NHD than in SHD (6.87 vs. 6.00 years; $p < 0.01$), and the average weight post dialysis at the beginning of observation was higher by 3.88 kg in NHD patients (78.99 vs. 75.11kg; $p < 0.05$). Consistent with longer treatment times on NHD (447.7 vs. 283.0 min; $p < 0.05$) the average Kt/V was higher in NHD (eKt/V: NHD 1.84 vs. SHD 1.36; $p < 0.05$).

Transferrin saturation (TSAT) was lower in NHD patients (NHD: 25.8% vs. SHD: 27.67 %; $p < 0.05$) but hemoglobin (Hb) was similar in both groups (NHD: 11.86 g/dL vs. SHD: 11.77 g/dL; $p = n.s.$). PO₄ and Calcium (Ca) were lower in NHD (PO₄: 1.74 mmol/L vs. 1.87 mmol/L; $p < 0.001$ and Ca: 2.23 mmol/L vs. 2.24 mmol/L;

$p < 0.05$). No difference was found for PTH between NHD and SHD. Creatinine and albumin were significantly higher than in SHD (NHD Creat: 10.17 mg/dL vs. 9.64 mg/dL and NHD Alb: 40.61 vs. 39.64 g/L; $p < 0.01$). These differences persisted throughout the observation period. For albumin there was a small decrease over time (21 months) in both groups, but reaching statistical significance only in NHD patients (in NHD: from 40.61 to 39.78 g/L; $p = 0.014$, in SHD: from 39.64 to 39.41 g/L; $p = n.s.$). There were no significant trends for Hb, TSAT, PO₄, Ca, PTH and creatinine.

Conclusions: In this large case control study NHD is associated with higher Kt/V and nutritional parameters such as albumin and creatinine. In contrast to previous reports no difference was found for Hb and PO₄ control. Differences between groups might be due to higher prevalence of comorbidities in the SHD group.

Comparison of Nutrition and Inflammation Markers Between Nocturnal and Conventional Hemodialysis Patients

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Introduction and Aims: Hemodialysis patients had increased cardiovascular mortality, and nocturnal hemodialysis (NHD) (3x8 hours/week) offers survival benefits over standard hemodialysis (SHD). Nutrition and inflammation are associated with increased mortality. In this study, we aimed to compare NHD with SHD regarding nutritional and inflammatory parameters.

Methods: Fourteen NHD patients (10 males, mean age 41 ± 10 years), 45 SHD patients (27 males, mean age 43 ± 11 years and 21 healthy control (13 males, mean age 39 ± 8 years) were included.

As inflammation markers IL-6, VCAM, CRP and TNF-alpha levels, and as nutritional markers serum leptin, IGF-1, adiponectin, resistin and ADMA levels were measured.

Results: Laboratory and demographic characteristics of the study groups are shown in the table. Serum ghrelin (1050 ± 1010 vs 230 ± 70 pg/mL), resistin (3.78 ± 1.65 vs 0.95 ± 0.38 ng/mL), adiponectin (34.37 ± 21.20 vs 22.08 ± 11.77 ng/mL) and phosphate (5.06 ± 1.31 vs 3.27 ± 0.39 mg/dL) levels of HD patients were significantly higher than healthy controls. HD patients had higher TNF-alpha (41.73 ± 23.35 vs 6.30 ± 4.42 pg/mL), VCAM (95.45 ± 27.94 vs 23.00 ± 10.79 ng/mL), CRP (12.90 ± 17.79 vs 2.07 ± 1.75 mg/L) levels than controls as expected. Serum IGF-1 (4.51 ± 1.53 vs 7.53 ± 2.56 ng/mL) and Hb levels were significantly lower in HD patients than in controls.

Serum IL-6, cholesterol, leptin and ADMA levels were similar between HD patients and controls. Serum TNF-alpha, ADMA, resistin, VCAM, adiponectin, CRP and phosphate levels were similar between NHD and SHD patients.

Nocturnal HD patients were characterized by higher ghrelin, IGF-1, albumin, Hb, and Ca levels as compared to conventional HD patients. Serum IGF-1 levels were significantly correlated with albumin (r=0.54, p<0.001), Hb (r=0.47, p<0.001), VCAM (r=-0.51, p<0.001), CRP (r=-0.30, p<0.05), resistin (r=-0.31, p<0.05) and TNF-alpha (r=-0.34, p<0.05) levels in HD patients.

Conclusions: Compared to healthy controls, hemodialysis patients have poor nutritional markers and worse inflammatory parameters, as expected. Moreover, nocturnal hemodialysis offers some advantages in terms of these parameters.

Comparison of Nutrition and Inflammation Markers between Nocturnal and Conventional Hemodialysis Patients

	Standard (SHD) (n:45)	Nocturnal (NHD) (n:14)	p
Age (yr)	43.32±11.10	40.78±9.83	NS
Gender (M/F)	27/18	10/4	NS
Duration of HD (months)	76.25±51.37	73.84±43.48	NS
Albumin (g/dL)	4.08±0.41	4.32±0.20	<0.05
CRP (mg/dL)	13.52±19.23	11.10±13.15	NS
Hb (g/dL)	11.39±1.27	12.68±1.39	<0.05
Ca (mg/dL)	8.69±0.89	9.47±0.75	<0.05
Leptin (µg/dL)	3.08±4.20	0.67±0.59	<0.05
IGF-1 (ng/mL)	4.16±1.36	5.61±1.60	<0.001
IL-6 (pg/mL)	0.93±0.53	0.59±0.29	<0.05
Resistin (ng/mL)	3.88±1.74	3.38±1.20	NS
Ghrelin (pg/mL)	850±920	1700±1030	<0.05

3. Issues of Fluid Status in Dialysis Patients

Prevalence of Fluid Overload in European HD Patients

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Introduction and Aims: Fluid overload remains one of the major causes of cardiovascular complications in HD patients. It has recently been shown by Wizemann (NDT 2009) that fluid overload (FO) of more than 2.5 L or 15% (FO/extracellular water (ECW)) is linked to a twofold increased mortality risk in the multivariate Cox analysis. Fluid overload remains often undetected in HD (and also PD) patients for various reasons. The clinical status of

the patients can be improved significantly if the fluid status is assessed objectively and frequently and corrective actions are taken on the basis of the normohydration target (Machek, NDT 2009). The aim of this data analysis was to assess the prevalence of fluid overload in chronic European HD patients.

Methods: We combined data of n=2125 patients originating from 34 European HD centres. In most centres all patients (eligible according to the inclusion criteria) being treated in the respective centre were measured. In some centres the patients were picked randomly.

All patients were measured with the BCM-Body Composition Monitor (Fresenius Medical Care – whole body bioimpedance spectroscopy) before the HD session

after a short dialysis interval for the first time.

Results: 28.3 % of patients presented a fluid overload exceeding 2.5 L pre dialysis which is regarded as severe fluid overload.

16.7% of patients presented a fluid overload after the HD session <-2L, this dehydration is linked to an increased incidence of intradialytic adverse events.

47.7% of patients presented a weekly time averaged fluid overload outside the physiologic range.

Conclusions: Optimisation of the fluid status will be beneficial to 45% of European HD patients. 28.3% of patients are exposed to an increased mortality risk caused by excessive fluid overload, while 16.7% are prone to suffer from intradialytic adverse events due to dehydration.

Figure 1: Fluid Overload in 2125 Patients from 48 Centres Measured with the BCM Body Composition Monitor

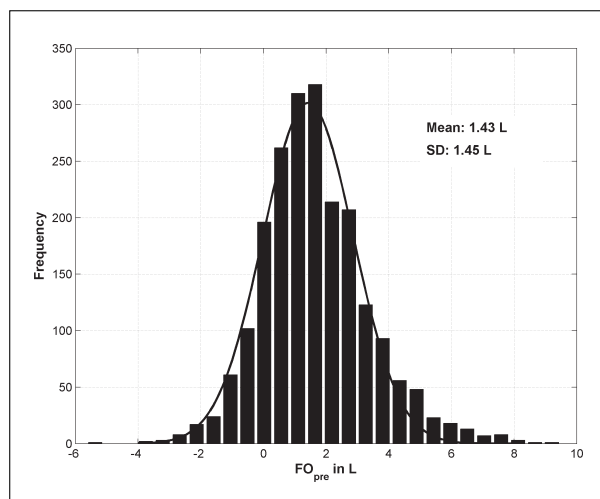
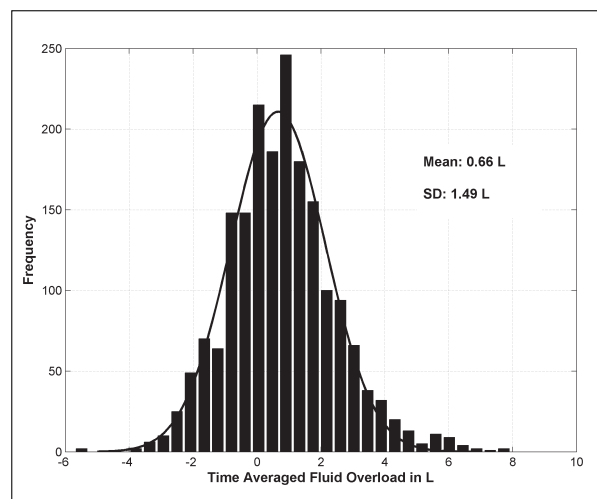


Figure 2: Time Averaged Fluid Overload in 2125 Patients from 48 Centres Measured with the BCM Body Composition Monitor



How Really Low is Dry Weight?

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Introduction and Aims: A surprisingly high prevalence of pulmonary hypertension (PHT) has been described among long-term hemodialysis patients. The cause of PHT in these patients is still not clear: arteriovenous fistula, high parathyroid hormone levels, high cardiac output, pulmonary artery calcification, erythropoietin use, cuprophane induced pulmonary hypertension have all been proposed as an explanation of this finding.

The aim of study was to evaluate the possibility that PHT could be triggered or aggravated by acute or chronic hyperhydration, so often present in hemodialysis patients.

Methods: The prevalence of PHT was prospectively determined by Doppler echocardiography, using the modified Bernoulli equation, in 160 patients on regular hemodialysis and in 25 patients receiving peritoneal dialysis (PD).

Results: PHT (Systolic Pulmonary Arterial Pressure >35 mmHg) was found in 41 out of 160 (25.6 %) hemodialysis patients (22 females and 19 males; 26 patients with a patent AVF, 15 with a deep venous access) and in none among those in peritoneal treatment. In 8 patients clinical marks of congestive state were evident where the others were free of symptoms (no pitting edema, no pulmonary stasis, no exertional dyspnea or otherwise unexplained raise in blood pressure).

The patients affected by PHT underwent an intensive ultrafiltration treatment, even those in which volume overload was not apparent: a significant decrease in dry weight (from 68.2 ± 8.6 to 62.7 ± 6.8 Kg, $p < 0.0001$) was achieved in all the patients and it was followed by dramatic changes in systolic pulmonary artery pressure (from 62.6 ± 11.5 to 25.9 ± 7.5 mmHg $p < 0.0001$), cardiac output (from 7.1 ± 0.6 to 5.7 ± 0.4 L/min;

$p < 0.0001$) and heart rate (from 93.5 ± 15.3 to 75.3 ± 8.5 b/min $p < 0.0006$). Systolic and diastolic blood pressure both decreased (from 157 ± 32.4 to 122.7 ± 25.6 mmHg $p < 0.0001$ and from 90.6 ± 18.7 to 75.4 ± 8.3 mmHg; $p < 0.0001$, respectively).

Conclusions: Mortality and morbidity from PHT exceed those expected from the underlying condition. In patients affected by cardiac shunts a postponed correction of the abnormal communication leads to irreversible pulmonary hypertension and exponentially increases the risk of death associated with this condition. We do not know if a chronic volume overload in hemodialysis patients can have the same clinical consequences but an early intervention to recognize and to reduce pulmonary pressure may prevent heart failure. Clinical marks of dry weight may be ineffective in detecting pulmonary hypertension in hemodialysis patients and when this condition has been diagnosed a trial towards a lower dry weight may lead to the normalization of pulmonary pressures.

The Effect of Volume Status on Blood Pressure and Left Ventricular Mass in Chronic Hemodialysis Patients

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Introduction and Aims: In this study we evaluated the effect of volume status on blood pressure (BP) and left ventricular muscle mass (LVM), that may be associated with them in hemodialysis (HD) patients.

Methods: Patients on HD therapy at least 3 months, were included to the study. Demographic, laboratory parameters, mean interdialytic weight gains (IDWG) (kg/day), mean percentage of ultrafiltration (UF), intradialytic complications in the last month were recorded. Pre-

dialysis and postdialysis BP datas were recorded during the last month. Echocardiography and 24 hour ABPM were performed at the same time on the day after mid-week dialysis session.

Results: Seventy four patients (36F, mean age 53.5 ± 15.3 yrs, mean duration of dialysis 41.5 ± 41 months) were divided into two groups according to volemia status. Group 1 (n=38), consisted of normovolemic patients (14F, mean age 50 ± 16.7 yrs, mean duration of dialysis 47.7 ± 47.7 months) and Group 2 (n=36), consisted of hypervolemic patients (15F, mean age 57.3 ± 12.7 yrs, mean duration of dialysis 34.9 ± 32 months).

There was no statistically significant difference according to the duration of HD, IDWG, UF(%) and intradialytic hypotension and cramp complications between the groups ($p < 0.05$).

While 11 (28.9%) patients were found dipper in group 1, eight (22.2%) patients were found dipper in group 2 ($p < 0.50$). LVH was found in 33 patients (91.7%) of group 2. Whereas 21 patients (55.3%) had LVH in group 1. Significant differences were noted regarding valvular damage and LVH between the two groups ($p < 0.002$ and < 0.001 respectively). We found a positive correlation between LVMI and cardiothoracic index (CTI), IDWG, UF(%), predialysis and postdialysis BP, day and night BP in 24 hours ABPM. Negative correlation was found between LVMI and Kt/V_{urea} and albumin.

Conclusions: Increased BP, IDWG and increased UF were independent predictors for developing LVH. Increasing volume and IDWG can lead to increase BP and LVMI.

24-hour ABPM and Echocardiographic Datas

	Group 1 (normovolemic)	Group 2 (hypervolemic)	p
SBP-day (mmHg)	125±21	142±26	0.003
Dipper	4.8±7.5	5.7±7.4	0.50
DBP-day (mmHg)	78±14	85±14	0.035
SBP-night (mmHg)	119±23	134±27	0.014
DBP-night (mmHg)	72±15	78±15	0.08
Interventricular septum thickness	1.18±0.29	1.3±0.2	0.062
LV end-diastolic diameter	4.6±0.47	4.9±0.5	0.022
LV posterior wall thickness	1.06±0.23	1.17±0.15	0.021
LVMI	131±44.9	168±42.7	0.001
EF	64±5.5	60±7.9	0.042

Assessing Body Composition in Hemodialysis Patients with a Multifrequency Bio-Impedance Device: A Multicentric Evaluation of Reproducibility

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Introduction and Aims: Evaluation of hydration status is important to assure adequate dialysis. MultiFrequency Bio-Impedance (MFBI) has been tested against golden standards, and single point BFMI derived parameters are associated with mortality. However, data on reproducibility of measurements in routine everyday clinical practice are lacking.

Methods: All HD patients from 4 different HD centres were included, unless they had exclusion criteria for BFMI. Measurements were done with the BCM device (Fresenius Medical Care, Bad Hombourg, Germany) on a regular midweek dialysis day, once immediately before and once at least 30 minutes after the HD session by the attending dialysis nurses. We assessed reproducibility with dif-

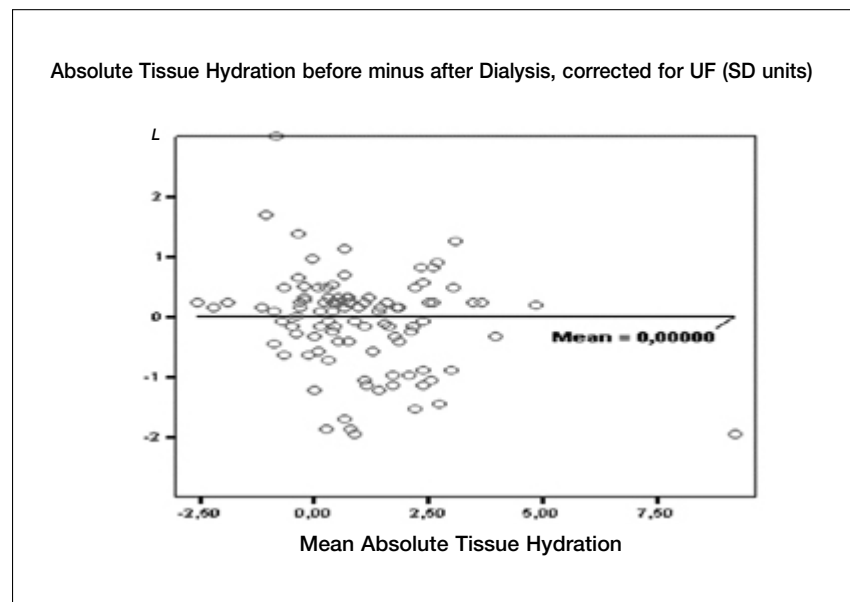
ferent calculations. First, lean tissue mass (LTM) was compared pre and post LTM using Bland Altman analysis (BA). Second, BA was used to compare 1) change in total body water (TBW); 2) change in absolute tissue hydration (ATH); 3) change in body weight (BW), all corrected for ultrafiltration (UF) during dialysis.

Results: In total, 104 patients (58 males) aged 67.8 ± 4.0 years, with a pre-dialysis TBW, intracellular water (ICW), extracellular water (ECW) of 32.7 ± 7.4 , 16.2 ± 4.2 , 16.7 ± 4.2 L and a LTM 30.9 ± 11.0 kg were included. Absolute TH was 1.8 ± 1.6 pre and 0.1 ± 1.8 L post dialysis respectively, after an UF of 2.0 ± 1.1 L. LTM was

30.9 ± 11.0 pre and 30.2 ± 10.6 kg post dialysis ($p=NS$, Spearman correlation 0.96).

BA analysis demonstrated a high level of agreement. Also for TBW, ATH and BW before and after dialysis, corrected for UF, there was a high level of agreement on BA (in declining order).

Conclusions: Evaluation of body composition as assessed by the BCM device appears to deliver reproducible results, even when performed in routine daily practice in a multicentric trial. BCM can as such be a useful tool to detect changes in body composition and hydration status over time, and thus help to maintain ideal weight.



Multifrequency Bioimpedance Assessment of Hydration Status in Peritoneal Dialysis and Factors Associated with Fluid Overload

Best Abstracts Presented by Young Authors

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Introduction and Aims: Hydration status in peritoneal dialysis (PD) is a parameter with complex pathogenesis and complications. Fluid overload (FO) is an important predictor of outcome and achievement of euvolemia a target of adequacy, but hydration status is difficult to assess in clinical practice. We aimed to characterize the hydration status of our population measured by multifrequency bioimpedance, to determine clinical factors associated with FO and to relate FO to hypertension (HT) and indices of cardiac overload.

Methods: We undertook a single centre cross-sectional study in 56 prevalent adult PD patients. Body Composition Monitor (BCM, Fresenius Medical Care, Bad Homburg, Germany) was used to measure hydration status and body composition and FO was defined as measured hydration > 15% of extracellular water. Pro-Brain Natriuretic Peptide (proBNP) was used both as marker of volume expansion and cardiac overload.

Results: Median overhydration was 1L [range -3.8L to 5.4L]; 10 (18%) patients had FO. Patients with FO were significantly older [68 years (53-78) vs. 52 years (39-62); $P=0.01$] and had significantly higher Davies comorbidity score [1 (0.5-1.5) vs. 0 (0-1); $P=0.04$]. The group with FO had significantly lower albumin levels [3.3g/dl (3.2-3.8) vs. 3.7g/dl (3.5-4.0); $P=0.03$] and had lower, although not significantly, Lean Tissue Index [11.2kg/m² (9.2-12.0) vs. 12.5 kg/m² (10.2-15.2); $P=0.07$], but nPCR was not significantly different between the groups. Renal replacement therapy and PD vintages, gender, diabetes mellitus, cardiovascular disease, C-reactive protein, anaemia, lipid profile, peritoneal transport, PD modality, solute adequacy, fluid removal, residual renal function, diuretic and icodextrin use were not significantly different in patients with FO, compared with patients without FO. Pro-BNP levels were significantly higher in the group with FO [5979 pg/mL (1424-18633) vs. 1203 pg/mL (645-2739); $P=0.007$]. We did not find significantly higher prevalence of systolic HT (50% vs. 52%; $P=NS$) neither did we find higher prevalence of diastolic HT (20% vs. 39%; $P=NS$) in the patients with FO compared with patients without FO and hypotensive drugs use was similar between the groups; left atrium diameter [43mm (42-43) vs. 39mm (35-42); $P=0.04$] and

interventricular septum measure [14mm (14-14) vs. 12 mm (11-13); $P=0.005$] were significantly higher in the group with FO. After multivariate adjustment analysis including age, comorbidity, lean tissue and proBNP only albumin remained significantly related with FO (OR=0.01, CI 0.01-0.8; $P=0.03$).

Conclusions: Fluid overload assessed by BCM was present in 18% of our prevalent PD population. Age, higher comorbidity, lower albumin levels and lower lean tissue mass were associated with FO in our cross-sectional analysis, but not traditional cardiovascular risk factors, inflammation, fluid removal, peritoneal transport or PD modality. Low albumin is highlighted as a marker of volume expansion in this study. Hypertension was not more prevalent in patients with FO, but humoral (proBNP) and structural markers of cardiac overload were clearly higher in overhydrated patients.

4. Anaemia Therapy in Dialysis Patients

Compliance with Guidelines on Treatment of Anaemia in a Cohort of Chronic Haemodialysis (HD) Patients

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Introduction and Aims: Recommendations and targets in the treatment of anaemia in patients with chronic kidney disease (CKD) are described in the revised European Best Practice Guidelines (EBPG) for Management of Anaemia in Patients with Chronic Kidney Disease (2004) and the KDO-QI guidelines on Anaemia in CKD (2006 and 2007). The goal of the present analysis is to describe to what extent target levels as mentioned in these guidelines are reached in a cohort of chronic HD patients.

Methods: This analysis is based on baseline data from consecutive patients included in the CONvec-tive TRANsport STudy (CON-TRAST; NCT00205556) from 26 centers (24 Dutch, 1 Norwegian and 1 Canadian). In this trial, chronic HD patients who are treated 2 or 3 times per week for at least 2 months and have a spKt/V >1.15 were included. Levels of haemoglobin (Hb), ferritin and transferrin saturation (Tsat) and data on use of erythropoiesis stimulating agents (ESA) and iron sup-

plementation were collected. The present analysis is not adjusted for case mix variables.

Results: 448 patients were included in the analysis (63% male, age 63.3 ±13.9 [mean ± SD]). 90% of all patients used ESA and 69% used intravenous iron supplementation. 83% had a Hb level ≥6.8 mmol/L, whereas 14% and 20% had a Hb level of >8.6 (EBPG upper limit) and >8.0 mmol/L (KDOQI upper limit) respectively. Only in a minority of patients, all EBPG or KDOQI treatment targets were met (table). Furthermore, a marked difference between centers in the percentage of patients reaching all treatment targets was observed: for the EBPG 2-52% (median 14%) and for KDOQI 0-29% (median 14%).

Conclusions: In a cohort of 448 chronic HD patients, 83% had a Hb of ≥6.8 mmol/L. Achievement of all target levels as recommended by EBPG and KDOQI guidelines on management of anaemia and iron status was relatively low (<20%) with a wide variation between centers.

Fulfilment of EBPG and KDOQI targets

EBPG targets	% of patients meeting EBPG targets	KDOQI targets	% of patients meeting KDOQI targets
Hb 6.8-8.6 mmol/L	79	Hb 6.8-7.4 mmol/L	34
Tsat ≥20%	59	Tsat ≥20%	59
Ferritin 200-500 µg/L	38	Ferritin ≥200 µg/L	69
Fulfilment of all targets	19	Fulfilment of all targets	15

(Hb = haemoglobin, Tsat = transferrin saturation)

International Experience in Erythropoietin (EPO) Dosing Following Large-Scale Switching From Subcutaneous (Sc) to Intravenous (IV) Epo Administration in the DOPPS

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Introduction and Aims: Uncertainty remains regarding the typical differences in dose requirements for SC vs. IV Epo in routine hemodialysis (HD) practice. This uncertainty is due to: (1) varying results from clinical trials, (2) study sample exclusions/restrictions, and/or (3) studies based in single centers. In 2002, many HD units in Europe and elsewhere switched from SC to IV Epo use over a short time period in response to reports of pure red cell aplasia. In this study, we have calculated the mean weekly Epo dose used while maintaining similar Hb levels across 48 facilities in 7 countries when switching from SC to IV Epo in the setting of typical HD practice.

Methods: Data were from the Dialysis Outcomes and Practice Patterns Study (DOPPS, 2002-04) from France, Italy, Spain, Sweden, UK, Canada, and ANZ. For patients prescribed Epo (750-100,000 u/wk) and with ESRD >180 days, analysis included 48 facilities using Epo <20% IV prior to the switch and >85% IV 4-8 months (mo) later, with 763 patients having ≥4 mo post-switch follow-up. Main outcome was prescribed facility mean weekly Epo dose, averaged over a 4 week interval. In addition, facilities (10 SC, 10 IV; n=327 patients) that did not switch their primary Epo route served as controls. Pre- and post-switch mean Epo doses and mean within-facility changes were compared by linear regression.

Results: The 48 facilities switched on average 95% of their patients from SC to IV Epo. The mean Epo dose 4-8 mo post-switch (to allow for steady-state attainment) was 18-20% higher than prior to switching, based on unadjusted (Table) and other patient and facility-level regression analyses adjusted for concurrent changes in Hb,

iron use and dose. Over this time period on average, mean Hb declined by 0.05 g/dl, and IV iron use and IV iron dose changed by <5%. These changes were not associated with mean Epo dose change. The increase in Epo dose was smaller, 0.5% and 6.9%, during the same time period in the SC-only and IV-only non-switch controls, respectively. Results did not vary by facility mean Hb level, or when analyzed among all patients (n=1,056) regardless of post-switch follow-up time. In the 10 facilities for which Hb changed less than 0.1 g/dl, the average Epo dose change was 1% (range: -15 to +18%) in 6 facilities and 44% (range: 30 to 59%) in the other 4 facilities.

Conclusions: On average, Epo doses increased by 1,864 u/wk (20%) across 48 facilities that switched from SC to IV Epo, but the dose change varied greatly across facilities (SD=2,568 u/wk). Future work is needed to identify factors that explain the between-facility variation in the Epo dose change.

Results of Switching from Subcutaneous to Intravenous Epo Administration

Facility Variable	Pre-Switch (Mean±SD)	4-8 Months Post-Switch (Mean±SD)	Change (Mean±SD)	Change %
Mean EPO dose (u/wk)	9.124±3.216	10.988±3.541	1.864±2.568	20.4*
Mean Hb (g/dl)	11.44±0.65	11.39±0.65	-0.05±0.64	-0.4
Mean IV Iron use (%)	71±21	70±21	-0.58±20	-0.8
Mean IV Iron dose (mg/month)	143±82	143±65	-0.64±70	-0.4

Based on 48 facilities and 763 patients in the study having ≥4 months post-switch follow-up

SD= standard deviation, approx. 95% of expected values fall in the range (mean ± 2*SD)

*unadjusted % change, change ranged from 18-20% in various patient- and facility-level regression models

Absence of Cardiac Disease and Recombinant Human Erythropoietin (r-HuEPO) Independence in Chronic Hemodialysis Patients

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Introduction and Aims: We have observed a substantial proportion of dialysis patients with high haemoglobin level without (r-Hu)EPO supplements at our single centre, where a strategy of strict volume control has been adopted for many years. Our aim was to analyse the characteristics of these patients and to compare them to all others.

Methods: This is an observational retrospective study performed at our single dialysis centre where a strategy of strict volume control has been adopted. This strategy consists of a low sodium diet prescription, the use of long dialysis sessions and continuous assessment and reassessment of dry weight in each session. A total of 86 stable prevalent dialysis patients (on dialysis > 180 days) were included. Of them, 15 patients (17%) were (r-Hu)EPO independent. EPO independence was defined as Haemoglobin (Hb) > 12 g/dl and no use of EPO for at least 12 months. Demographic characteristics, clinical, haematological and biochemical data, dialysis techniques and comorbidities were compared between EPO dependent and EPO independent patients. Cardiac disease (previous history of angina, myocardial infarction, heart failure or arrhythmias) was analysed independently of other comorbidities. For all biochemical data, a mean value of the multiple measurements during the last 12-month period was included.

Results: Comparing to the EPO dependent patients, our EPO independent patients had higher Hb level (13.2 ± 0.4 vs 11.9 ± 0.9 g/dl; $p < 0.001$), showed a higher proportion of men ($p = 0.02$), were more frequently ($p < 0.05$) on on-line hemodiafiltration, had less frequently clinical evident cardiopathy (20% vs 62%; $p < 0.005$) and

showed lower levels of NT-proBNP (median value 2360 vs 5620 pg/ml; $p < 0.001$) despite they were on dialysis for a longer (not significant) period (median dialysis vintage: 6 vs 3.5 years; p :NS). Logistic multivariate regression analysis showed that only male gender and absence of cardiopathy were independent predictors of high Hb levels without EPO supplements. We found no differences between the two groups in other comorbidities not related to cardiac disease, patients' age, iron stores, nutritional data, CRP, PTH levels or the proportion of patients with vitamin D supplements. Systolic BP was also similar (129 ± 14 vs 127 ± 17 mmHg; p :0.8). BP was well controlled with a low proportion of patients with antihypertensives (13% vs 22%; p :NS) in both groups.

Conclusions: Compared to other reports, the proportion of EPO independent patients at our single centre with a strategy of strict volume control is high. Absence of cardiac disease seems to be the key factor associated with the likelihood of having high Hb without needing EPO supplements. Our results highlight the importance of continuous prevention of fluid overload in order to prevent myocardial damage and suggest an interaction between cardiac damage and anemia also among dialysis patients.

Variation in Parenteral Iron Use over Time and Between Countries: The Dialysis Outcomes and Practice Study (DOPPS)

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Introduction and Aims: It is recognized that there is large variability in erythropoiesis stimulating agents (ESA) use and hemoglobin (Hb) values across countries for HD patients but little is known about the prescribing patterns of IV iron preparations.

Methods: Iron use data were collected from Phases I (96-01), II (02-04) and III (05-08) for HD patients in facilities of 12 countries participating in the DOPPS, an HD cohort study. Trends in IV iron use (n = 18,646) and different iron products (n = 11,406) over phas-

es were from prevalent cross-sections of patients with ESRD > 90 days over 4 months (mo) at study entry. Distributions of iron use by country were based on 1-mo and 4-mo intervals in 07-08 (n = 6,685).

Results: In 07-08, IV iron was used over 1 mo (Table) in 23% of patients in Japan and 48% of patients in all other countries (max 68% in Spain). IV iron use over 4 mo was 40% in Japan and 66% in all other countries (max 83% in Sweden). There was a trend towards higher % IV iron use from Phase I/II to Phase III in most countries [e.g. over 4 mo, in France from 55 to 68% (I to III); Germany 67 to 79% (I to III); UK 58 to 78% (I to III); US 60 to 76% (II to III)]. However, % IV iron use was almost unchanged over time in Belgium, Canada, and Japan. The types of IV iron products used varied, with the specific type largely un-changed between phases in 9 of 12 countries. Exceptions were increased use of iron sucrose (IS) in France [96% maltofer (I) to 99% IS (III)]; Spain [98% gluconate (I) to 98% IS (III)]; US [18% dextran,

50% gluconate and 31% IS (II) to 36% gluconate and 63% IS (III)]. Among patients receiving IV iron, dosing more often than once weekly was uncommon (<10%) in all countries except Japan (20%), Germany (34%), and Italy (39%). Total monthly dose >400 mg/mo was prescribed to <10% of patients in Japan, ANZ, and Spain; 32% of patients in Italy; and 11-18% of patients in the other countries.

Conclusions: Iron choice may be influenced by practice guidelines, reimbursement pressures (e.g. bundling), and current understanding of toxicity. IV iron use has varied widely over time and between countries. Among patients receiving IV iron, most receive relatively small maintenance doses, though the use of higher monthly doses (e.g. >400 mg) is common in some countries. Japan's low % use of IV iron may reflect conservative anemia treatment, with low ESA doses and lower achieved Hb (DOPPS data). Additional evaluation of the effectiveness and safety of these IV iron dosing strategies in routine practice is required.

Distributions of IV Iron Use over 1 Month (2007-2009)

Country	Among all patients (n=6,685) % Using any IV iron	Country	Among all patients (n=6,685) % Using any IV iron
Japan	23	France	62
Canada	48	Belgium	64
UK	49	Germany	65
US	52	Sweden	66
Italy	54	Spain	68
Australia – New Zealand	58	Overall Use	42

Based on 6,685 cross-section patients in 2007-2009 with ESRD > 90 days. Minimum n of Patients = 296 in UK, maximum n of patients = 1,811 in Japan.

Determining the Iron Overload by Magnetic Resonance Imaging and the Relation with Serum Iron Parameters in Hemodialysis Patients

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Introduction and Aims: Recently, the issues stem from overload of iron that is intensively used for therapy of anemia in hemodialysis patients are frequently debated. Hematological parameters (ferritin and transferrin saturation) are used in the evaluation of iron stores in daily practice. Magnetic resonance imaging (MRI) is a reliable, non-invasive method for showing iron overload. This study compared serum iron parameters with MRI findings for detection of iron overload and investigated factors that effect on iron accumulation, including genotype.

Methods: A total of 36 hemodialysis patients (18 female, 18 male and mean age 51.3 ± 15.6 years) were taken into the study. The mean duration of dialysis of the patients was 103.4 ± 79.0 months. The average Hb, ferritin, transferrin saturation values and the average dose of erythropoietin and iron that they have used in the last 2 years were calculated. 1.5 Tesla multiTE gradient echo MRI was performed to the patients to determine the iron overload in the liver and myocardium. A T-score of <7 msn at liver and <20 msn at myocardium was evaluated to be in favor of overload. Gene mutations were determined using HFE strip assay by reverse hybridization method.

Results: According to T-scores, iron accumulation was observed in nine patients. No differences between mean Hb values, average doses of erythropoietin were detected in patients with or without iron overload. The average ferritin and transferrin saturation values were higher in patients with overload (604.0 ± 505.4 vs. 432.9 ± 263.7 ng/ml and 34.0 ± 6.6 vs. 30.9 ± 10.2 %) but did not reach statistical significance ($p > 0.05$). Patients without iron overload were treated with higher iron dose (55.8 ± 52.7 vs. 105.4 ± 97.7 mg/month) but statistically significant difference was not found. The mean dialysis duration was similar in both of the groups. Interestingly, most of the patients with

iron overload had ferritin values between 300 and 500 ng/ml, transferrin saturation $<40\%$ and iron dose <50 mg/month. Multi-variable logistic regression analysis shows that the only risk factor for iron overload was HFE gene mutation positivity (OR: 11.6).

Conclusions: In this study, it is shown that there wasn't any significant difference regarding serum iron parameters and dose of iron administered, between patients with and without iron overload in myocardium and liver. Serum parameters were found to be inadequate for evaluation of the iron overload. Iron overload can be seen with iron supplementation although serum parameters are within the target range suggested for treatment. Genotype is an important risk factor for iron overload.

Frequent Low-Dose Iron Supplementation in Haemodialysis Patients: Better Response to Epo and Smaller Yearly Amount of Iron

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Introduction and Aims: Anaemia is an important complication of chronic kidney disease. Treatment includes the use of epoetin (EPO) and iron supplementation. However, the optimal schedule of iron supplementation remains to be defined.

Methods: Out of 60 patients included in our prospective observational study, 31 completed the study. Patients were treated for one year (period 1) with EPO and an intermittent pulse regimen consisting of 100 mg of iron sucrose, administered after different dialysis sessions, depending on serum ferritin and other laboratory values,

but no more than once per week. During the next three years (period 2), patients were treated with EPO and need-based, continuous, low-dose iron. Iron doses were determined on the basis of values and changes of serum ferritin and transferrin saturation every fourth week after the longest interdialysis time interval. Iron doses ranged from 10-60 mg of iron sucrose, and were given one to three times per week. If grounded, we gradually reduced or even abolished the iron doses.

Results: Results are shown in the table. A significant increase in the haemoglobin concentration and haematocrit during period 2 in comparison with period 1 was observed. The use of EPO did not change significantly during period 2, while the dose of iron per year was signi-

ficantly lower in period 2. Significantly lower values were obtained for serum ferritin, saturation of transferrin, and total serum iron-binding capacity (TIBC) during period 2 versus period 1. We did not find any significant differences in PTH, CRP, and albumin during period 2 in comparison with period 1.

Conclusions: Our study shows that a better response to EPO therapy is achieved with need-based, continuous, low-dose iron replacement. This is reflected in the significantly higher values of haemoglobin and haematocrit for period 2, with the use of a significantly smaller yearly amount of iron during period 2. Moreover, we may infer that our treatment leads to the smaller use of expensive EPO for preserving the same haemoglobin value.

Dose and Laboratory Measures	Period 1	Period 2	p-value*
ESA-weekly dose (IU)	6680.7±4346.2	7090.9±5680.9	0.495
ESA (IU/kgBW/week)	106.6±84.3	112.6±106.26	0.483
Iron-dose per year (mg)	2168.6±855.2	860.7±317.1	0.0001*
Haemoglobin (g/L)	121.9±9.1	127.3± 7.1	0.0001*
Haematocrit	0.37±0.03	0.38±0.02	0.0001*
Hypochromic erythrocytes (%)	2.3±1.9	2.1±1.1	0.305
Thrombocytes (×10 ⁹ /L)	208.7±47.5	210.1±52.3	0.738
Serum ferritin (µg/L)	744.7±210.9	670.7± 111.5	0.030*
Saturation of transferrin (%)	26.7± 6.6	24.3±5.1	0.018*
TIBC (µmol/L)	50.9±3.9	47.9± 4.0	0.0001*
Parathyroid hormone (ng/L)	208.8± 47.5	210.1±52.3	0.738
Serum albumins (g/L)	42.5±2.0	45.2± 11.9	0.215
CRP (mg/L)	11.9±13.3	11.5±13.3	0.698
Kt/V	1.64±0.31	1.71±0.27	0.009*

*p<0.05 = statistical significance

5. Diabetes Mellitus in Dialysis Patients

Relative Risks for All-Cause Mortality by Levels of Fasting Glucose on Hemodialysis Patients with or without a History of Diabetes Mellitus

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Introduction and Aims: Our previous study has shown that hemodialysis (HD) patients with fasting blood glucose (FBG) levels greater than 100mg/dl are associated with increased all-cause mortality. Whether this phenomenon stands true for patients with or without a history of diabetic mellitus (DM) at commencement of HD is unknown. We aimed to investigate the association between fasting blood glucose (FBG) levels and mortality hazards of HD patients with or without a history of DM at commencement of HD.

Methods: An observational cohort analysis based on database of Taiwan Renal Registry.

Patients: Adult patients (n=50112) on chronic HD for at least 90 days at 450 facilities in Taiwan from 1995 to 2005. Survival status was observed until December 31,2008. All patients have complete observation of study factors, e.g. age, gender, primary renal disease, comorbidity, FBG, hematocrit, serum albumin, calcium, phosphate and i-PTH.

Predictor: Time-averaged FBG level.
Statistics: Three Cox proportional hazard models were used: Model 1 (unadjusted model), Model 2 (case-mix-adjusted model) and Model 3 (case-mix-and multiple covariates adjusted model).

Results: At entry of HD, 46.8% of our patients had a history of DM, while 53.2% did not have DM. Mean follow-up time was 4.81±3.36 years. We found an overall J-shaped relationship between all-cause mortality and levels of FBG in both diabetic and non-diabetic populations. A significant increases in mortality starting at ≥ 110 mg/dl as well as <80 mg/dl were observed in non-diabetic patients (Fig.1) while significant increases in mortality observed only starting at levels ≥ 240 mg/dl as well as <80

mg/dl in diabetic patients (Fig.2). The adjusted hazard ratios (HR) for FBG levels <60, 110-124, 140-159, 180-199, 220-239, 260-279, ≥280 mg/dl were 2.34, 1.14, 1.37, 1.95, 2.02, 2.2 and 2.13 (P<0.0001,all ranges) for non-diabetic patients. The corresponding HRs for diabetic patients were 1.49(P=0.01), 1, 0.95, 1.1, 1.08, 1.15(P=0.02) and 1.38(P<0.0001).

Conclusions: There is a stepwise increase of all-cause mortalities, starting from FBG higher than 110 mg/dl in non-diabetic patients on chronic HD, while this trend is less prominent in diabetic population. Besides, a higher threshold (≥240mg/dl) was observed. Extremely low FBG (<60mg/dl) levels have highest risk for death in both diabetic and non-diabetic patients.

Figure 1: FBG Levels and Hazard Ratio of Death in Non-Diabetic Patients

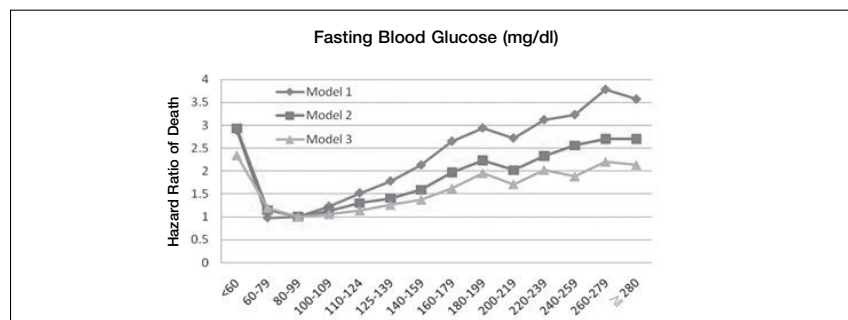
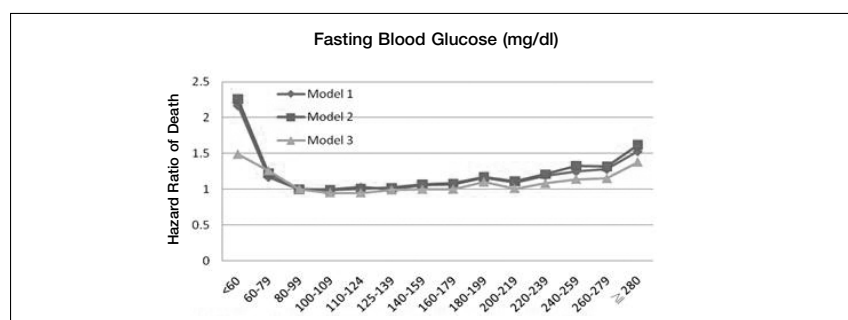


Figure 2: FBG Levels and Hazard Ratio of Death in Diabetic Patients



Modest Salt Reduction in Impaired Glucose Tolerance and Type 2 Diabetes Lowers Blood Pressure and Urinary Albumin Excretion

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Introduction and Aims: Reducing salt intake lowers blood pressure, irrespective of whether blood pressure levels are normal or raised. Tight control of blood pressure in diabetics lowers the risk of strokes, heart attacks and heart failure and slows the progression of diabetic kidney disease. Despite the high cardiovascular risk of these patients and theoretical reasons for increased salt sensitivity in these patients, the current knowledge of the role of salt in regulating blood pressure in diabetes is limited.

Methods: We therefore carried out a randomized controlled crossover study of placebo or slow sodium, each for 6 weeks in 26 diet controlled type 2 diabetics and 20 individuals with impaired glucose tolerance with untreated normal or high normal blood pressure. We measured the effect of a modest salt reduction on clinic and ambulatory blood pressure and urinary albumin excretion.

Results: 24h urinary sodium was 165 ± 9 mmol/24h on slow sodium and 117 ± 10 mmol/24h on placebo, with a reduction in urinary sodium of 49 ± 9 mmol/24h, equivalent to 2.9 g/day salt. This modest salt reduction significantly lowered SBP from 135.5 ± 2.0

mmHg to 131 ± 1.9 mmHg, a fall of -4.2 ± 1.5 mmHg ($p < 0.01$). DBP was also reduced from 81.3 ± 1.1 mmHg to $79.71.2$ mmHg, a reduction of -1.7 ± 0.9 mmHg, with borderline significance ($p = 0.055$). This effect was also evident in ambulatory blood pressure monitoring with a reduction in mean day SBP by -3.3 ± 0.9 mmHg, mean night BP by $4.3 \pm 1.2/2.3 \pm 0.9$ mmHg and mean 24h BP by $-3.3 \pm 0.9/1.8 \pm 0.8$ mmHg. Albumin-creatinine-ratio (ACR) was reduced from 0.73 (IQR 0.5-1.5) mg/24h on slow sodium to 0.64 (IQR 0.3-1.1) mg/24h on placebo ($p = 0.014$). There was therefore a 12% reduction in ACR with this modest reduction in salt intake.

Conclusions: This modest salt reduction causes significant and clinically relevant falls in blood pressure in type 2 diabetes and impaired glucose tolerance, where initial blood pressure levels are normal or high normal. Furthermore other additional benefit was found in the small reduction in albumin creatinine ratio. These findings support the recommendation to reduce salt intake in diabetes as recommended in hypertension guidelines to less than 6 g/day.

Atorvastatin and Low Density Lipoprotein Cholesterol in Patients with Type 2 Diabetes Mellitus on Hemodialysis: A post-hoc Analysis of the 4D Study

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Introduction and Aims: Patients undergoing maintenance hemodialysis are at high cardiovascular risk. Lowering LDL cholesterol with statins has reduced the incidence rate of cardiovascular events. Two randomized, prospective, placebo-controlled trials (4D, AURORA) have been completed in hemodialysis patients which showed no significant effects of statins on cardiovascular outcomes.

Methods: We conducted a post hoc analysis of the 4D study (Die Deutsche Diabetes Dialyse Studie) to investigate a) whether LDL cholesterol at baseline is predictive of cardiovascular events and b) whether the effect of atorvastatin on clinical outcomes depends on LDL-C levels at baseline.

Results: High levels of LDL cholesterol by trend increased the risks of cardiac endpoints and all-cause mortality. Concordantly, atorvastatin significantly reduced the rates of adverse outcomes in the highest

quartile of LDL cholesterol (greater 145 mg/dl or 3.76 mmol/l). The hazard ratios and 95 percent confidence intervals were 0.69 (0.48-1.00) for the composite primary endpoint, 0.58 (0.34-0.99) for cardiac death, 0.62 (0.33-1.17) for non fatal myocardial infarction, 0.68 (0.47-0.98) for all cardiac events combined and 0.72 (0.52-0.99) for death from all causes, respectively. No such decrease was seen in any of the other quartiles of LDL cholesterol at baseline.

Conclusions: In patients with type 2 diabetes mellitus undergoing hemodialysis atorvastatin significantly reduces the risk of cardiac events and death from any cause if pretreatment LDL cholesterol exceeds 145 mg/dl (3.76 mmol/l).

Vitamin D Deficiency is Associated with Sudden Cardiac Death, Combined Cardiovascular Events and Mortality in Diabetic Haemodialysis Patients

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Introduction and Aims: Dialysis patients experience an excess mortality, predominantly of sudden cardiac death (SCD). Accumulating evidence suggests a role of vitamin D for myocardial and overall health. This study investigated the impact of vitamin D status on cardiovascular outcomes and fatal infections in haemodialysis patients.

Methods: 25-hydroxyvitamin D (25[OH]D) was measured in 1109 diabetic haemodialysis patients who participated in the German Diabetes and Dialysis Study (4D Study) and were followed-up for a median of 4 years. By Cox regression analyses, we determined hazard ratios (HR) for pre-specified, adjudicated endpoints according to baseline 25(OH)D levels: SCD (n=146), myocardial infarction (MI, n=174), stroke (n=89), cardiovascular events (CVE; n=414), death due to heart failure (n=37), fatal infection (n=111) and all-cause mortality (n=545).

Results: Patients had a mean age of 66±8 years (54% male), and mean 25(OH)D of 18.0±9.8 ng/ml. Patients with severe vitamin D deficiency (25[OH]D ≤10ng/ml) had a 3-fold higher risk of SCD compared to those with sufficient 25(OH)D levels >30ng/ml (HR 3.0; 95% confidence interval 1.4-6.4). Furthermore, CVE and all-cause mortality were strongly increased (HR 1.8, 95% CI 1.2-2.7, and HR 1.7, 95% CI 1.2-2.5, respectively), all persisting in multivariate models. There was a trend for higher risks of stroke and fatal infection, while MI and deaths due to heart failure were not significantly affected.

Conclusions: Severe vitamin D deficiency was strongly associated with SCD, CVE and mortality, and by trend with stroke and fatal infection in diabetic haemodialysis patients. Whether vitamin D supplementation decreases adverse outcomes, requires further evaluation.

6. Miscellaneous

Impacts of Cardio-Protective Drugs on Outcomes in Maintenance Hemodialysis Patients

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Introduction and Aims: Cardiovascular disease (CVD) is the leading cause of death in dialysis patients. This study analyzes the impact of cardio-protective, in particular angiotensin-converting enzyme inhibitors (ACEs), angiotensin receptor blockers (ARBs), and β -blockers (BB) on patient outcomes in a cohort of patients from Renal Research Institute (RRI).

Methods: We performed a retrospective record review in all in-center hemodialysis patients treated in one of the RRI clinics in Nov 2007 (baseline period). We assessed whether these patients were on ACEs, ARBs, or BB in the baseline period or received it in the follow up period, defined as Dec 2007 to Dec 2009. Baseline measures such as albumin, pre-dialysis systolic blood pressure (preSBP),

and pre-dialysis weight (preWeight) were noted. Patient survival was observed in the follow up period. Unadjusted Kaplan Meier analysis was completed comparing patients with and without cardio-protective drugs; Cox proportional hazards model adjusted for age, gender, race, diabetic status, clinic site, and baseline measures was performed comparing patients with and without cardio-protective drugs.

Results: 5,090 patients were analyzed. Overall, RRI patients have seen an increase in the use of cardio-protective drug therapy between 2007 and 2009: growing from 43% to 66% of the patients using cardio-protective drugs. During the same period, mortality has dropped from 14.4 to 13.5 deaths per 100 pt years.

In Kaplan Meier analysis mean survival time in patients on cardiac drugs was 690 days (95% CI: 684-697) while it was 670 days (95% CI: 659-680) for patients not

on cardio-protective drugs (log-rank test, $p < 0.05$). The adjusted Cox proportional hazards model showed a 17% reduction in mortality in patients on cardio-protective drugs (Hazard ratio=0.83 (95% CI 0.72-0.94).

Conclusions: This retrospective analysis shows that cardio-protective drug use is associated with improved patient survival, both in univariate & multivariate analysis. Potential limitations of the study are its observational nature and variation in prescription practices between clinics. We tried to account for prescription variability by adjustment for clinic site in the Cox model. Indication bias, while critical, should overestimate the impact of being on cardiac drugs even further thus suggesting that being on the cardio-protective drugs is even more beneficial. Ultimately, randomized controlled studies are necessary to assess whether cardio-protective drugs improve patient outcomes.

Table: Patient Characteristics (Mean \pm SD)

Group	Number of patients	Male (%)	DM (%)	Black (%)	White (%)	Age	Vintage	Albumin (g/dl)	PreSBP (mmHg)	PreWeight (kg)
Not on ACE, ARB, BB	1643	55	32	49	42	61.00 (15.6)	4.03 (4.5)	3.88 (0.5)	144.42 (21.6)	82.33 (22.1)
On ACE, ARB, BB	3447	56	40	52	39	61.28 (14.7)	3.66 (3.7)	3.89 (0.4)	153.65 (20.6)	80.36 (20.5)

The Predictive Value of Cardiac Troponin T in Hemodialysis Patients: A Two Year Prospective Study

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Introduction and Aims: Cardiovascular events still represent the main cause of death in hemodialysis patients (HDpatients). Cardiac troponin T (cTnT), a subunit of the cardiac actin-myosin complex, is released into the circulation even in silent myocardial necrosis. High levels of cTnT are associated with an increased cardiovascular mortality in HDpatients.

The aim of our study was to evaluate the prognostic value of cTnT in our hemodialysis population.

Methods: Eighty four (47 males) HD patients with a mean age of 65.24 ± 10.67 years, on hemodialysis for 69.17 ± 54.73 months were included in the study. Twenty four (28.4 %) patients were diabetics and 26 (31%) had a history of ischemic heart disease (IHD). The

patients were followed prospectively for 24 months after the determination of cTnT. A cut-off of ≥ 0.1 ng/ml was used in assessing the prognostic significance of cTnT. The outcome after 24 months was chosen as the endpoint. Also at the beginning of the study patients clinical and laboratory data were collected (Table). cTnT was correlated with clinical and laboratory parameters and outcome.

Results: Nineteen patients (22.6%) had an cTnT ≥ 0.1 ng/ml. The patients with cTnT ≥ 0.1 ng/ml had a lower serum albumin level (3.52 ± 0.31 vs. 3.74 ± 0.3 g/L, $p=0.007$), a higher incidence of previous IHD (73.7% vs 18.5%, $p=0.0004$) and a higher vascular score (1.11 ± 0.49 vs. 0.03 ± 0.5 , $p=0.0004$). In the multivariate analysis only two variables showed a correlation with cTnT ≥ 0.1 ng/ml, namely serum albumin ($p=0.0006$) and vascular score ($p=0.0003$).

During the study 19 patients (22.6%) died (11 males), 10 from cardiovascular causes. Twelve

(63.1%) had a cTnT ≥ 0.1 ng/ml. 63.2% (12/19) of the patients with a high cTnT died versus 10.8% (7/65) of the patients with a low cTnT ($p=0.0002$). The Kaplan Meier survival curve showed a significant difference in survival time between the patients with cTnT ≥ 0.1 ng/ml and the patients with cTnT < 0.1 ng/ml ($p=0.003$). Survival was also analyzed with a Cox's proportional hazards model. After adjustment for age, sex, hemoglobin and albumin level, URR, history of IHD and vascular score survival time was significantly influenced only by the level of cTnT ≥ 0.1 ng/ml ($p=0.01$).

Conclusions: cTnT is a significant independent predictor of outcome in in our hemodialysis population and it seems that it could be used in cardiovascular risk stratification and in selecting patients that would benefit from a more invasive cardiologic investigation and intervention.

Patients Clinical and Laboratory Data

n	cTnT ng/ml	Albumin g/L	Hb g/L	CRP mg/L	URR %	Vascular Score (0-3)* n
84	0.062 ± 0.062	3.69 ± 0.32	$11.95 \pm .54$	2.69 ± 8.9	64.42 ± 10.2	34=1, 8=2, 42=0

vascular score: scoring for peripheral vascular disease of amputation, cerebrovascular disease and history of ischemic heart disease

Vitamin D Status and Mortality Risk in Incident Dialysis Patients: Results from the NECOSAD Study

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Introduction and Aims: The majority of dialysis patients suffer from vitamin D deficiency, which might contribute to an adverse health outcome. We aimed to elucidate whether European dialysis patients with low 25-hydroxyvitamin D (25 [OH]D) levels are at increased risk of mortality and specific fatal events.

Methods: From a prospective cohort study of incident dialysis patients in the Netherlands (NECOSAD), we selected all patients with measured 25(OH)D at 12 months after the start of dialysis, the baseline for our study. By Cox regression analyses, we assessed the impact of 25(OH)D levels on early (6 months follow-up) as well as long-term mortality (3 years follow-up). Associations of 25(OH)D levels with cardiovascular and non-cardiovascular mortality were also determined.

Results: Data from 762 patients (39% females, age 59±15years, 25(OH)D=18±11 ng/ml) were available. Fifty-one and 213 patients

died during a follow-up of 6 months and 3 years, respectively. After adjustments for possible confounders the hazard ratio (HR) (with 95% CI) for mortality was 1.9 (1.0-3.6) for early and 1.4 (1.0-1.9) for long-term mortality when comparing patients with 25(OH)D levels ≤10 ng/ml with those presenting with 25(OH)D levels > 10 ng/ml. Adjusted HRs for cardiovascular mortality were 2.8 (1.1-6.7) and 1.6 (1.0-2.5) for early and long-term mortality, respectively. For non-cardiovascular mortality we observed no relevant association. **Conclusions:** Vitamin D deficiency in dialysis patients is associated with an adverse health outcome, in particular with early cardiovascular mortality. Intervention studies are urgently needed to evaluate whether vitamin D supplementation improves health outcomes of dialysis patients.

Bone Fractures in Haemodialysis Patients

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Introduction and Aims: Renal osteodystrophy is a multifactorial disorder of bone metabolism. One of the most important clinical consequences of renal osteodystrophy are bone fractures. Several studies have shown that there is increased incidence and prevalence of bone fractures, particularly hip fractures in hemodialysis patients.

The aim of this multicentric, retrospective study was to detect the prevalence of bone fractures in hemodialysis patients.

Methods: A total of nine dialysis centers with 767 hemodialysis patients were included in the study. Demographic data (age, sex, hemodialysis duration), laboratory data (PTH, Ca, P, total alkaline phosphatase), and bone fracture data (hip, forearm, upper arm, rib, vertebrae, lower leg, femur, hand) were collected from medical records as well as therapy with analogs of vitamin D.

Results: In 31 patients a total of 36 fractures were recorded, i.e. the prevalence of bone fractures was 4.7 %. The mean age of patients with fractures was 77.6 (range 40-85) years and hemodialysis duration was 63.3 (range 5-265) months. There were 9 male and 22 female patients. Only six patients were diabetics. Of all patients suffering fractures, there were 14 with a hip fracture (39%), 8 with a forearm fracture (22%), 5 with an upper arm fracture (14%), 4 with a femur fracture (11%), 2 with a lower leg fracture (5%), one with a rib, vertebrae or hand fracture (9%). In patients less than 40 years of age no bone fractures were observed. Eight patients (26%) aged between 41 and 60 had bone fractures as well as 23 patients (74%) older than 60 years. Bone fractures were observed in 10 patients (28%) with PTH < 180


pg/ml bone fractures and in 12 patients (33%) with PTH between 181 and 300 pg/ml; in 14 (39%) with PTH > 300 pg/ml. Patients with hip fractures had the highest level of PTH, 541.4 (range 23-1790) pg/ml. The lowest PTH was in patients with forearm fractures 198.5 (range 57.3-310.9) pg/ml. Sixteen patients were on therapy with calcitriol or paricalcitol at least six months before fractures.

Conclusions: The prevalence of bone fractures in our group of hemodialysis patients is high, particularly among female patients. The higher age and hemodialysis duration is undoubtedly a risk factor for bone fractures. Although there is a slightly higher incidence of fractures in patients with higher PTH (particularly hip fracture), there are also patients with bone fractures and a very low level of PTH. This is just one more proof that there are multifactorial risk factors for bone fractures in hemodialysis patients. More data from prospective studies is needed to detect the incidence, prevalence and risk factors for bone fractures in hemodialysis patients.

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