

Improving the Care of Patients with CKD: Registries and Beyond

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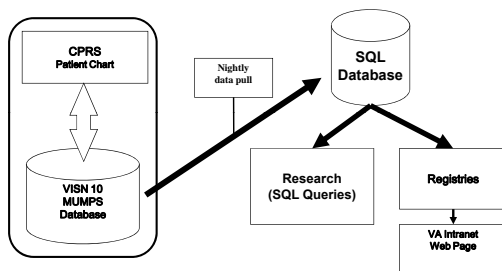
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Outline

- Cleveland VA Database
- Chronic kidney disease (CKD)
 - National Kidney Foundation guidelines
 - Adherence
- Pilot study – preliminary results
- Proposal for study

Cleveland VA Database



Database contents

- Demographic
- Vital signs
- Laboratory
- Medications
- Notes
- ICD-9 codes
- Radiology procedures
- Chronic Disease Registries
 - CKD
 - Diabetes
 - Coronary artery disease
 - Heart failure
 - Hepatitis C

Database contents – scope

- Vital signs (BP, pulse, temp, weight, respiratory rate)
 - 325,822 patients have had at least one BP measured
 - 10,686,607 BPs (6,984,823 clinic, 3,683,062 ward)
- Laboratory – Date, type, result
 - 230,895 patients with at least one lab in the last 5 years
 - Creatinine – 1,488,044
 - Hemoglobin – 1,254,356
- CKD Registry
 - 17,108 patients with CKD (GFR <60)
 - 6,540 GFR <45
 - 587 GFR <15
- Diabetes registry – 53,663 patients

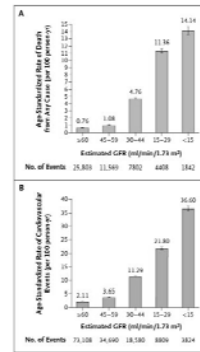
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Chronic kidney disease (CKD)

- Decrease in function of kidneys
 - Kidney functions
 - Filter toxins
 - Maintain balance
 - Make hormones
- Affects up to 26 million people in the US

Age-Standardized Rates of Death from Any Cause and Cardiovascular Events According to the Estimated GFR among 1,120,295 Ambulatory Adults



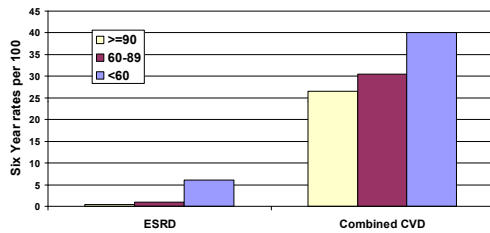
All-cause mortality

Cardiovascular events
 - Hospitalization for coronary heart disease
 - Heart failure
 - Ischemic stroke
 - Peripheral arterial disease.

Go et al, NEJM 2006



CKD Morbidity and Mortality



Combined CVD – death from CHD, nonfatal MI, stroke, coronary revascularization, angina, heart failure, peripheral arterial disease

Rahman et al, Ann Int Med 2006

Guidelines

- National Kidney Foundation Kidney Disease Outcomes and Quality Initiative (KDOQI)
 - Published in 2002
 - Define CKD
 - Who to screen
 - How to evaluate
 - Monitor for complications
 - Treatments – BP, metabolic complications

KDOQI Guidelines

- Definition of CKD
 - $GFR < 60 \text{ mL/min/1.73 m}^2$ for > 3 months
 - Or kidney damage (hematuria, proteinuria, abnormalities on imaging)
- Stages
 - I – $GFR \geq 90$
 - II – $GFR 60-89$
 - III – $GFR 30-59$
 - IIIa – $GFR 45-59$
 - IIIb – $GFR 30-44$
 - IV – $GFR 15-29$
 - V – $GFR < 15$ or on renal replacement therapy

KDOQI Guidelines

- CKD patients
 - Monitor for complications
 - Anemia
 - Disorders of Ca and phosphorus
 - Metabolic acidosis
 - Hyperkalemia

Complications

- Anemia – hemoglobin yearly
- Ca, Phos, PTH
 - Stage III – Ca, phos, PTH yearly
 - Stage IV and V – Ca, phos, PTH every 3 months
- Metabolic acidosis
 - Stage III – serum bicarb yearly
 - Stage IV and V – serum bicarb every 3 months
- Hyperkalemia
 - No specific recommendations

KDOQI – Treatment

- Anemia
 - Epo for hemoglobin < 10mg/dL (goal 11-12mg/dL)
 - Iron for patients with iron deficiency
- Ca/phos/PTH
 - Phosphate binders
 - Replete Vitamin D
- Metabolic acidosis
 - NaHCO₃
- Hyperkalemia
 - Low K diet
 - Kayexalate

KDOQI – Treatment

- Hypertension
 - Goal blood pressure < 130/80
 - Treatment
 - Low salt diet (<2.4 g/day, < 100 mmol/day)
 - Diuretics
 - ACE-I/ARB in patients with proteinuria or diabetes

KDOQI – Preparation for RRT

- Patients with eGFR < 30
 - Refer to nephrology
 - Preparation for kidney replacement therapy
 - Transplant
 - Peritoneal dialysis
 - Hemodialysis
 - Fistula placed 6 months prior to initiating dialysis

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KDOQI – Low adherence

- Health insurance data
 - 1933 patients with eGFR ≤ 30
 - Percent receiving recommended testing by referral status

Lab	No referral (N = 802)	Seen by nephrologist (N = 1131)
Ca and Phos (q3mo)	28.0	52.1
PTH (at least once)	6.5	67.0
Hemoglobin (q3mo)	41.1	59.1
Workup of anemia	63.1	83.9
Tx for Fe deficiency	45.2	51.7

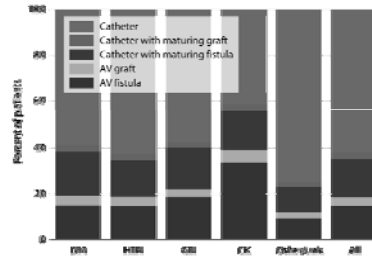
Patwardhan et al, Clin J Am Soc Nephrol, 2007

Blood pressure control

- Chronic Renal Insufficiency Cohort
 - 86% prevalent hypertension
 - 99% of patients were aware
 - 98% of patients were treated
 - 67% BP < 140/90
 - 46% BP < 130/80
- Rates of BP awareness and control significantly higher in CRIC than Framingham, NHANES, and KEEP

Muntner, AJKD, 2010

Access use at first outpatient dialysis, 2007



http://www.usrds.org/2009/pdf/V2_03_09.PDF

Causes of low adherence

- Physicians
- Patients
- Health care systems
- Society



Summary

- CKD is prevalent and associated with increased morbidity and mortality
- Guidelines exist for care of patients with CKD
- Guideline adherence is low
- Attempts to increase adherence will likely need to be multifactorial

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Objectives

- Evaluate the impact of a multifactorial clinical intervention on CKD guideline adherence among VA primary care providers

Cleveland VA

- Cleveland Wade Park VAMC
 - Firm system (A and B)
 - Patients
 - Providers
 - Physicians/Nurse practitioners
 - Residents

Study groups

Provider type (Firm)	Education	CKD Reference Card	Academic detailing	CKD Registry
Residents (A)	X	X		
MD/NPs (A)	X	X		
Residents (B)	X	X	X	X
MD/NPs (B)	X	X		X

Subjects

- Patients
 - Inclusion
 - CKD
 - Primary care visit in last 18 months
 - Exclusion
 - Dialysis or kidney transplant
- Providers
 - All residents, MDs, NPs providing primary care at the Wade Park VAMC

Outcomes

- Primary process outcome
 - PTH adherence score (0 to 100)
 - Percent of recommended PTH evaluations in the past 12 months
 - Stage 3 – recommended every 12 months
 - Stage 4 and 5 – recommended every 3 months
- Primary clinical outcome
 - Percent of patients at goal BP (< 130/80)

CKD reference card

CKD Reference Card

CKD Reference Card

Diagnosis of CKD – Laboratory diagnosis (creatinine, hemoglobin, hemoglobin A1c) – primary care visit in last 18 months

Who should be screened for CKD? Patients with the following conditions should be screened by their primary care provider:

- Diabetes
- Diabetes with albuminuria
- Diabetes with hypertension
- Age greater than 75 years

CKD Stages – (based on creatinine) $\text{GFR} < 15 = \text{stage 5}$; $15-29 = \text{stage 4}$; $30-59 = \text{stage 3}$; $60-89 = \text{stage 2}$; $90-120 = \text{stage 1}$

Stage	Estimated GFR (ml/min/1.73m ²)
1	90-120
2	60-89
3	30-59
4	15-29
5	< 15

Goals of Treatment

1. Stop progression of disease
 - a. ACE inhibitors or ARBs
 - b. SGLT2 inhibitors
 - c. DPP-4 inhibitors
 - d. SGLT2 inhibitors
 - e. SGLT2 inhibitors
2. Control blood pressure
 - a. ACE inhibitors or ARBs
 - b. SGLT2 inhibitors
 - c. SGLT2 inhibitors
3. Control diabetes
 - a. ACE inhibitors or ARBs
 - b. SGLT2 inhibitors
 - c. SGLT2 inhibitors

CKD Reference Card

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 - b. SGLT2 inhibitors
 - c. SGLT2 inhibitors

CKD Registry

VISN 10 CKD PATIENT LIST TARGET SELECTION

Select a Target Group and then Individual Target(s)

Firm Provider

Assigned PC Team

Select Targets:

Stage 1: Yes No Stage 4: Yes No Transplant: Yes No

Stage 2: Yes No Stage 5: Yes No Dialysis: Yes No

Stage 3: Yes No

Blood Pressure: Last Systolic > [130] or Diastolic > [80]

Most Recent PTH > [70] or Missing For More Than [3] Months

Most Recent Phosphorous > [4.5] or Missing For More Than [3] Months

Most Recent Hgb < [10] or Missing For More Than [1] Years

All Filter by Age

Search

Registry – Results

VISN
Primary Care
Target Group
Total Patient:

Patient Specific Data for [REDACTED]

Demographic Data

Gender: MALE
Blood Cholesterol Group: CHOLESTEROL
Address: [REDACTED]
Home Phone: [REDACTED]
PC Team: (P) [REDACTED]
PC Provider: [REDACTED]

Most Recent Lab Results

GFR	K	HC03	Ca	Phos	PTH	Hgb	TIBC/Val	Ferritin	Urea	LDL
33.4(95)	5.0	22.0	8.4	5.0	7	5.3	21	180	67.0	60

Most Recent Vital Data

BP: 105/51 (7/10/2009)
Height: 71
Weight: 203.3
Date: 01/03/09

Miscellaneous

On Ace Inhibitor/Arb: No
ACE Inhibitor Allergic: Yes
Other Anticoagulant: No
Status: FC: 08/1/0
Last Fibroid: 08/01/08
Pneumococ: 7/12
Tuberculin: 7/02

Next Scheduled Appointments

Next Home Appt: [REDACTED]
Next Home Location: [REDACTED]
Next Nurse Clinic Stop: [REDACTED]
ACA Pending: [REDACTED]
Next Appt: 10/05/09
Next Appt Location: (P) [REDACTED]

Most Recent Appointments

Last Outpatient Visit: [REDACTED]
Date: 10/14/08
Location: SE - IV
CARE/AC/EMERG/SC/ [REDACTED]
Last Primary Care Visit: [REDACTED]
Date: 05/07/09
Location: 241

Patient resources

How well are your kidneys working?

These kidney tests are used to measure your GFR (glomerular filtration rate).

1. A GFR of 60 or higher is the normal range.

2. A GFR below 60 may mean kidney disease.

3. A GFR of 15 or lower may mean kidney failure.

Your GFR should be checked again in _____.

How to keep your kidneys healthy

No matter what your GFR result is:

- Keep your blood pressure below 130/80 mmHg.
- Keep your blood glucose and blood cholesterol at your target range.
- Eat healthy and cut back on salt.
- Stop smoking.
- Talk to your doctor about your possible risks.

What your kidneys do

You have two kidneys. They remove extra fluid, waste and extra salts out of your blood and make urine.

Why your kidneys are being checked

A blood test helps us measure your glomerular filtration rate or GFR. This tells how well your kidneys are filtering. Your health care provider should also do a urine test to check for kidney disease.

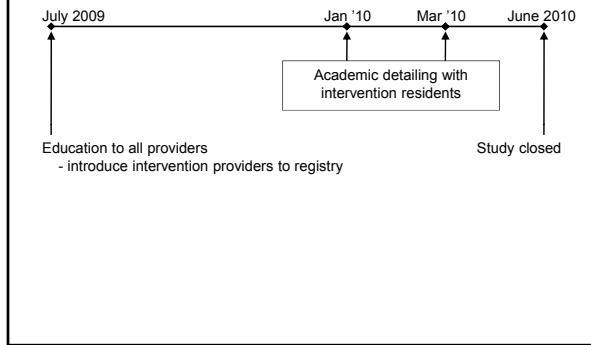
Why your kidneys are being checked

You need to take steps to slow down kidney disease before a lot of damage is done. If your kidneys feel better and better, you may see your doctor. Work with your provider on the best treatment plan for you.

You can plan for later, you can take care for today, your kidneys healthy.

The most information, visit www.nidk.nih.gov or call 1-800-458-5231. The National Kidney Disease Education Program is an initiative of the National Institutes of Health. NIDDK Publication #10-0207-10a-2009

Study timeline



Baseline characteristics

Variable	Control N = 458	Intervention N = 480	P value
Age, years	71.4 (10.3)	71.4 (10.9)	0.99
Gender, male	445 (97.2)	464 (96.7)	0.66
Race			0.59
Black	204 (44.5)	198 (41.2)	
White	163 (35.6)	187 (39.0)	
Other/unknown	91 (19.9)	95 (19.8)	
GFR	45.1 (11.2)	44.1 (12.6)	0.17
Stage of CKD			0.12
III	408 (89.1)	406 (84.6)	
IV	41 (9.0)	59 (12.3)	
V	9 (2.0)	15 (3.1)	

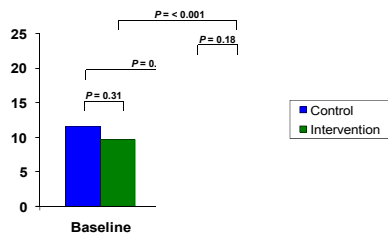
Baseline characteristics (cont)

Variable	Control N = 458	Intervention N = 480	P value
PTH Adherence	11.5 (30)	9.6 (26)	0.31
≥ 1 PTH in last year (%)	14.8	14.8	0.98
Systolic BP, mmHg	132.3 (20.3)	132.3 (20.4)	0.99
Diastolic BP, mmHg	71.4 (12.3)	70.3 (13.1)	0.16
BP < 130/80	49.7	49.4	0.93

Preliminary results

Variable	Control N = 461	Intervention N = 458	P value
PTH Adherence score	17.6 (36)	20.9 (38)	0.18
≥ 1 PTH in last year	21.7	26.2	0.11
Systolic BP, mmHg	132.4 (18.9)	132.8 (18.2)	0.76
BP < 130/80	42.1	42.4	0.92

Preliminary Results PTH Adherence score



Secular trend?

Variable	Baseline	12 months	P value
PTH Adherence score (mean (SD))			
Intervention	9.6 (26)	20.9 (38)	< 0.001
Control	11.5 (30)	17.6 (36)	0.006
Other CBOCs	3.4 (17)	4.3 (19)	0.001
≥ 1 PTH in last year (%)			
Intervention	14.8	26.2	< 0.001
Control	14.8	21.7	0.007
Other CBOCs	4.7	5.7	0.002

Registry Use

- Resident A – 2 occasions
- Resident B – 1 occasion
- Attending X – 5 occasions
- Attending Y – 1 occasion
- Attending Z – 1 occasion

Conclusions

- CKD guideline adherence is poor
- Multifactorial intervention may improve guideline adherence
- However – provision of a CKD registry does not appear to affect guideline adherence

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Next Pilot Study

- System level intervention
- Incorporate aspects of the Chronic Care Model
- Pharmacist/NP collaboration with PCPs
 - Identify CKD patients not achieving guideline recommended care
 - Protocol for contacting patients
 - Discuss CKD
 - Assess knowledge, medication adherence, lifestyle
 - Order labs
 - PRN: nutrition for low Na diet, medication changes, etc
 - Communicate with PCPs via notes in CPRS

Chronic Care Model

- Guide to improving the quality of care for patients with chronic diseases
- Six elements
 - The community
 - The health care organization, specifically support from key leaders
 - Delivery system design and coordination of care
 - Decision support such as guidelines and education
 - Self-management support in the form of education and resources for patients
 - Clinical information systems such as disease registries and performance data

Wagner et al, Health Aff, 2001

Pharmacists and Co-management of Hypertension

- Providence Primary Care Research Network
 - Non-academic clinics
 - Pharmacists
 - Reviewed medications and lifestyle habits
 - Identified barriers to adherence
 - Provided education
 - Optimized the antihypertensive regimen
 - Patients – last BP \geq 160/100 mmHg

Hunt et al, JGIM, 2008

Pharmacists and Co-management of Hypertension – Oregon

- Providence outcomes after 12 months
 - 233 usual care and 230 intervention subjects

Outcome	Usual Care N = 233	Intervention N = 230	P value
Systolic BP	143 (18)	137 (17)	0.007
Diastolic BP	78 (11)	75 (9)	0.003
BP < 140/90	44%	62%	0.003

Hunt et al, JGIM, 2008

Next study

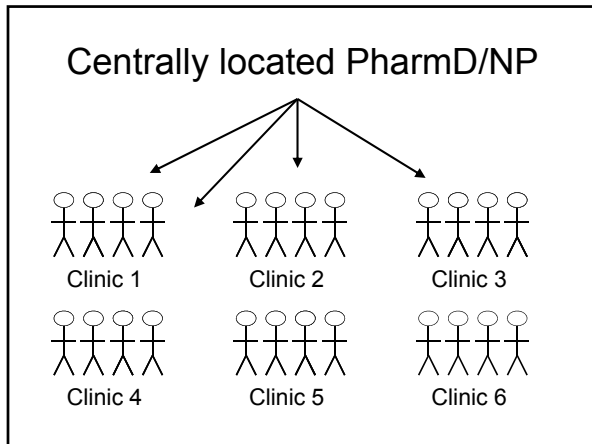


Next study

- Centrally located pharmacist/NP
 - Access to registry
 - Call patients
 - Discuss CKD
 - Assess knowledge and medication adherence
 - Order appropriate tests
 - Follow-up on results
 - Arrange follow-up prn
 - Nutrition for low Na diet
 - Nephrology for advanced CKD
 - Adjust/add medications as needed

Hypothesis

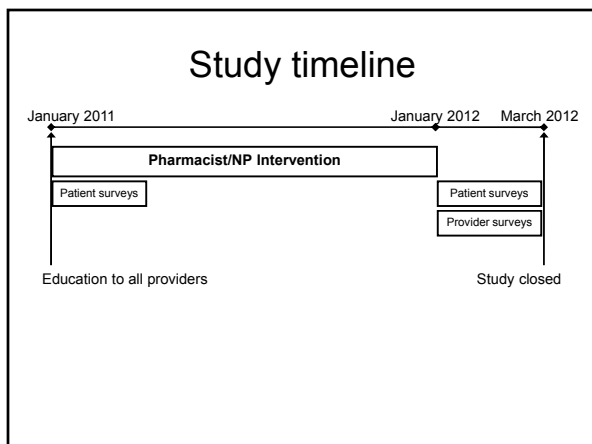
- Implementing a chronic care model based CKD intervention including system level support in the form of collaborative care management, a CKD registry, and provider education will:
 - Reduce systolic BP in patients with poorly controlled hypertension
 - Increase the percentage of patients appropriately monitored for metabolic complications
 - Decrease the rate of catheter use in patients initiating dialysis



- ### Eligibility
- Patients
 - Inclusion
 - CKD (eGFR <45)
 - Primary care from CBOC
 - PCP visit in the last 18 months
 - Exclusion
 - Dialysis or renal transplant
 - Providers
 - All CBOC primary care providers

- ### Outcomes
- Primary process outcome
 - PTH adherence
 - Primary clinical outcome
 - Average BP in subjects with baseline BP greater than 130/80
 - Preliminary data
 - Death rate
 - Rate of medication use (phos binders, iron, epo)
 - Rate of progression to ESRD (access placement)

- ### Surveys
- Patients
 - Pre and post
 - Assess
 - CKD and hypertension awareness
 - Medication adherence
 - Reaction to intervention
 - Physicians
 - Assess
 - Reaction to intervention
 - Openness to similar interventions for other guideline recommended care (e.g., cancer screening)



Projected sample size

CBOC	Stage 3b	Stage 4	Stage 5	Stage 3b-5
Akron	248	68	27	343
Brecksville	195	39	21	255
Canton	308	77	32	417
Lorain	148	30	26	204
Mansfield	147	36	10	193
Mc Cafferty	74	20	7	101
New Philadelphia	105	30	10	145
Painesville	171	49	12	232
Ravenna	76	10	4	90
Sandusky	93	25	7	125
Warren	99	28	12	139
Youngstown	291	61	28	380
Total	1955	473	196	2624

Potential subjects

- 2622 patients with GFR < 45
 - 1416 have diabetes
 - 2196 have hypertension
 - 1027 – last SBP > 130 mmHg
 - 487 – last SBP > 140 mmHg

Potential subjects

- 2545 patients with GFR 15 to 45

Lab	# checked in last year	# not at goal	# treated
PTH	319	153	102
Phosphorus	1249	114	30
Bicarbonate	2242	168	24

PTH goal < 110, tx = Vit D
Phos goal ≤ 4.6, tx = phos binder
Bicarb goal > 20, tx = bicarb

Power analysis

- Currently 2624 patients in NE Ohio with an eGFR <45
 - 1027 patients with last SBP >130
 - Difference in SBP detectable (mmHg) for different powers and sample sizes

Power	Sample Size (per group)			
	200	300	350	400
80%	4.2	3.4	3.2	3.0
90%	4.9	4.0	3.7	3.4

Chronic Care Model

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 - Clinical information systems such as disease registries and performance data

Wagner et al. Health Aff. 2001

Association of Oral Calcitriol with Improved Survival in Nondialyzed CKD

Abigail B. Shobeni,¹ Kyle D. Rudez,¹ Ian H. de Boer,² Bessie Young,³ and Bryan Kestenbaum⁴

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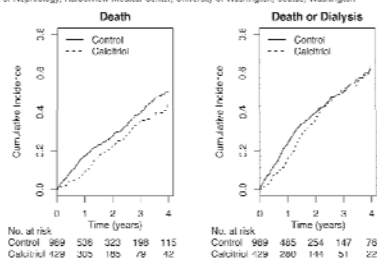
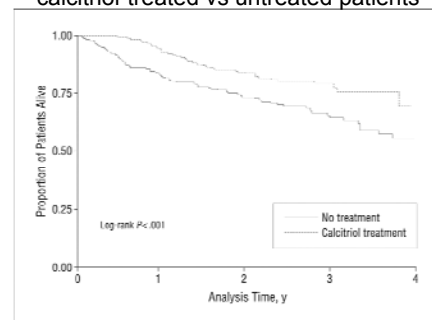


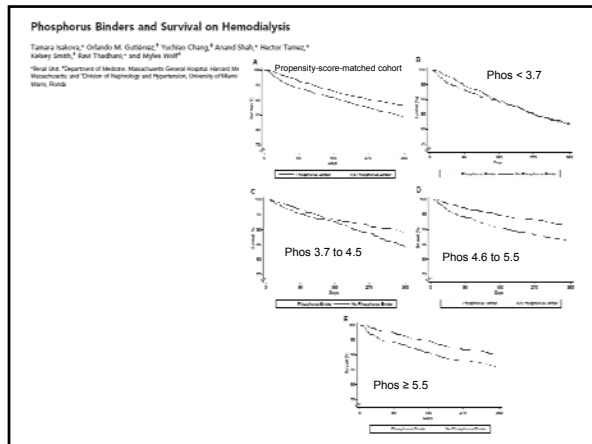
Figure 1. Cumulative incidence of mortality and mortality plus dialysis among the study cohort.

Kaplan-Meier curves for all-cause mortality, comparing calcitriol-treated vs untreated patients



Kovesdy, C. P. et al. Arch Intern Med 2008;168:397-403. (Calcitriol N = 255, no tx N = 252)

ARCHIVES OF
INTERNAL MEDICINE



Bicarb in hypertensive nephropathy

- GFR 60 to 90
- Albuminuria 200-2000mg/g Cr
- Non-malignant hypertension
- Tx for 5yrs – 0.5mEq/kg NaHCO₃

Target	Placebo (N = 40)	NaHCO ₃ (N = 40)	P value
eGFR	64.0 (6)	67.6 (5)	0.017
Ualb (mg/g Cr)	507.5 (228)	387.5 (163)	0.026
Systolic BP	133.3 (8)	135.1 (6)	-

Mahajan et al, KI, 2010

Bicarb in advanced CKD

- GFR 15 to 30
- Serum bicarb 16 to 20
- Tx for 2yrs – usual care vs NaHCO₃ 600mg TID titrated to bicarb ≥ 23

Target	Control (N = 67)	NaHCO ₃ (N = 67)	P value
CrCl decline	5.93	1.88	< 0.01
CrCl decline (>3)	45%	9%	< 0.001
ESRD	33%	6.5%	< 0.001

Cr Cl decline – ml/min/1.73m²/year

De Brito-Ashurst et al, KI, 2010