Biochemical Abnormalities

Novel Risk Predictors

Presenter Disclosure Information

I will not discuss off label use and/or investigational use in my presentation.

I have financial relationships to disclose:

Consultant for: Roche, Baxter, Genzyme

Research support from: Astra Zeneca, Baxter, Genzyme, Amgen, Roche

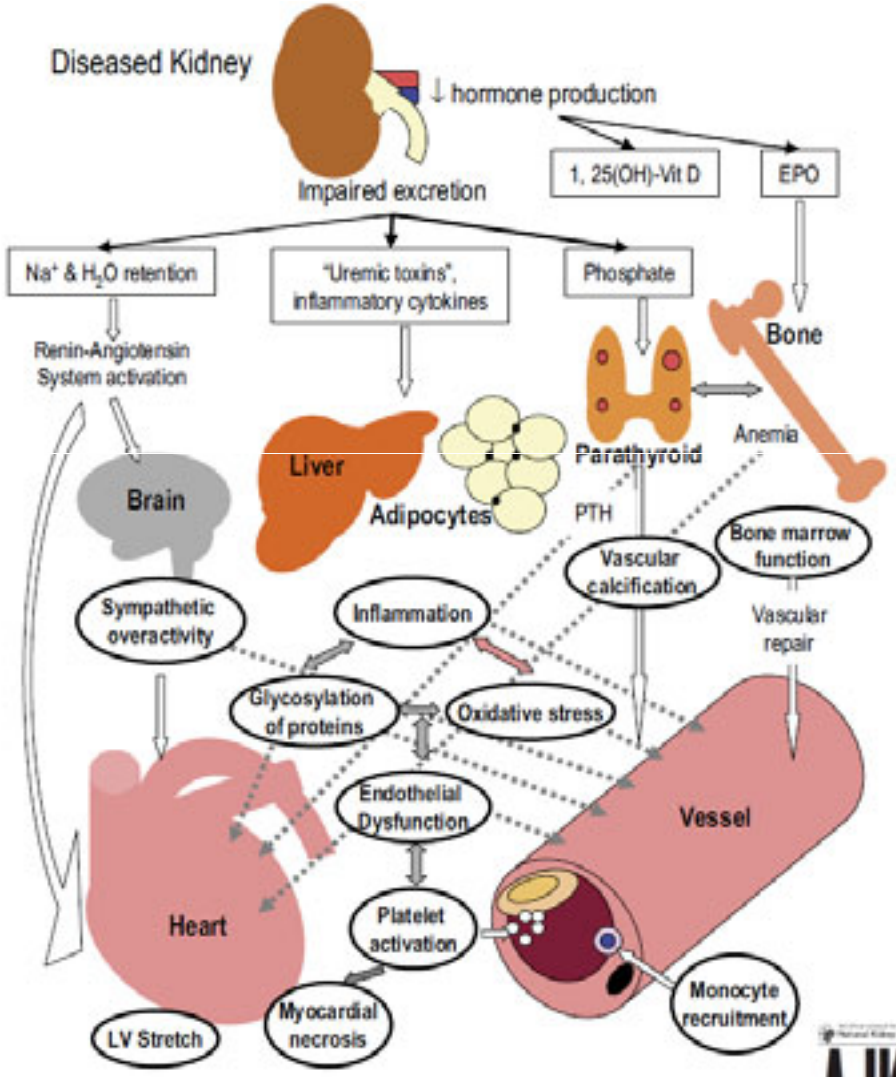
Honoraria from: Abbott, Mantecorp, Genzyme, Gambro, Baxter

Biomarkers as risk predictors

- Characteristic that is objectively measured and evaluated as an indicator of biological processes or responses to therapeutic intervention
  - *Introduced by Medical Subject Heading (MESH) in 1989, revised by the NIH, 2001*

Cardiovascular Biomarkers in CKD: Pathophysiology and Implications for Clinical Management of Cardiac Disease

Matthew A. Roberts, MD, FRACP, David L. Hare, MD, FRACP, Sujiva Ratnaike, MD, FRCPA, and Francesco L. Ierino, MD, PhD



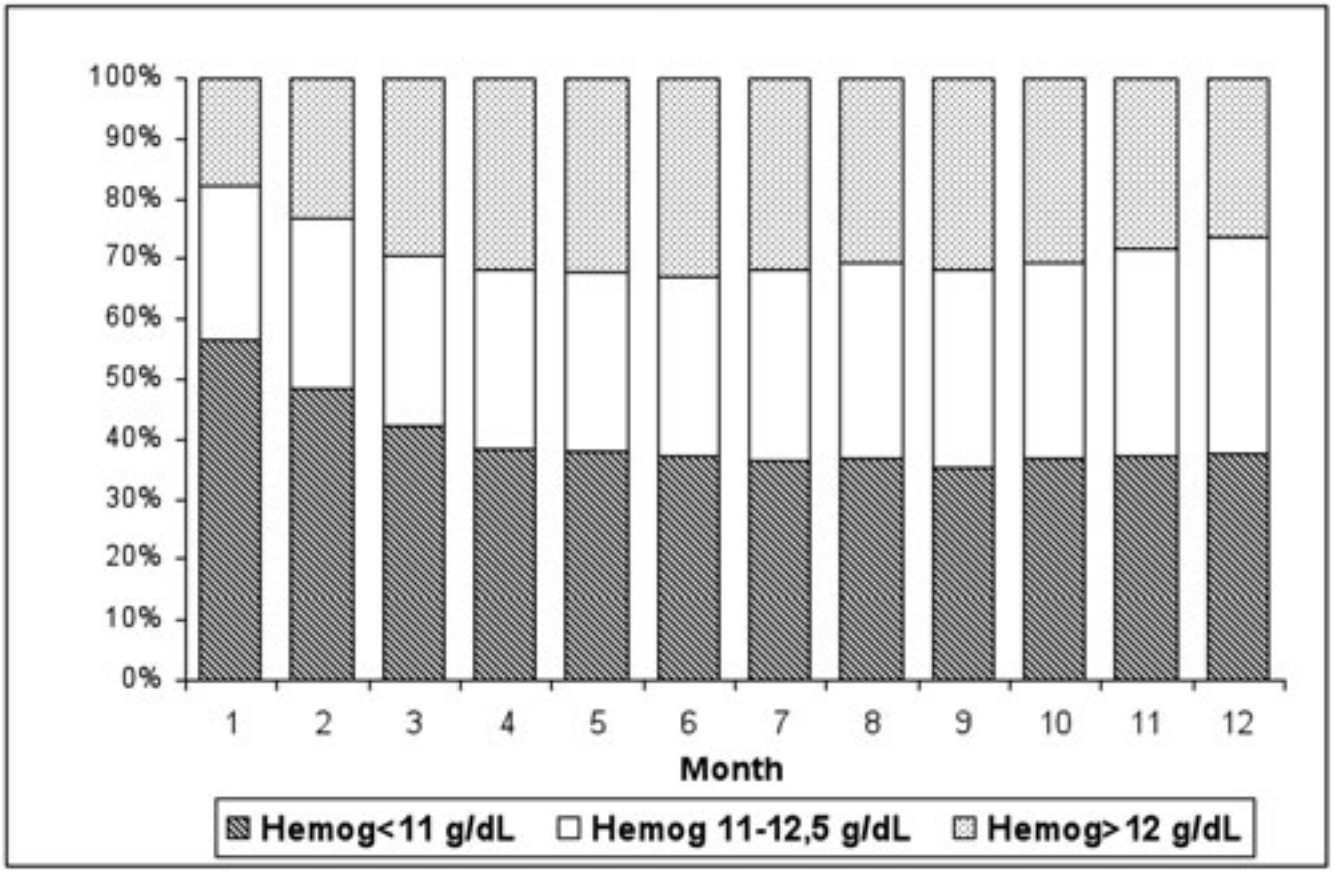
VOL 48, NO 3, SEPTEMBER 2006
AJKD American Journal of Kidney Diseases

Phases:	**Phase 1** Preclinical Exploratory	**Phase 2** Clinical Characterization & Assay Validation	**Phase 3** Clinical Association: Retrospective Repository studies	**Phase 4** Clinical Association: Prospective Screening studies	**Phase 5** Disease control
Objective	Target Biomarker Identification, Feasibility	Study assay in people with & without disease	Case-control studies using repository specimens	Longitudinal studies to predict disease	Clinical use
Site	Biomarker Development Lab	Biomarker Validation Lab	Clinical Epidemiologic Centers	Cohort Studies	Community
Design	Cross-sectional	Cross-sectional	Case-control	Prospective	RCT
Sample Size	Small	Small	Modest	Medium	Large
Validity	Content & construct validity	Criterion validity	Predictive validity	Efficacy of strategy	Effectiveness
Result	Assay precision reliability, sensitivity	Reference limits, intra-individual variation	Screening characteristics, true & false+ rates	ROC analyses	No.-needed-to screen/treat

New biomarkers in anemia

Analysis of the factors associated with anemia and its impact on peritoneal dialysis patient outcome

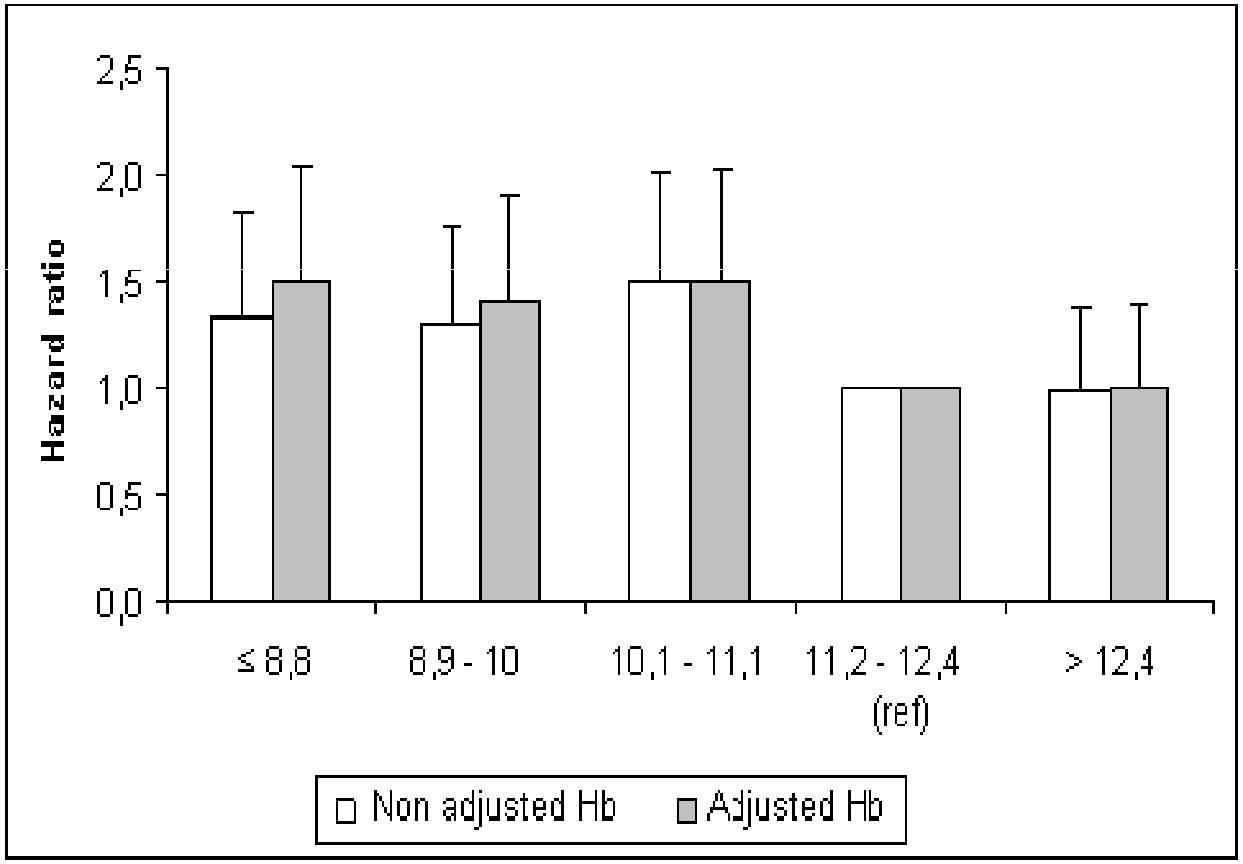
*Simone M. Gonçalves, Natália Fernandes, Eduardo Andreazza Dal Lago, Sandra Contador Kloster, Márcia Olandowski, José Carolino Divino Filho, Roberto Pecoits-Filho: o*n behalf of the BRAZPD Study investigators, BRAZIL



Sumitted 2010

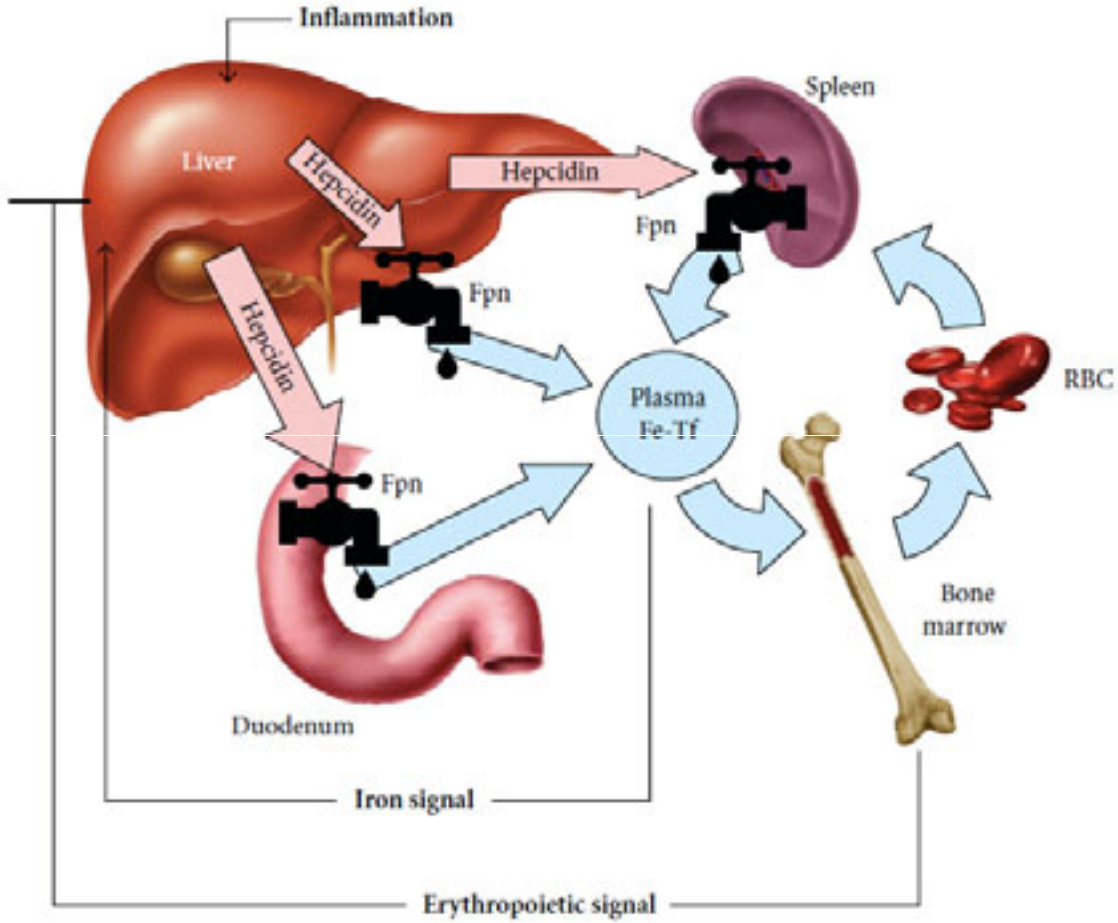
Analysis of the factors associated with anemia and its impact on peritoneal dialysis patient outcome

*Simone M. Gonçalves, Natália Fernandes, Eduardo Andreazza Dal Lago, Sandra Contador Kloster, Márcia Olandowski, José Carolino Divino Filho, Roberto Pecoits-Filho: o*n behalf of the BRAZPD Study investigators, BRAZIL



Sumitted 2010

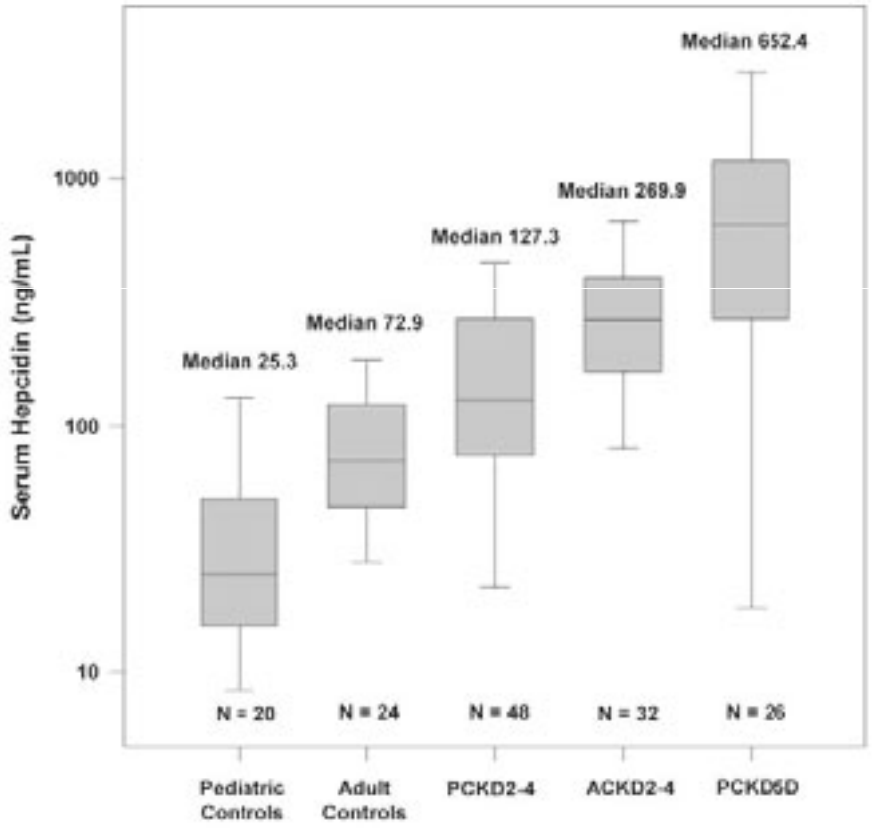
Targeting the Hepcidin-Ferroportin Axis in the Diagnosis and Treatment of Anemias



Advances in Hematology
Volume 2010, Article ID 750643,

Hepcidin—A Potential Novel Biomarker for Iron Status in Chronic Kidney Disease

Joshua Zaritsky,* Brian Young,† He-Jing Wang,‡ Mark Westerman,§ Gordana Olbina,§ Elizabeta Nemeth,† Tomas Ganz,† Seth Rivera,† Allen R. Nissenson,† and Isidro B. Salusky*

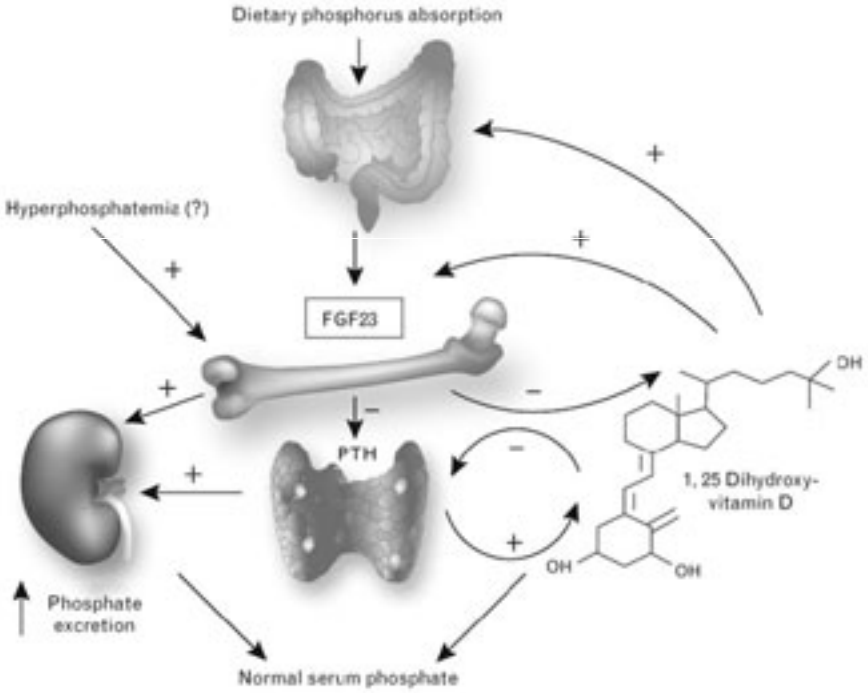


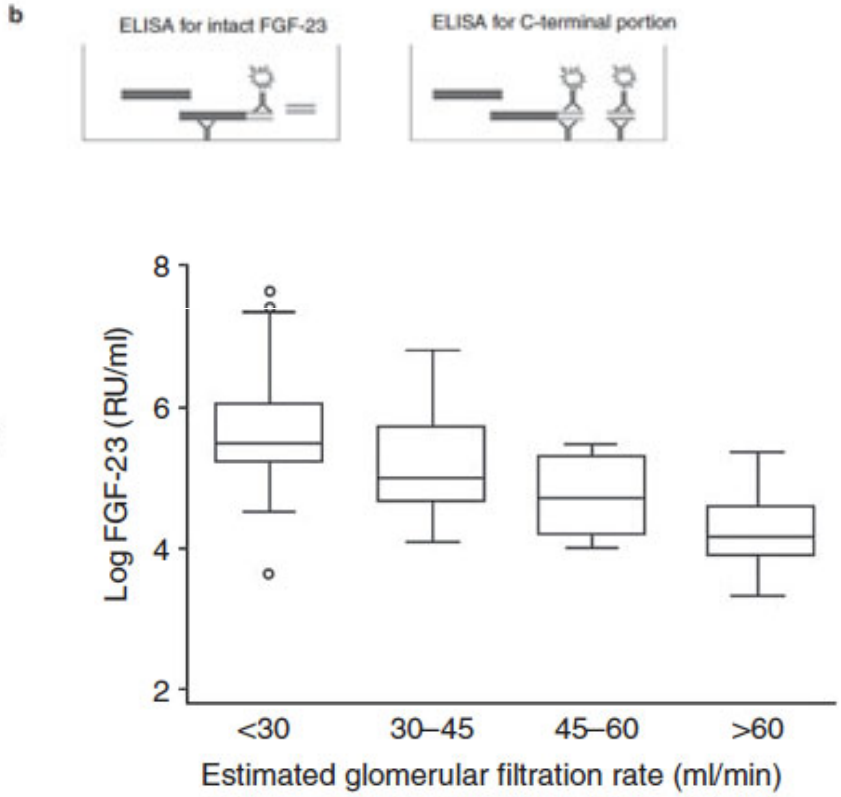
Clin J Am Soc Nephrol 4: 1051–1056, 2009.

New biomarkers in mineral metabolism disorders

Fibroblast growth factor 23 and the future of phosphorus management

Myles Wolf





Current Opinion in Nephrology and Hypertension 2009, 18:463–468

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION
American Heart Association. Learn and Live.

Fibroblast Growth Factor 23 and Left Ventricular Hypertrophy in Chronic Kidney Disease

Orlando M. Gutiérrez, MD, MMSc; James L. Januzzi, MD; Tamara Isakova, MD; Karen Laliberte, RN, MS; Kelsey Smith, BA; Gina Collerone, AS; Ammar Sarwar, MD; Udo Hoffmann, MD; Erin Coglianese, MD; Robert Christenson, PhD; Thomas J. Wang, MD, MPH; Christopher deFilippi, MD; Myles Wolf, MD, MMSc

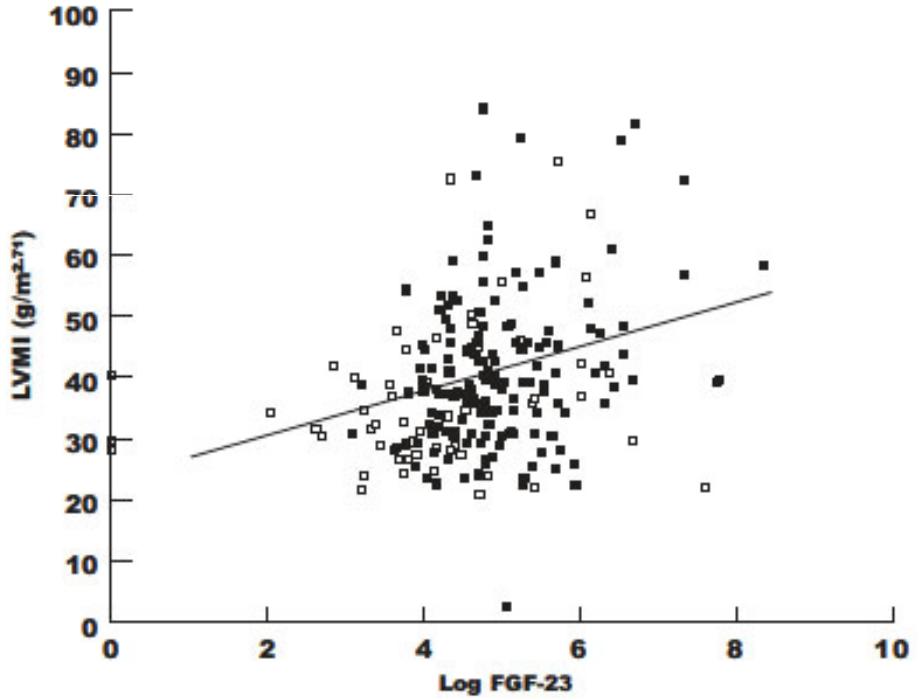


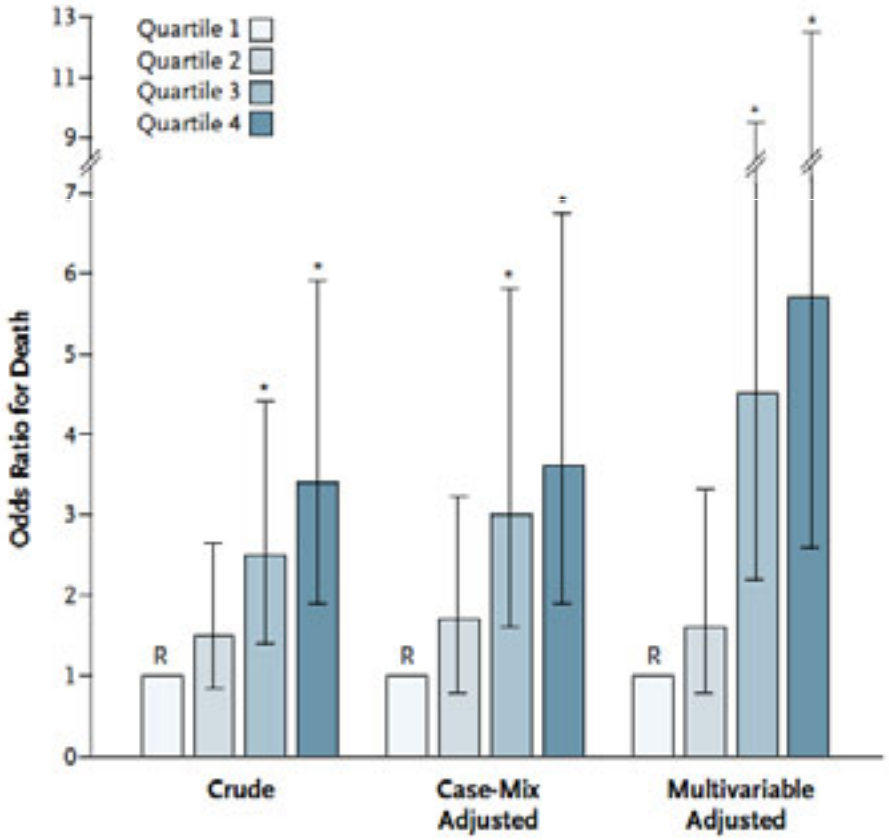
Figure 2. Correlation between log FGF-23 and LVMI (r=0.27, P<0.001). □ Indicates non-CKD subjects; ■, subjects with CKD.

(*Circulation*. 2009;119:2545-2552.)

The NEW ENGLAND JOURNAL of MEDICINE

Fibroblast Growth Factor 23 and Mortality among Patients Undergoing Hemodialysis

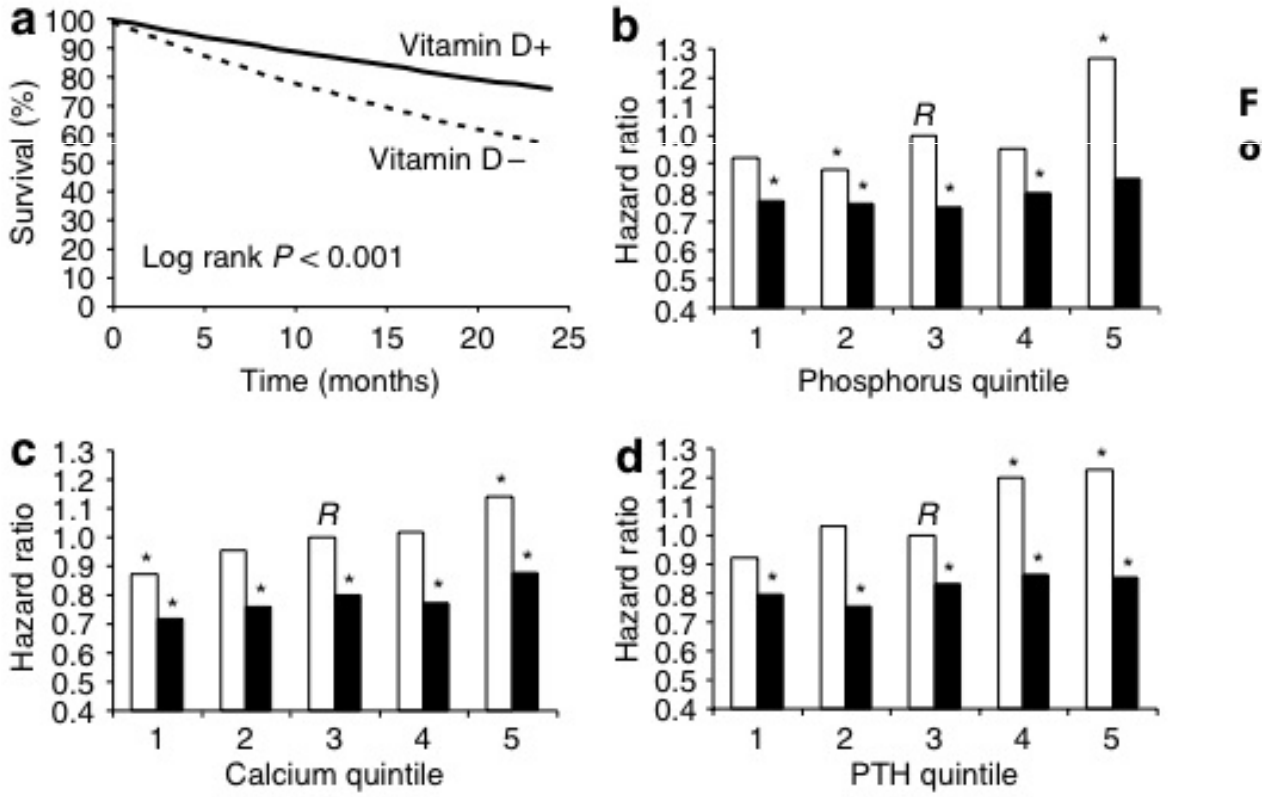
Orlando M. Gutiérrez, M.D., M.M.Sc., Michael Mannstadt, M.D., Tamara Isakova, M.D., Jose Alejandro Rauh-Hain, M.D., Hector Tamez, M.D., Anand Shah, M.D., Kelsey Smith, B.A., Hang Lee, Ph.D., Ravi Thadhani, M.D., M.P.H., Harald Jüppner, M.D., and Myles Wolf, M.D., M.M.Sc.



Vitamin D in chronic kidney disease: A systemic role for selective vitamin D receptor activation

DL Andress[1]

[1]Department of Medicine, VA Puget Sound Health Care System, Division of Nephrology, University of Washington, Seattle, Washington, USA



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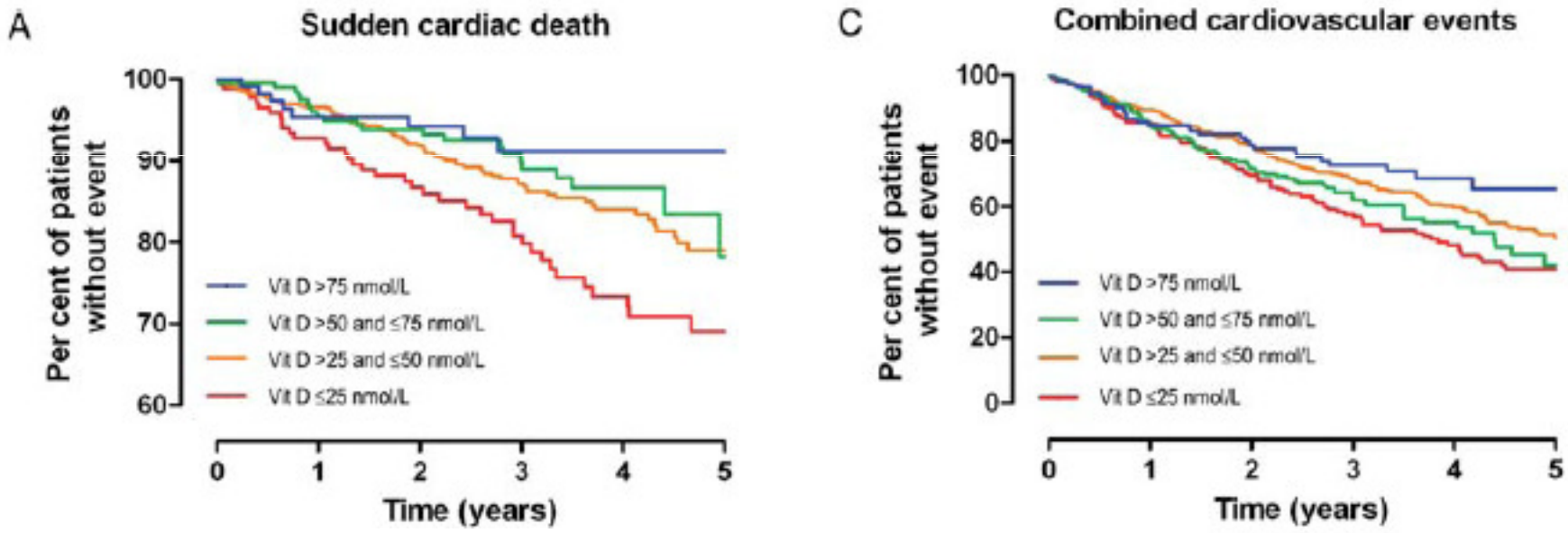
Vitamin D deficiency is associated with sudden cardiac death, combined cardiovascular events, and mortality in haemodialysis patients

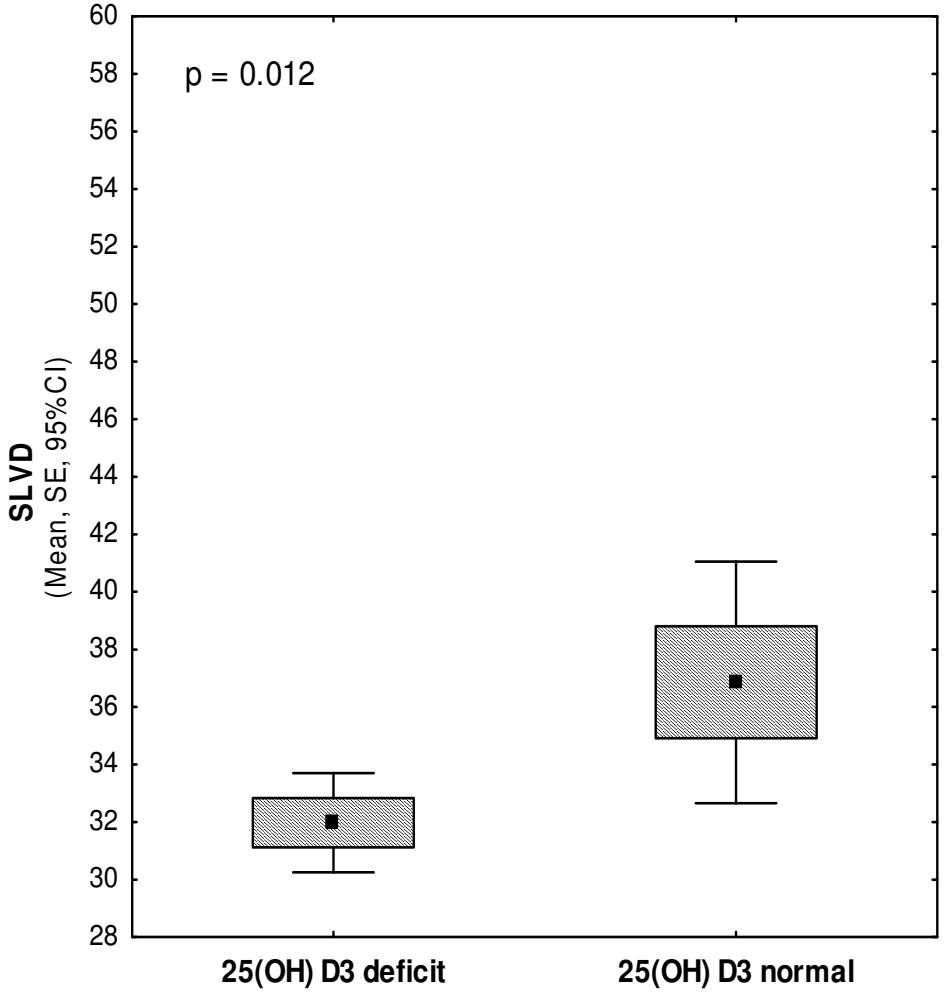
Christiane Drechsler[1,2*†], Stefan Pilz[3†], Barbara Obermayer-Pietsch[3], Marion Verduijn[2], Andreas Tomaschitz[3], Vera Krane[1], Katharina Espe[4], Friedo Dekker[2], Vincent Brandenburg[5], Winfried März[6,7], Eberhard Ritz[8], and Christoph Wanner[1]

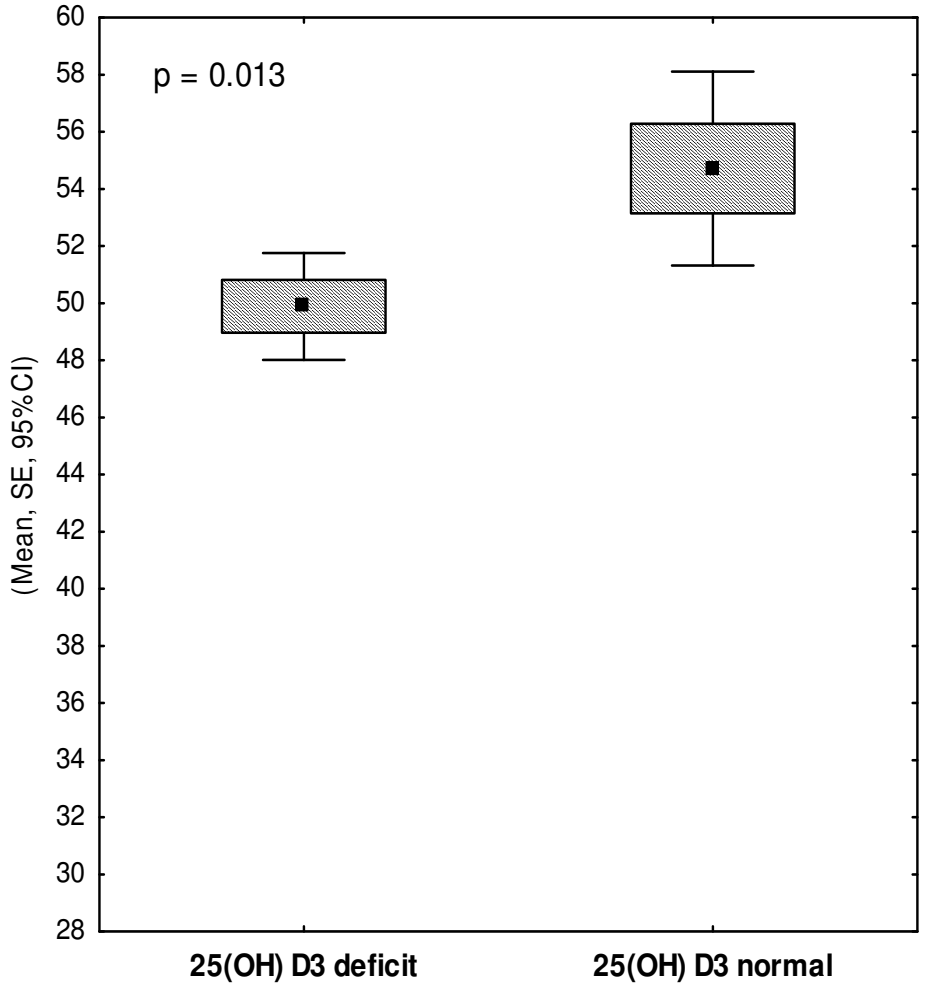
EUROPEAN SOCIETY OF CARDIOLOGY®



European Heart Journal (2010) **31**, 2253–2261

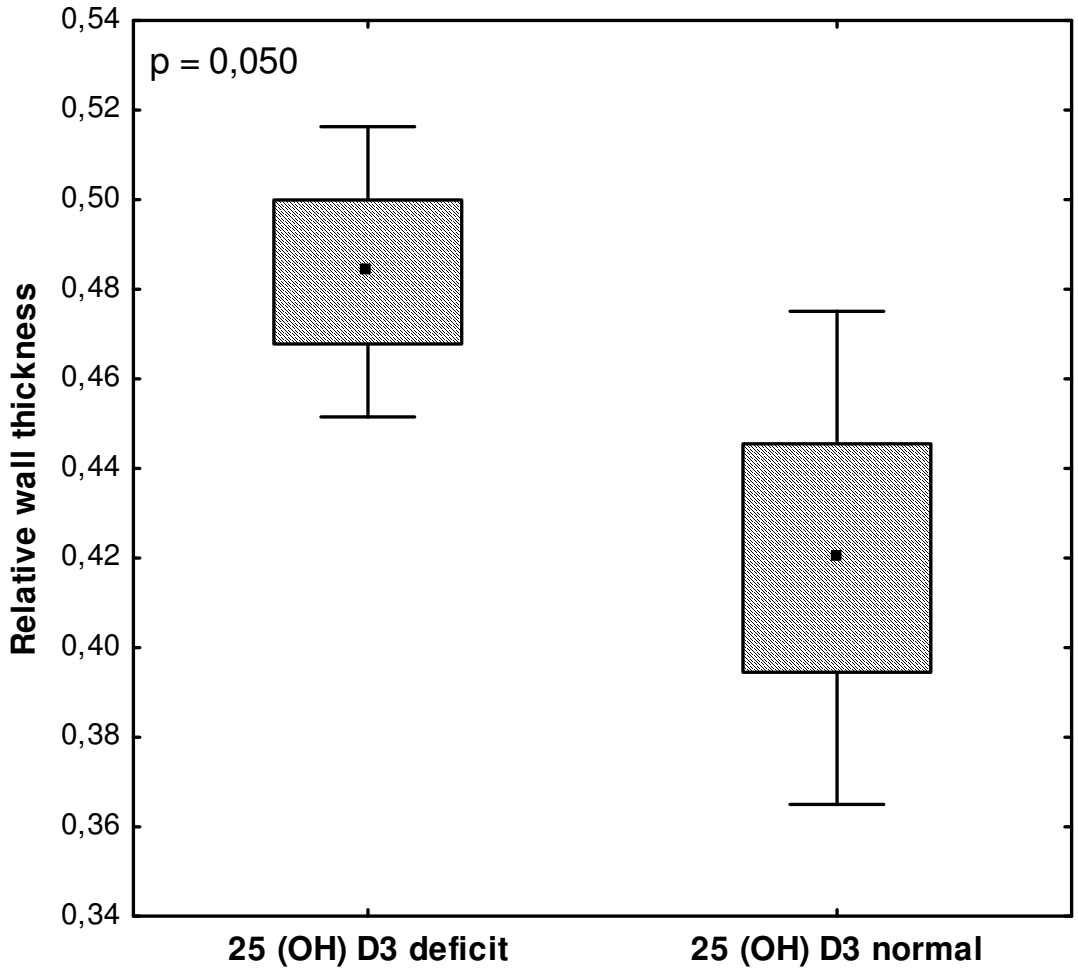
Low levels of 25(OH)D3 are associated with geometric remodelling of the left ventricle





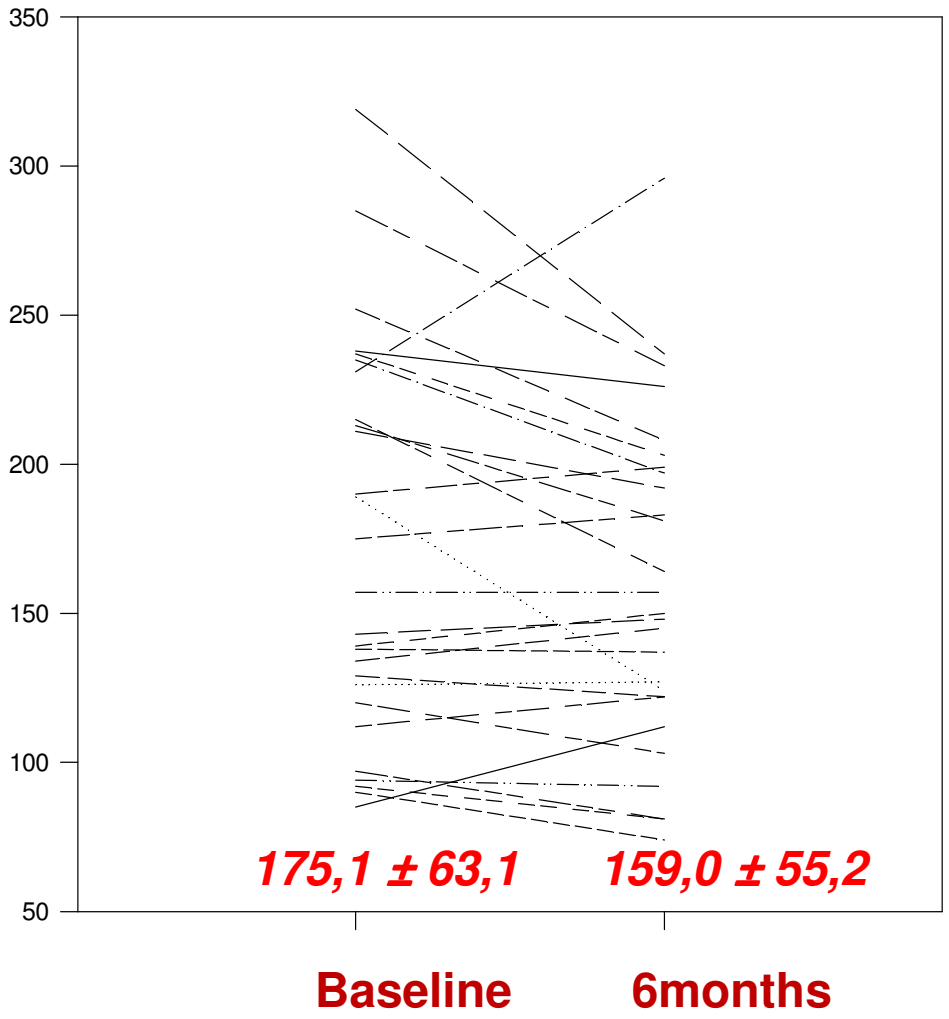
Bucharles S, Pecoits-Filho. *Submitted 2010.*

Low levels of 25(OH)D3 are associated with geometric remodelling of the left ventricle

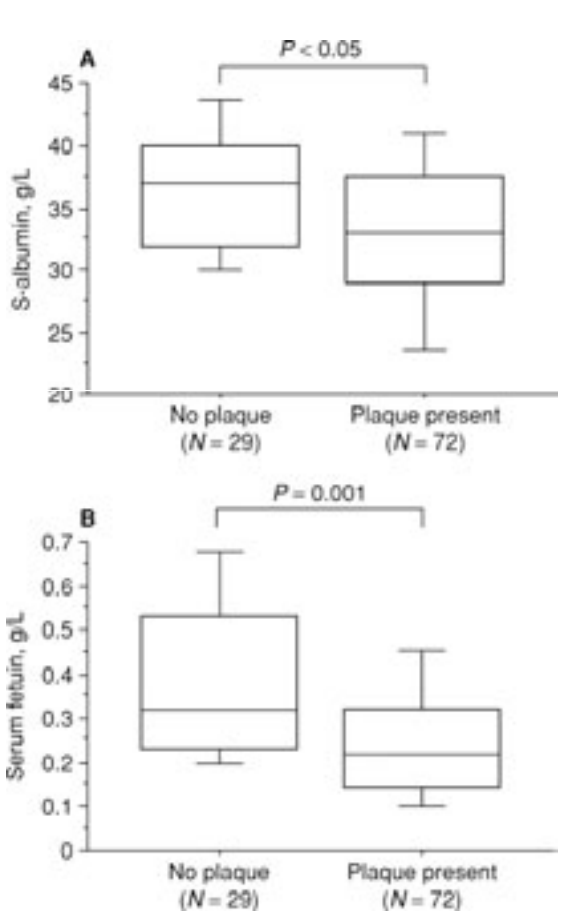


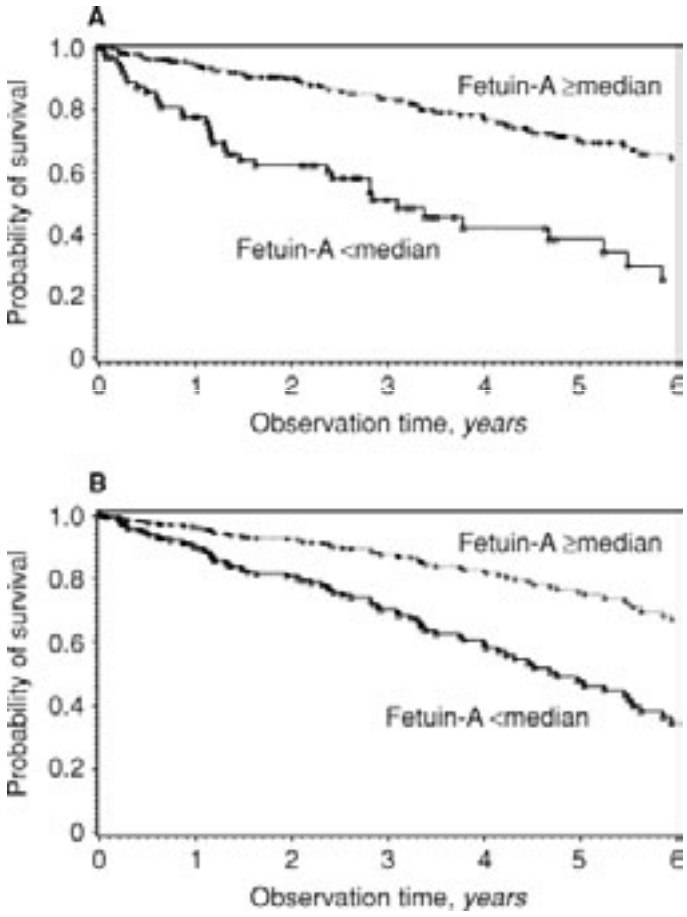
Bucharles S; Pecoits-Filho *Submitted 2010*

Cholecalcipherol decreases LVH in HD patients

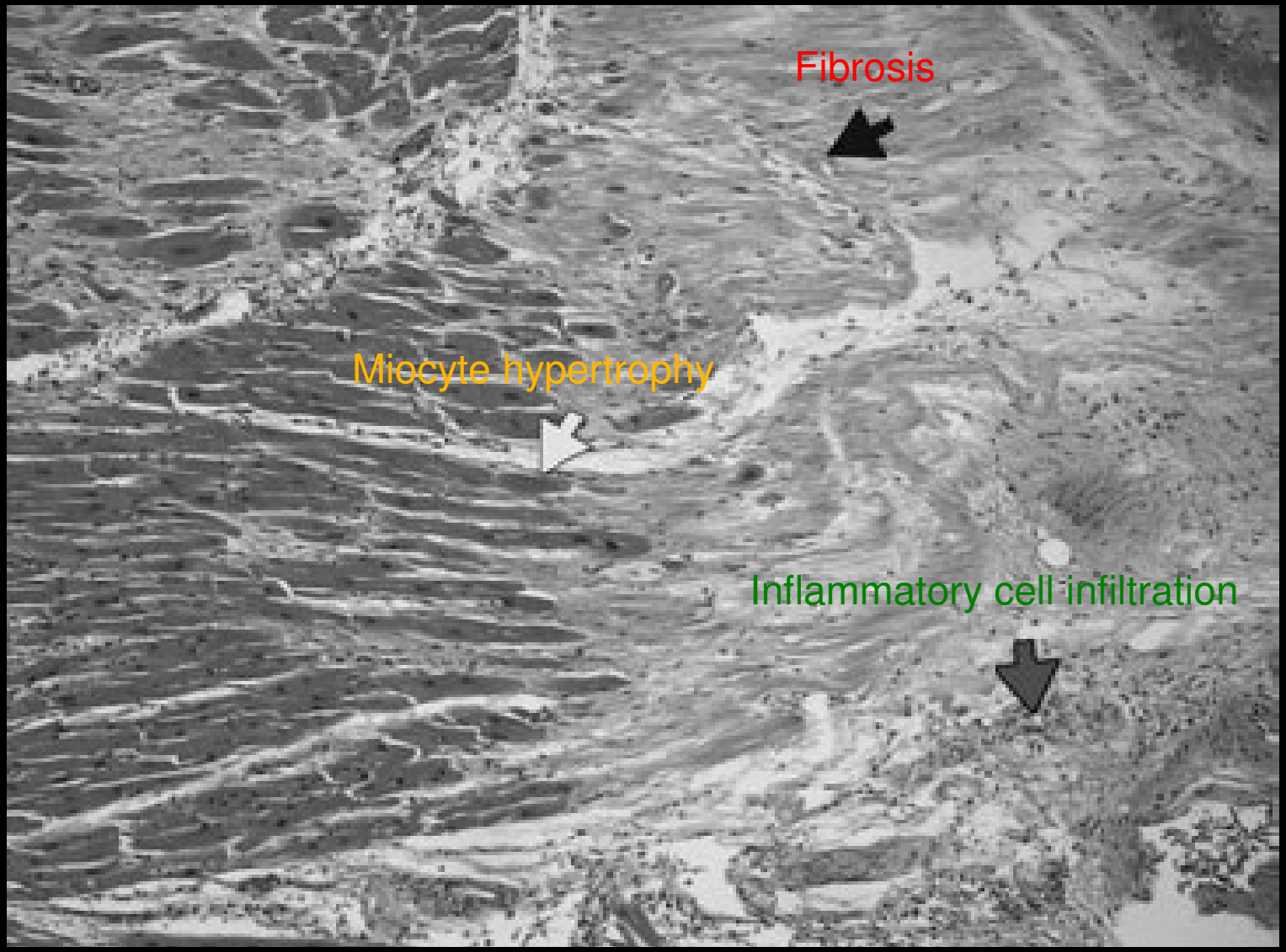


Anti-calcification proteins and inflammation





Stenvinkel, Pecoits-Filho et al. Kidney Int 2005



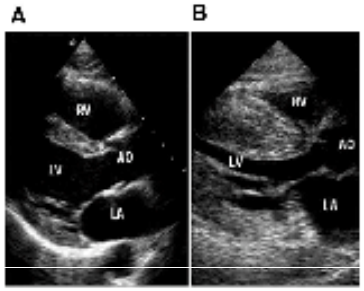
Marie-Luise Gross and Eberhard Ritz. Seminars in Dialysis, 2008.

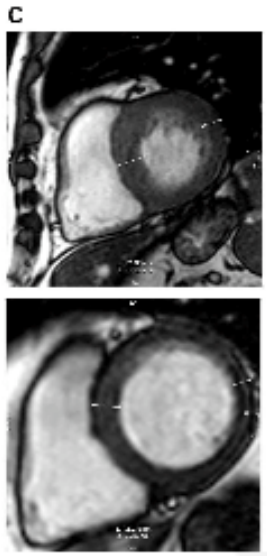
New biomarkers in left ventricle alterations

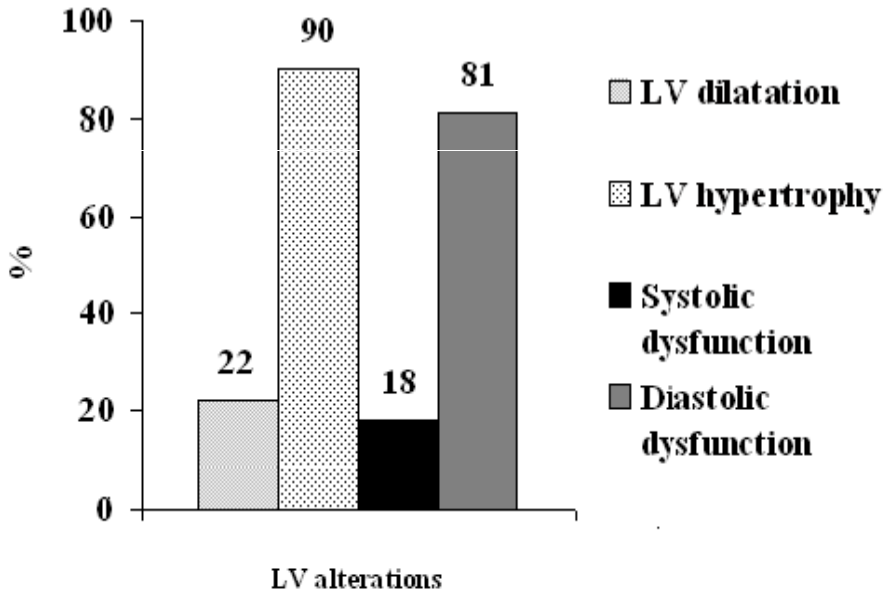
Left Ventricular Mass in Chronic Kidney Disease and ESRD

Richard J. Glassock,* Roberto Pecoits-Filho,† and Silvio H. Barberato†

*The David Geffen School of Medicine at UCLA, Los Angeles, California; and †Center for Health and Biological Sciences, Pontificia Universidade Catolica do Parana, Curitiba, Brazil







Clinical Journal of the American Society of Nephrology, 2009

Use of Cardiac Biomarkers in End-Stage Renal Disease

Angela Yee-Moon Wang and Kar-Neng Lai

University Department of Medicine, Queen Mary Hospital, University of Hong Kong, Hong Kong

BRIEF REVIEW www.jasn.org

Table 1. Summary of studies that evaluated the diagnostic potentials of BNP or NT-pro-BNP for LV disorders in CKD[a]

Author	No. of Patients	AUC for LVH, LVSD	Best Cutoff for LVH and LVSD
Mallamaci *et al.*,[33] 2000	212 HD and 34 PD	0.81, 0.78	LVH (BNP): 23.4 pmol/L (sens 62%, spec 88%, PPV 95%, NPV 61%) LVSD (BNP): 38.9 pmol/L (sens 74%, spec 76%, PPV 31%, NPV 95%)
Mark *et al.*,[42] 2006	55 HD	0.664, 0.532	LVH (BNP): ND (sens 68%, spec 67%, PPV 79%, NPV 53%)
David *et al.*,[46] 2007	62 HD	ND, 0.95	LVSD (BNP): ND (sens 94%, spec 21%, PPV 46%, NPV 83%)
deFilippi *et al.*,[27] 2005	207 with stages 1 through 5 CKD	0.73, ND (based on 99 patients)	LVSD (NT-pro-BNP): 7168 pg/ml (sens 98%, spec 79%) LVH (NT-pro-BNP): 271 pg/ml (sens 76%, spec 60%)
Khan *et al.*,[28] 2006	54 with CKD	0.72, ND (NT-pro-BNP)	LVH (NT-pro-BNP): 762 pg/ml (sens 63%, spec 67%, PPV 70%, NPV 57%)
		0.72, ND (BNP)	LVH (BNP): 200 pg/ml (sens 60%, spec 71%, PPV 72%, NPV 59%)

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University Department of Medicine, Queen Mary Hospital, University of Hong Kong, Hong Kong

BRIEF REVIEW www.jasn.org

Table 3. Summary of studies that evaluated the prognostic value of BNP and NT-pro-BNP in ESRD[a]

Author	Patients	Follow-up	No. of Events	Outcome and HR (95% CI)
Studies using BNP				
Zoccali *et al.*,[38] 2000	212 HD and 34 PD	26 ± 10 mo	63 deaths, 74 CV events	Death: HR 1.62 (1.20 to 2.17), $P = 0.001$ for 1-unit increase in log-BNP CV death, T3 versus T1: HR 6.72 (2.44 to 18.54), $P = 0.0002$
Cataliotti *et al.*,[37] 2001	112 HD	26 ± 10 mo	16 CV deaths	CV death: HR 2.18 (1.26–3.76), $P = 0.005$ for 1-unit increase in log-BNP
Naganuma *et al.*,[39] 2002	164 HD	36 mo	13 cardiac deaths	Cardiac death, Q4 versus Q1: HR 51.9 (6.5 to 416.3)
Goto *et al.*,[50] 2002	53 HD	11.3 ± 0.3 mo	13 CV events	CV events: HR not given ($P < 0.0001$)
Rutten *et al.*,[51] 2006	68 PD	At least 18 mo	10 deaths	Death, BNP > median: HR 8.5 (1.0 to 73.8), $P = 0.05$

Use of Cardiac Biomarkers in End-Stage Renal Disease

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University Department of Medicine, Queen Mary Hospital, University of Hong Kong, Hong Kong

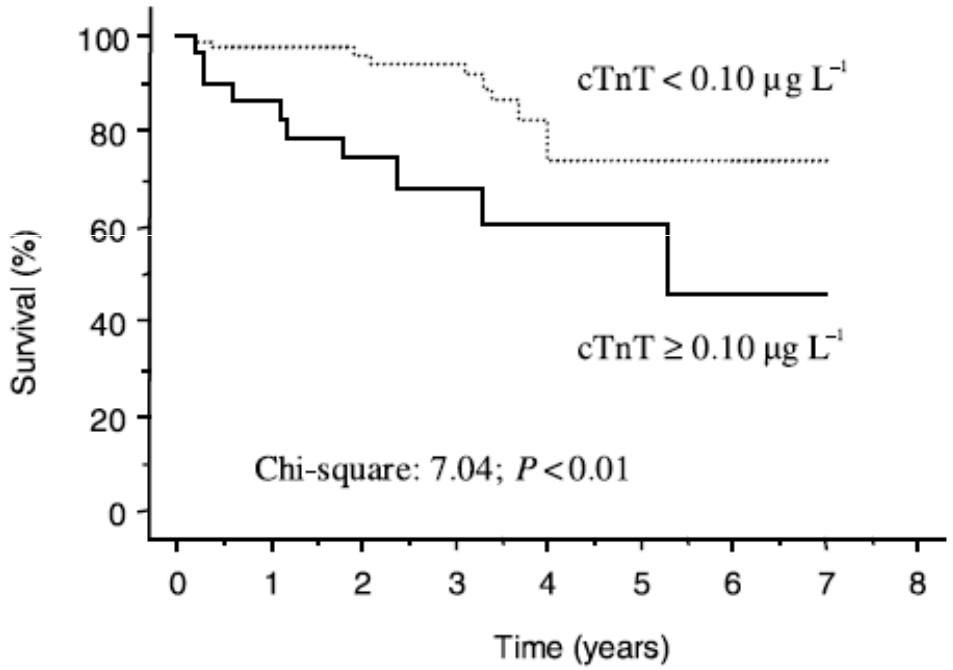
BRIEF REVIEW www.jasn.org

Table 3. Summary of studies that evaluated the prognostic value of BNP and NT-pro-BNP in ESRD[a]

Author	Patients	Follow-up	No. of Events	Outcome and HR (95% CI)
Studies using NT-pro-BNP				
Apple *et al.*,[31] 2004	399 HD	24 mo	101 deaths	Death, upper tertile: NT-pro-BNP >18,692 pg/ml increased mortality
Wang *et al.*,[35] 2007	240 PD	36 mo	66 deaths, 87 circulatory congestion, 43 CV deaths, 78 CV events	Death, Q4 *versus* Q1: HR 4.97 (1.35 to 18.28), $P = 0.016$ Circulatory congestion, Q4 *versus* Q1: HR 4.25 (1.56 to 11.62), $P = 0.005$ CV death – Q4 *versus* Q1: HR, 7.50 (1.36 to 41.39), $P = 0.021$ CV events, Q4 *versus* Q1: HR 9.10 (2.46 to 33.67), $P = 0.001$
Madsen *et al.*,[32] 2007	190 HD	24 mo	34 deaths	Death, pre-HD log-NT-pro-BNP: HR 1.42 (1.10 to 1.82), $P = 0.007$ Death, post-HD log-NT-pro-BNP: HR 1.52 (1.18 to 1.96), $P = 0.001$
Sommerer *et al.*,[52] 2007	134 HD	36 mo	74 deaths and CV events	Death and CV events: HR 3.2 (1.70 to 6.02), $P < 0.001$
Satyan *et al.*,[34] 2007	150 HD	24 mo	46 deaths, 26 CV deaths	Death, Q4 *versus* Q1: HR 4.03 (1.31 to 12.40), $P = 0.02$ CV death: HR 8.54 (1.04 to 69.98), $P = 0.05$
Sharma *et al.*,[53] 2007	50 HD and 29 PD	2.25 ± 0.71 yr	21 deaths	Death: HR 5.57 (3.14 to 8.21), $P = 0.02$ (univariate analysis)

Elevated cardiac troponin T in predialysis patients is associated with inflammation and predicts mortality

C. LÖWBEER[1], P. STENVINKEL[2], R. PECOITS-FILHO[2,3], O. HEIMBÜRGER[2], B. LINDHOLM[2,3], S. A. GUSTAFSSON[1,4] & A. SEEBERGER[2]

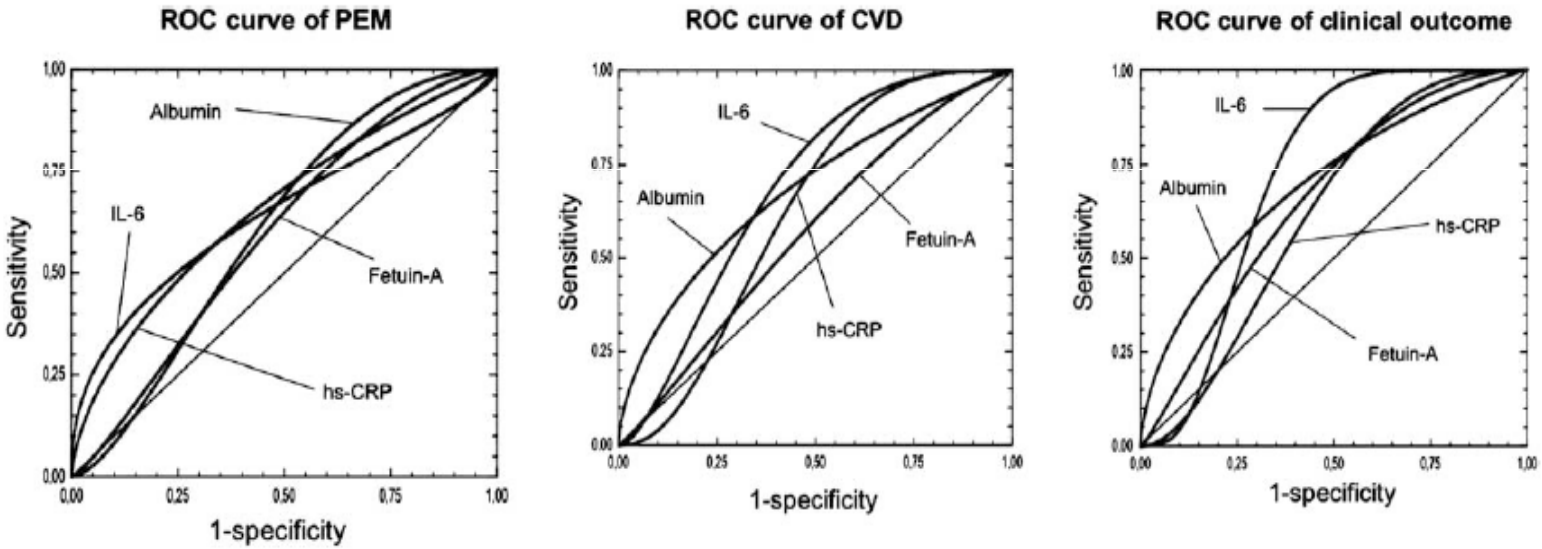


Journal of Internal Medicine 2003; 253: 153–160

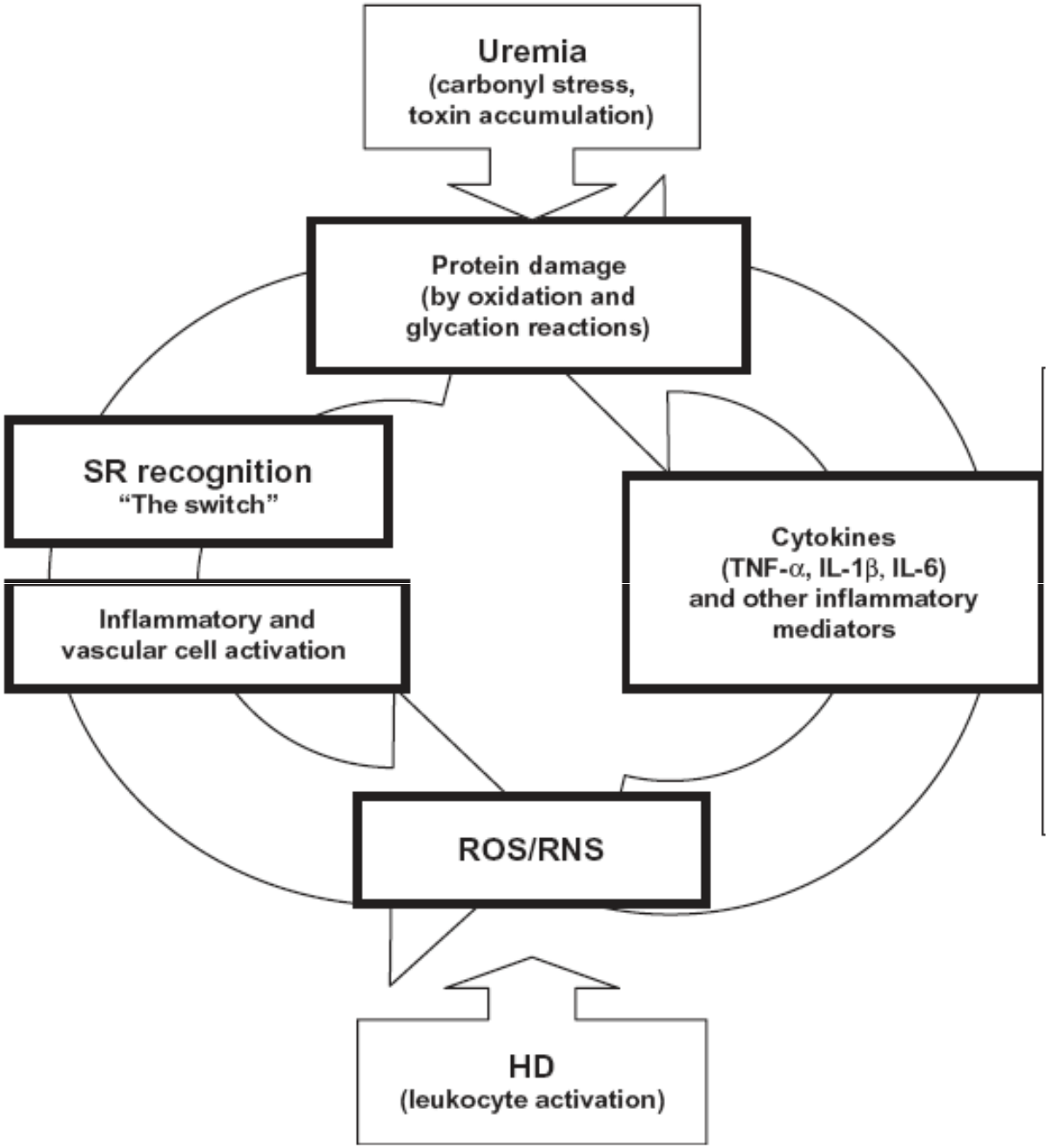
New markers in the area of inflammation

Serum Albumin, C-Reactive Protein, Interleukin 6, and Fetuin A as Predictors of Malnutrition, Cardiovascular Disease, and Mortality in Patients With ESRD

Hirokazu Honda, MD, PhD, Abdul Rashid Qureshi, MD, PhD, Olof Heimbürger, MD, PhD, Peter Barany, MD, PhD, Kai Wang, MD, Roberto Pecoits-Filho, MD, PhD, Peter Stenvinkel, MD, PhD, and Bengt Lindholm, MD, PhD



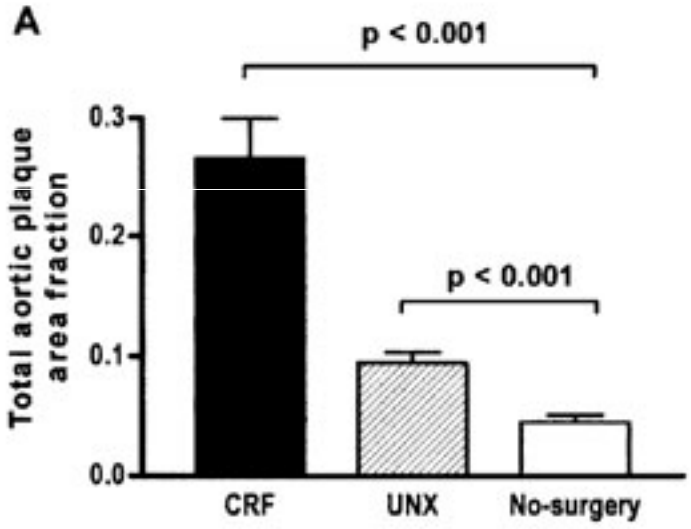
American Journal of Kidney Diseases, Vol 47, No 1 (January), 2006: pp 139-148

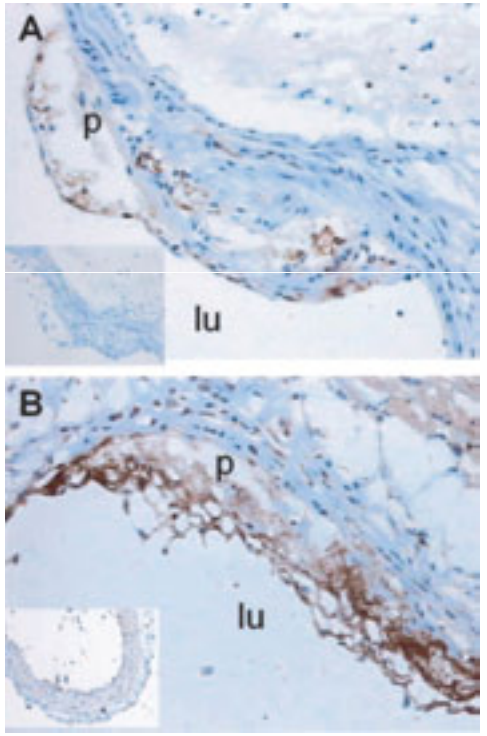

Uremia
(carbonyl stress,
toxin accumulation)
Protein damage
(by oxidation and
glycation reactions)
SR recognition
"The switch"
Cytokines
(TNF-α, IL-1β, IL-6)
and other inflammatory
mediators
Inflammatory and
vascular cell activation
ROS/RNS
HD
(leukocyte activation)

Chronic Renal Failure Accelerates Atherogenesis in Apolipoprotein E–Deficient Mice

SUSANNE BRO,*† JACOB F. BENTZON,§ ERLING FALK,§ CLAUS B. ANDERSEN,‡ KLAUS OLGAARD,* and LARS B. NIELSEN†

*Departments of *Nephrology, †Clinical Biochemistry, and ‡Pathology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; and §Department of Cardiology and Institute of Experimental Clinical Research, Aarhus University Hospital (Skejby), Aarhus, Denmark*





J Am Soc Nephrol 14: 2466–2474, 2003

Original Paper

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Clinical
Practice

Nephron Clin Pract 2009;111:c117–c126
DOI: 10.1159/000191205

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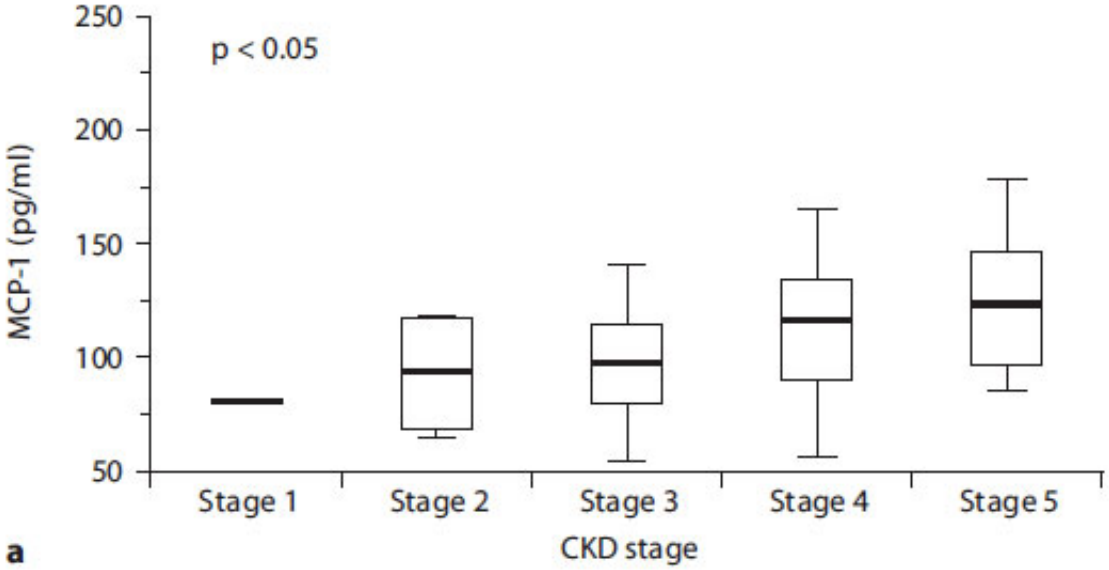
Published online: January 16, 2009

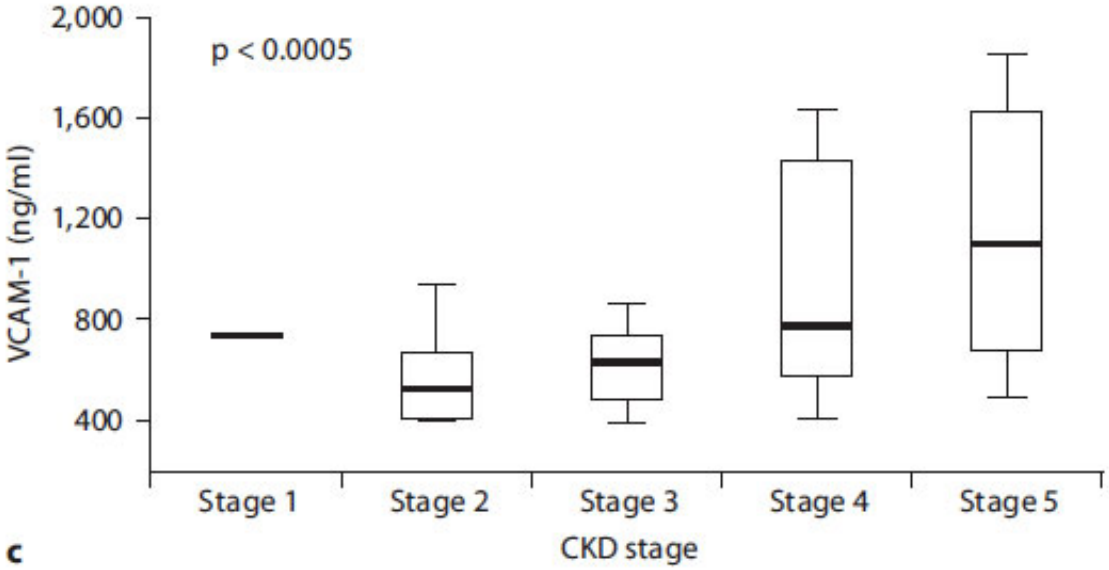
Increased Plasma and Endothelial Cell Expression of Chemokines and Adhesion Molecules in Chronic Kidney Disease

A.E.M. Stinghen S.M. Gonçalves E.G. Martines L.S. Nakao M.C. Riella
C.A. Aita R. Pecoits-Filho

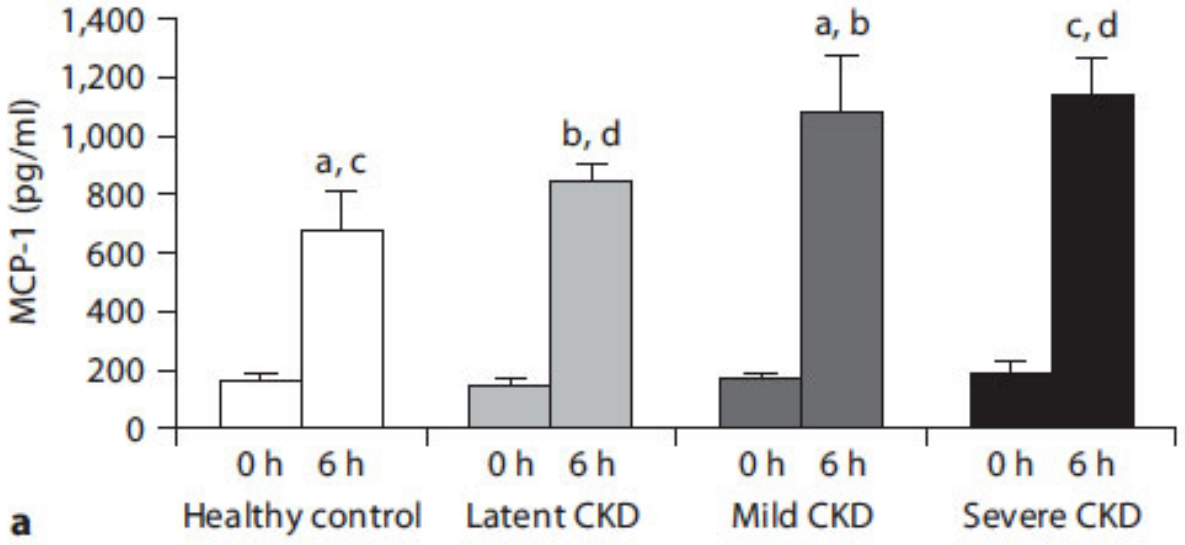
Center for Health and Biological Sciences, Pontifícia Universidade Católica do Paraná, Curitiba, Brazil

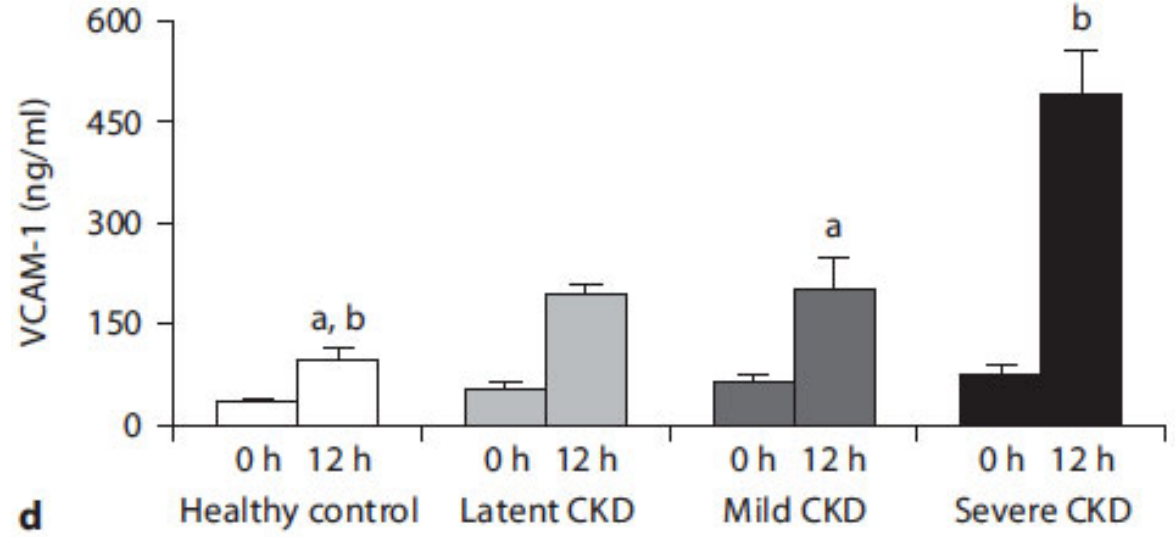

250
200
150
100
50
MCP-1 (pg/ml)
p < 0.05
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
CKD stage

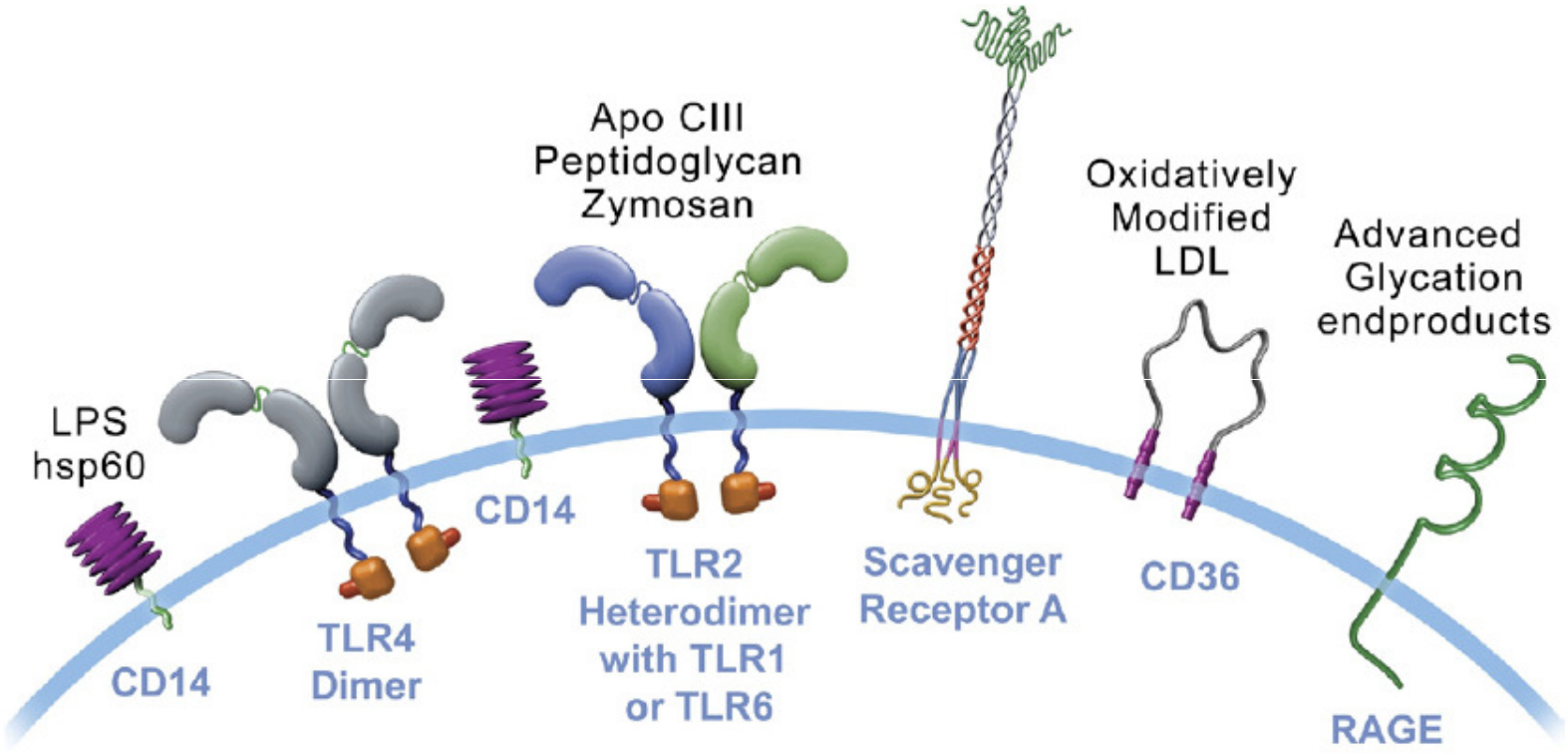
a


2,000
1,600
1,200
800
400
VCAM-1 (ng/ml)
p < 0.0005
Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
CKD stage

c


MCP-1 (pg/ml)
1,400
1,200
1,000
800
600
400
200
0
a, c
b, d
a, b
c, d
0 h 6 h
Healthy control
Latent CKD
Mild CKD
Severe CKD
a


VCAM-1 (ng/ml)
600
450
300
150
0
a, b
a
b
0 h 12 h
Healthy control
Latent CKD
Mild CKD
Severe CKD
d



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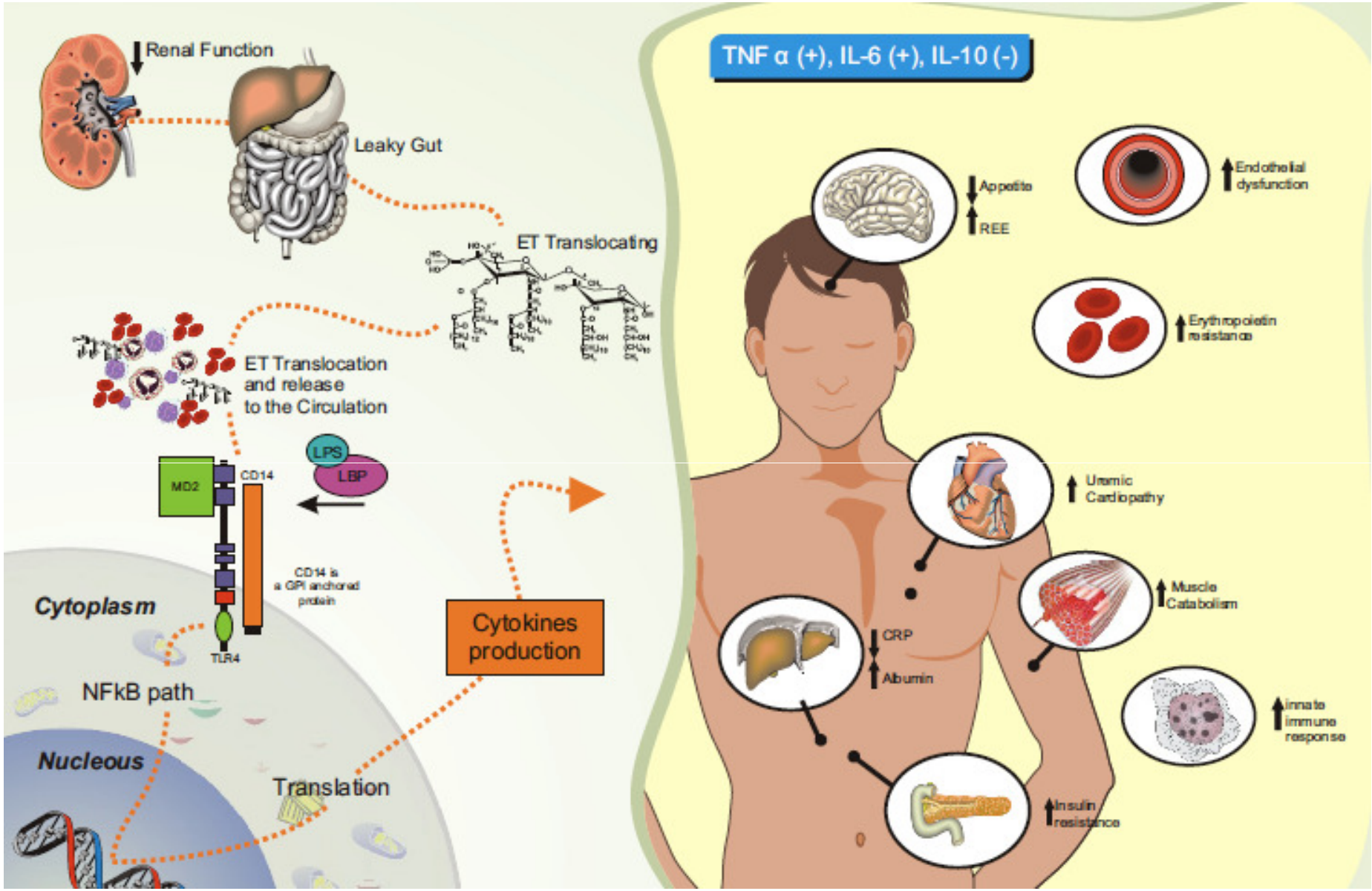
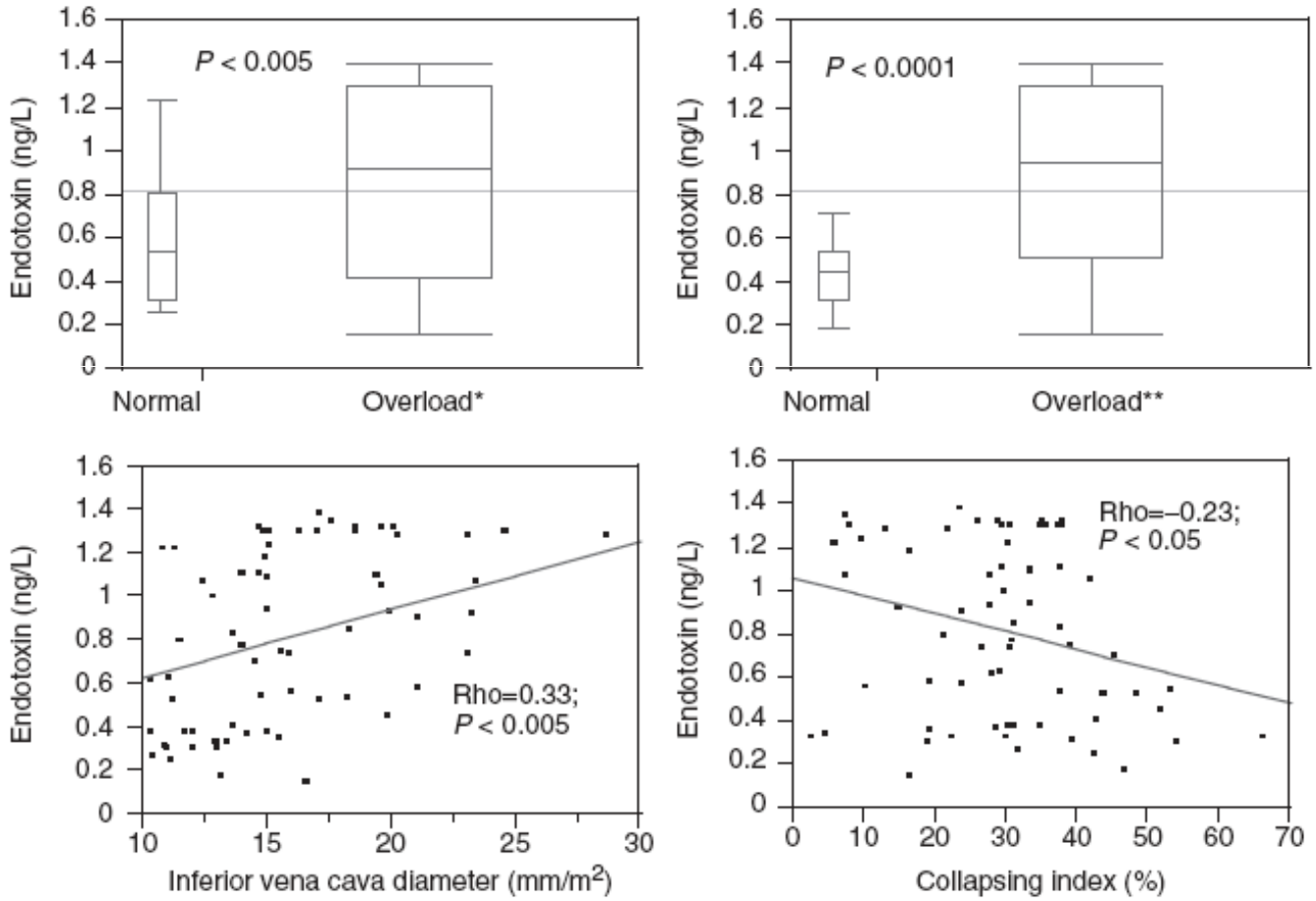


Hauser, Gonçalves, Stinghen and Pecoits-Filho, Nephron Clinical Practice 2010

Fluid overload and endotoxemia in CKD



Gonçalves S., Pecoits-Filho et al. Nephrol, Dial, Transplant 2006

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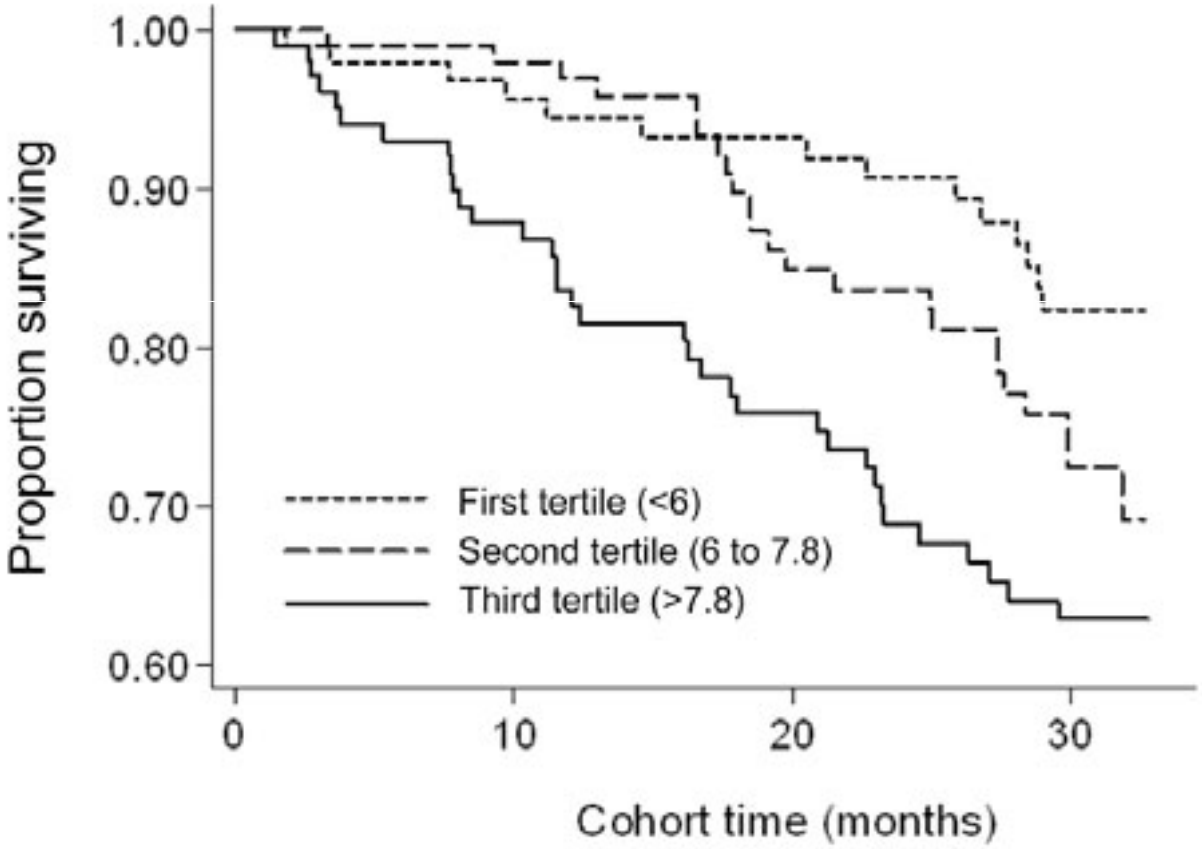
- Endotoxemia is Related to Systemic Inflammation and Atherosclerosis in Peritoneal Dialysis Patients
  - Cheuk-Chun Szeto, Bonnie Ching-Ha Kwan, Kai-Ming Chow, Ka-Bik Lai, Kwok-Yi Chung, Chi-Bon Leung, and Philip Kam-Tao Li

    - Department of Medicine and Therapeutics, Prince of Wales Hospital, The Chinese University of Hong Kong, Shatin, Hong Kong, China

2008 Mar;3(2):431-6. Epub 2008 Feb 6

Association of Soluble Endotoxin Receptor CD14 and Mortality Among Patients Undergoing Hemodialysis

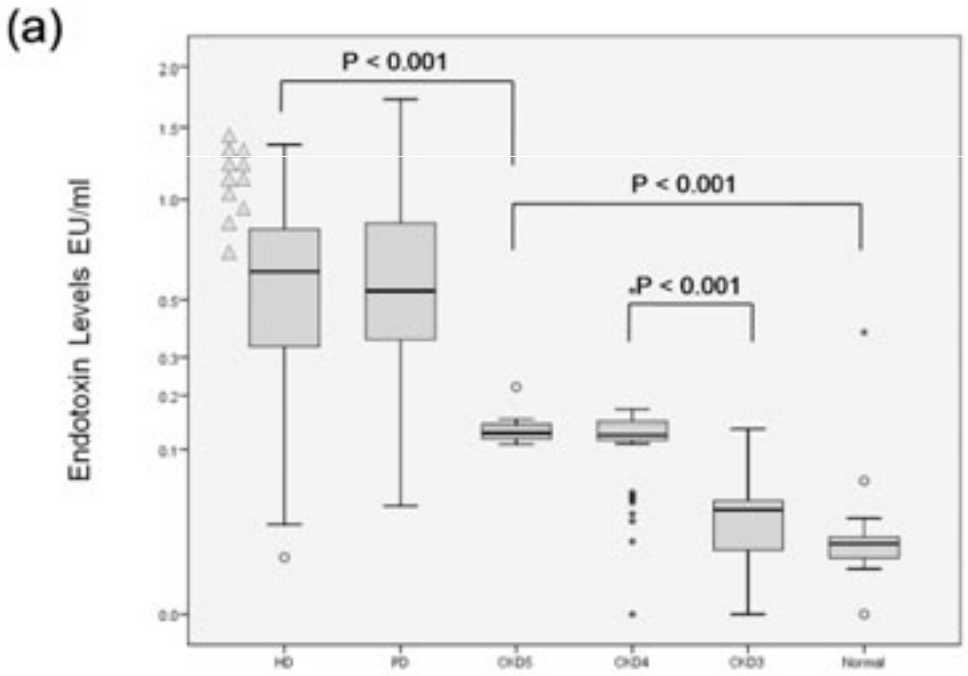
Dominic S.C. Raj, MD,[1] Vallabh O. Shah, PhD,[2] Mehdi Rambod, MD,[3] Csaba P. Kovesdy, MD,[4] and Kamyar Kalantar-Zadeh, MD, MPH, PhD[3]



AJKD 2009

Circulating Endotoxemia: A Novel Factor in Systemic Inflammation and Cardiovascular Disease in Chronic Kidney Disease

Christopher W. McIntyre,*† Laura E.A. Harrison,* M. Tarek Eldehni,* Helen J. Jefferies,* Cheuk-Chun Szeto,‡ Stephen G. John,* Mhairi K. Sigrist,* James O. Burton,* Daljit Hothi,§ Shvan Korsheed,* Paul J. Owen,* Ka-Bik Lai,‡ and Philip K.T. Li‡



Clin J Am Soc Nephrol. 2010 Sep 28.

Circulating Endotoxemia: A Novel Factor in Systemic Inflammation and Cardiovascular Disease in Chronic Kidney Disease

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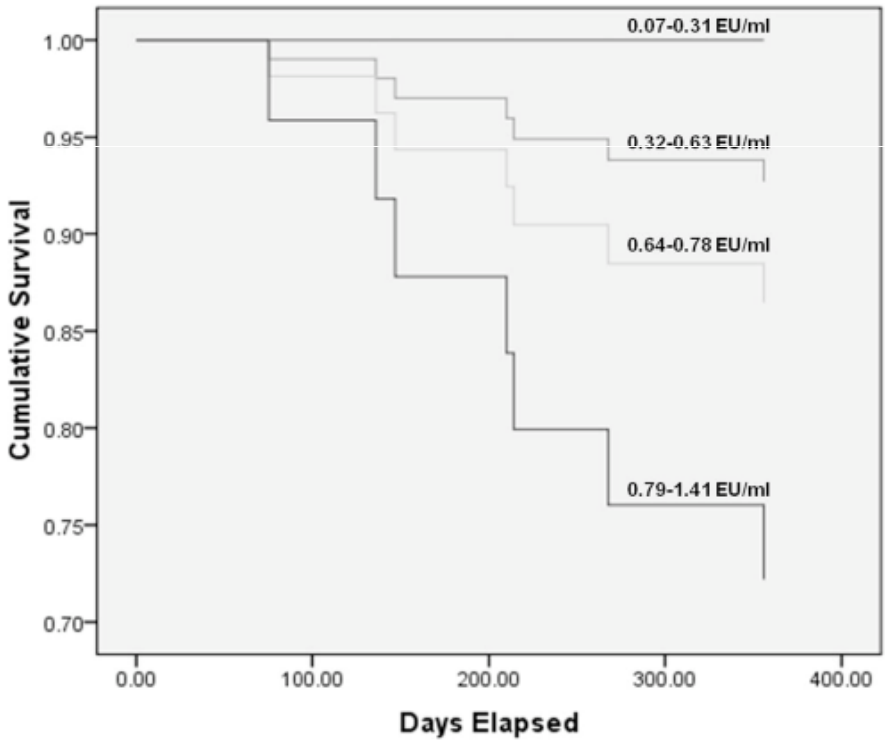


Clin J Am Soc Nephrol. 2010 Sep 28.

Biomarkers of risk

- Accurate / Reproducible
- Acceptable to the patient
- Easy to interpret
- Associated with outcome
- Explain independently a reasonable portion of the outcome
- Multiple studies
- Knowledge of the marker changes management

Targeting the Hepcidin-Ferroportin Axis in the Diagnosis and Treatment of Anemias

Condition	Expected hepcidin levels	Other iron parameters	Hepcidin therapy
Iron deficiency anemia	Low	Low Tsat and ferritin	
Iron-refractory iron deficiency anemia	High	Low Tsat and ferritin	Antagonist
Iron-loading anemias	Low (unless transfused)	High Tsat and ferritin	Agonist
Anemia of inflammation	High	Low Tsat, normal-to-elevated ferritin	Antagonist
Mixed anemia (AI/IDA)	Normal	Low Tsat, low-to-normal ferritin	Antagonist
Chronic kidney disease	High	Variable	Antagonist
Erythropoietin resistance	High	Variable	Antagonist

Advances in Hematology
Volume 2010, Article ID 750643,

AJKD American Journal of Kidney Diseases VOL 48, NO 3, SEPTEMBER 2006

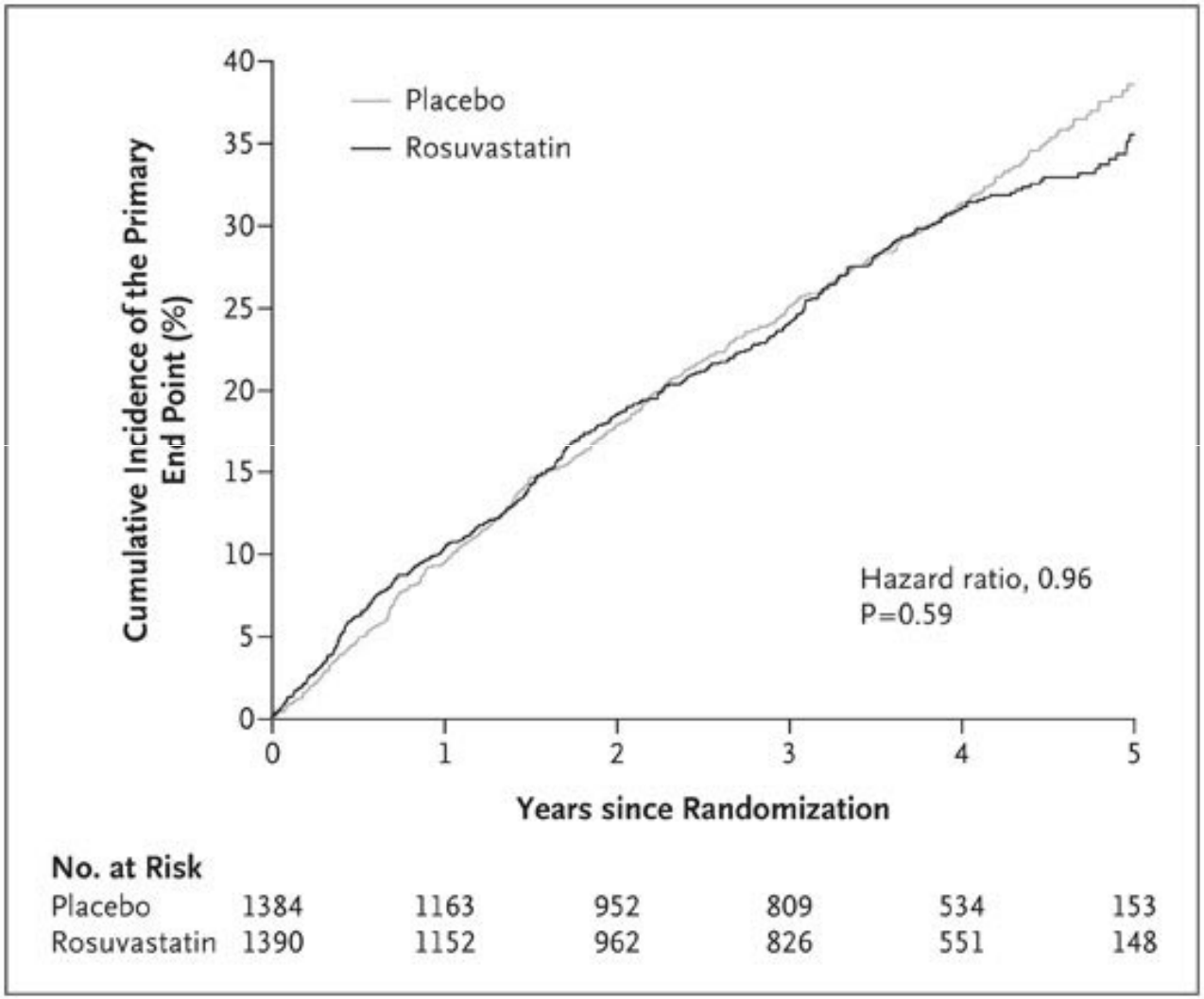
Cardiovascular Biomarkers in CKD: Pathophysiology and Implications for Clinical Management of Cardiac Disease

Matthew A. Roberts, MD, FRACP, David L. Hare, MD, FRACP, Sujiva Ratnaike, MD, FRCPA, and Francesco L. Ierino, MD, PhD

Cardiovascular Biomarker	Potential Therapy
ADMA	L-Arginine[22]
Homocysteine	Folic acid,[35,36] vitamin B_6, vitamin B_{12} supplementation
AHSG	Stricter calcium and phosphate target levels Calcimimetic agents, novel phosphate binders Diet or dialysis regimen (nocturnal dialysis)
CRP (IL-6)	Aspirin Statins[80,246] Renin-angiotensin system inhibition[81]
Oxidative stress markers	Vitamin E[119] *N*-Acetylcysteine[120]
Neuropeptide Y	β-Blocker therapy
AGEs	Dietary modification[135] Cross-link breakers (ALT-711) Benfotiamine Renin-angiotensin system inhibition*[137]
sCD40L	Antiplatelet therapy (GPIIb/IIIa inhibitors) Clopidogrel
BNP-32/NT-proBNP$_{1-76}$	Renin-angiotensin system inhibition Carvedilol[247] Revision of dry weight
cTnI, cTnT	Invasive investigation and treatment for coronary lesion

AURORA

The NEW ENGLAND JOURNAL of MEDICINE



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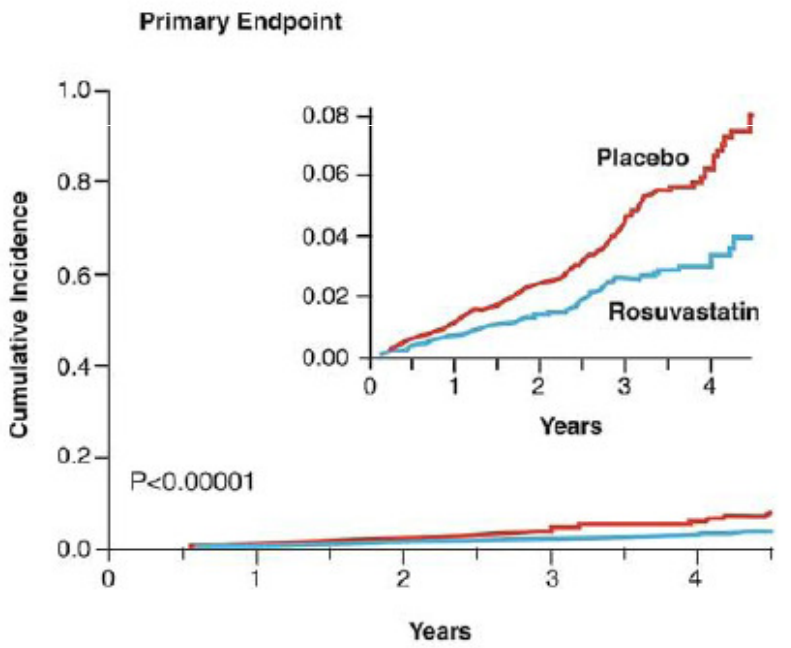
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 20, 2008 VOL. 359 NO. 21

Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein

Paul M Ridker, M.D., Eleanor Danielson, M.I.A., Francisco A.H. Fonseca, M.D., Jacques Genest, M.D., Antonio M. Gotto, Jr., M.D., John J.P. Kastelein, M.D., Wolfgang Koenig, M.D., Peter Libby, M.D., Alberto J. Lorenzatti, M.D., Jean G. MacFadyen, B.A., Børge G. Nordestgaard, M.D., James Shepherd, M.D., James T. Willerson, M.D., and Robert J. Glynn, Sc.D., for the JUPITER Study Group*

A



No. at Risk

Rosuvastatin	8901	8631	8412	6540	3893	1958	1353	983	538	157
Placebo	8901	8621	8353	6508	3872	1963	1333	955	531	174

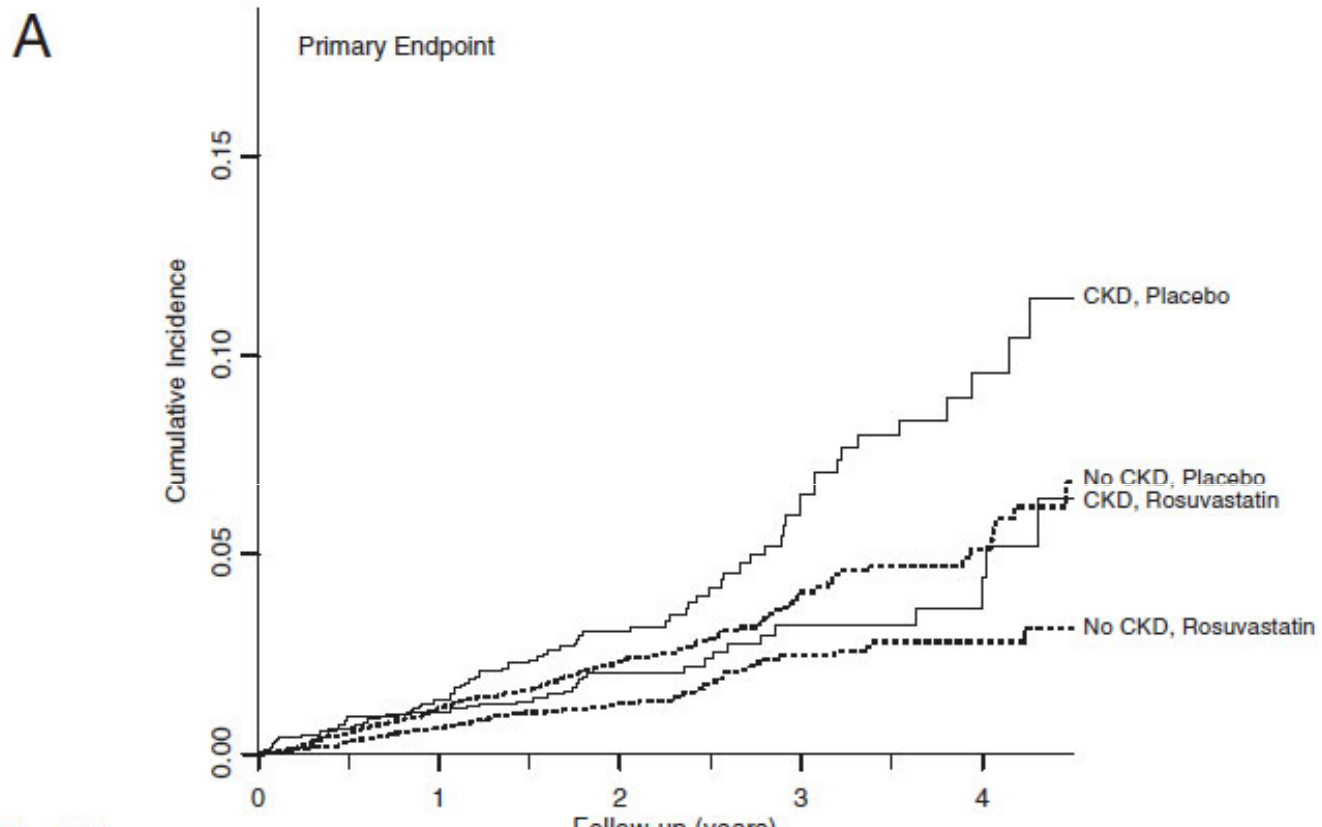
JACC
JOURNAL of the AMERICAN COLLEGE of CARDIOLOGY

Efficacy of Rosuvastatin Among Men and Women With Moderate Chronic Kidney Disease and Elevated High-Sensitivity C-Reactive Protein

A Secondary Analysis from the JUPITER (Justification for the Use of Statins in Prevention–an Intervention Trial Evaluating Rosuvastatin) Trial

Paul M Ridker, MD, MPH,*† Jean MacFadyen, BS,* Michael Cressman, DO,‡ Robert J. Glynn, ScD*

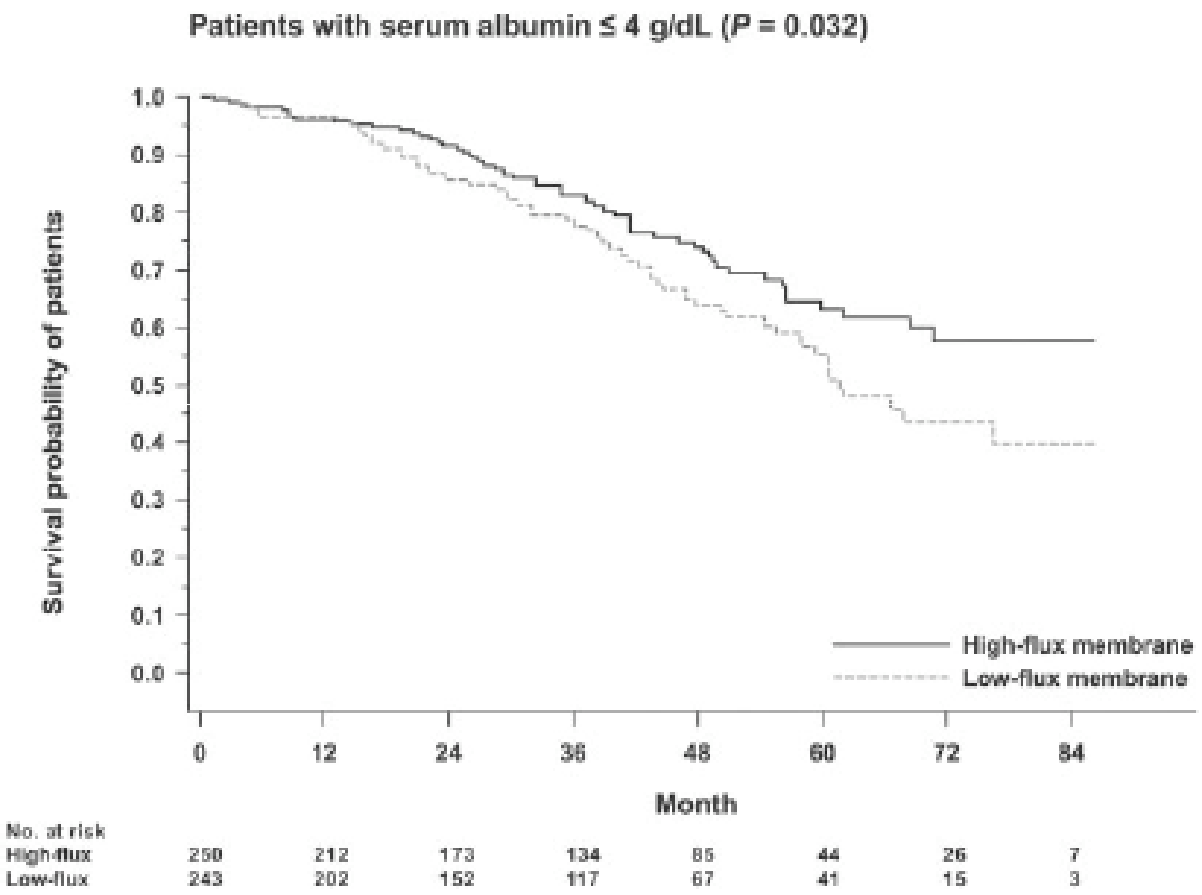
Figure 1 **Cumulative Incidence of Cardiovascular Events in the JUPITER Trial Among Those With and Without Moderate CKD, According to Rosuvastatin or Placebo Assignment**



No. at Risk

CKD	Rosuvastatin	1,638	1,574	1,538	1,281	871	550	352	247	129	39
	Placebo	1,629	1,557	1,510	1,234	838	516	345	243	131	40
No CKD	Rosuvastatin	7,259	7,054	6,871	5,256	3,020	1,407	1,000	736	409	118
	Placebo	7,269	7,061	6,840	5,272	3,033	1,447	988	712	400	134

MPO study



J Am Soc Nephrol 20: 645–654, 2009

Original Report: Laboratory Investigation

American Journal of Nephrology

Am J Nephrol 634
DOI: 10.1159/000XXXXXX

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Accepted: February 4, 2008
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Endotoxin-Binding Affinity of Sevelamer Hydrochloride

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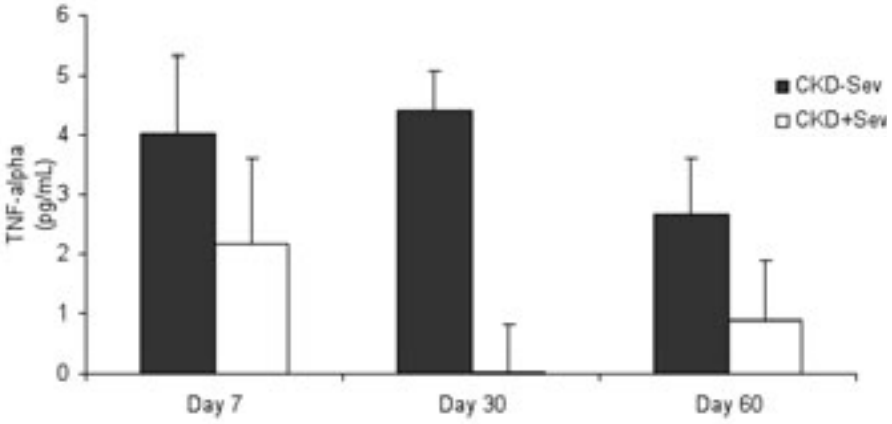
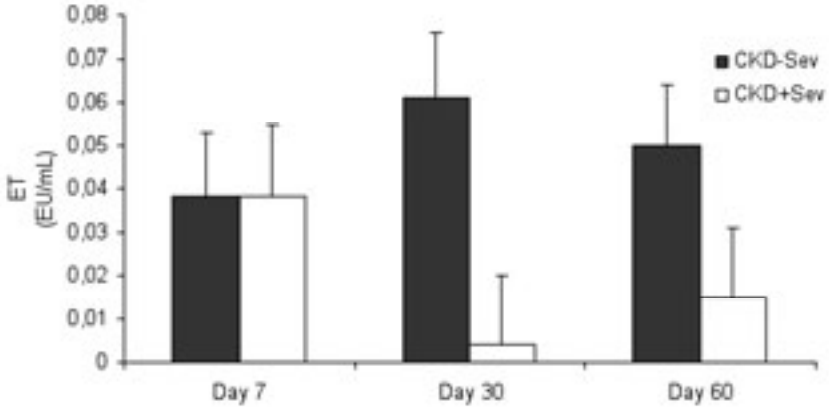
Department of Medicine, Division of Nephrology, Kidney and Dialysis Research Laboratory, Caritas St. Elizabeth's Medical Center, Boston, Mass., USA

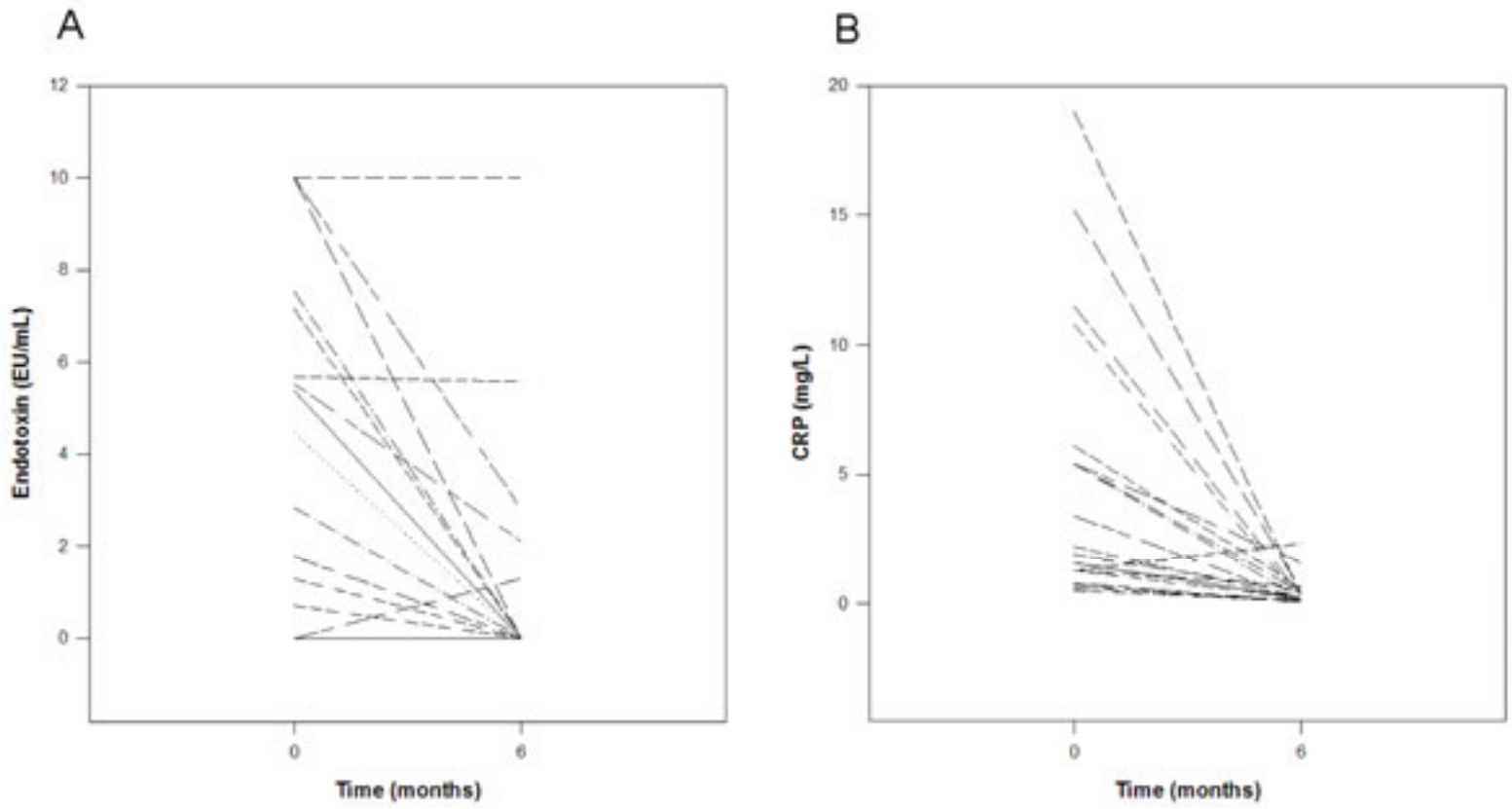
Sevelamer induces a decrease in inflammation and endotoxemia: experimental study





Hauser et al. Blood Purification 2010

Sevelamer induces a decrease in inflammation and endotoxemia: clinical study



Stinghen et al. Blood Purification 2010

In summary

- There is a clear need for identifying novel markers of CV risk in CKD;
- Based observational studies define mineral metabolism disorders, anemia and inflammation as main areas of opportunity;
- New biomarkers should be increasingly utilized in clinical trials to increase understanding of mechanisms, defining sample size, endpoints, and defining patients who most likely will benefit from a particular intervention.