WHAT IS WRONG WITH CURRENT DIALYSIS

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The Dialysis Prescription

The detailed biochemical basis of the dialysis prescription remains obscure—other than for H^+, K^+ Na^+, H2O, Ca^{++} and PO_4 - despite 45 years of clinical experience with this therapy.

Urea Kinetic Modeling has been successfully used to define clinical outcome equivalent doses for low efficiency, virtually continuous peritoneal dialysis (CAPD) and high efficiency thrice weekly Hemodialysis (HEMO)

Daugirdas II

Kt/V = -lN (R – 0.008 x t) + (4-3.5 x R) x UF/BW

Approximation for Kt/V

Dose is based on urea kinetics because that is where the evidence is

DOSE OF AN INDIVIDUAL DIALYSIS

$$\frac{\text{Urea Clearance X time}}{\text{Urea distribution volume}} \qquad \frac{K*t}{V}$$

Three expressions of the dose:

URR = 70 Pre/Post BUN Rx trial and error
Not corrected for Qf and/or rate

spKt/V = 1.4 Not corrected for rate & rebound

eKt/V = 1.2 Corrected for rate & rebound

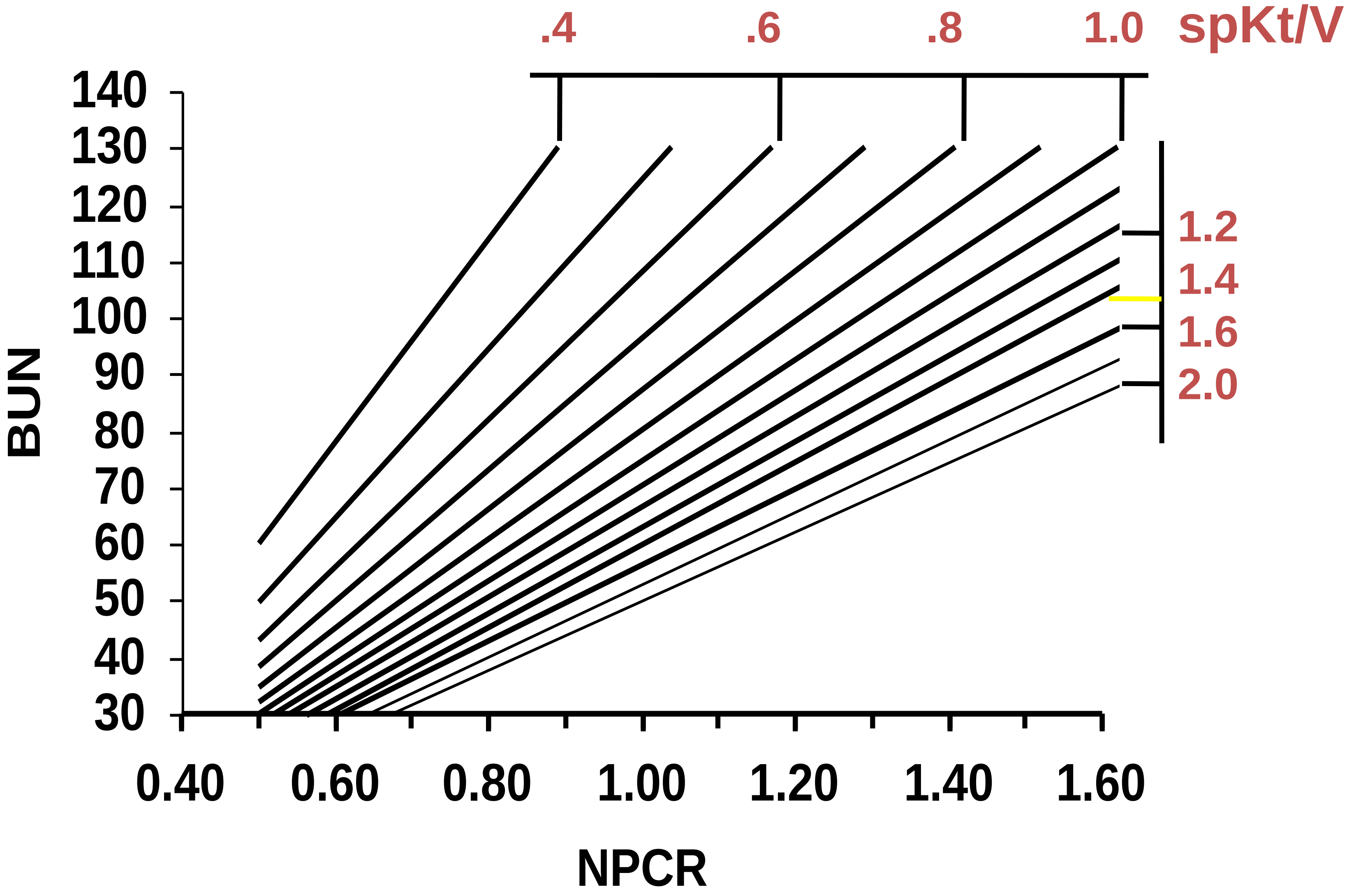
BAD DIALYSIS

- NOT reaching the correct Kt/V
- NOT reaching the appropriate protein intake

Why do some units have poor Kt/Vs

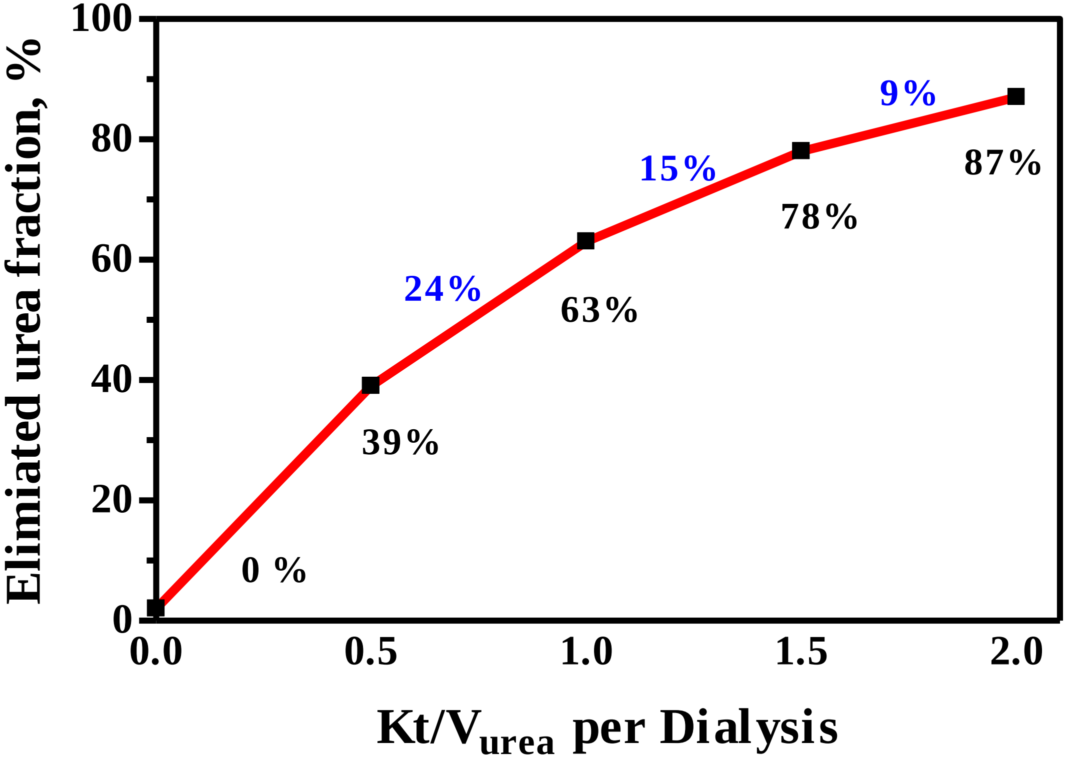
- Prescription incorrect for Body V
- Poor accesses are tolerated
  - Low K
- Patient end their treatment early
  - Low t

- Prescription not followed
  - blood flow not correct from initiation
  - t wrong
  - wrong dialyzer
  - wrong dialysate flow
  - access inadequate or recirculation
  - clotting of dialyzer
  - blood drawn incorrectly



Solution of the single pool urea kinetic model for pre dialysis mid week BUN as a function of NPCR and spKt/V shows a family of spKt/V curves relating BUN to NPCR.

Limits of Dialysis Efficiency



Efficiency of toxin elimination decreases exponentially when eKt/V of a single treatment is increased

Association Between Higher Dose and Relative Overall Risk of Mortality for Males and Females Among Three Studies

	Relative Risk of Mortality for Higher *vs.* Lower Dose[1]				Dose Effect by Gender[2]
	Female		Male		
	RR	p-value	RR	p-value	p-value
HEMO Study [3]	0.81		1.16		<0.01
DOPPS (per 0.37 eKt/V) [4]	0.80	<0.001	0.93	0.23	0.08
CMS (URR >75% *vs.* 70%-75%)	0.85	<0.0001	0.96	0.22	0.003

[1] P-values test whether high dose is associated with a reduction in mortality for each sex.

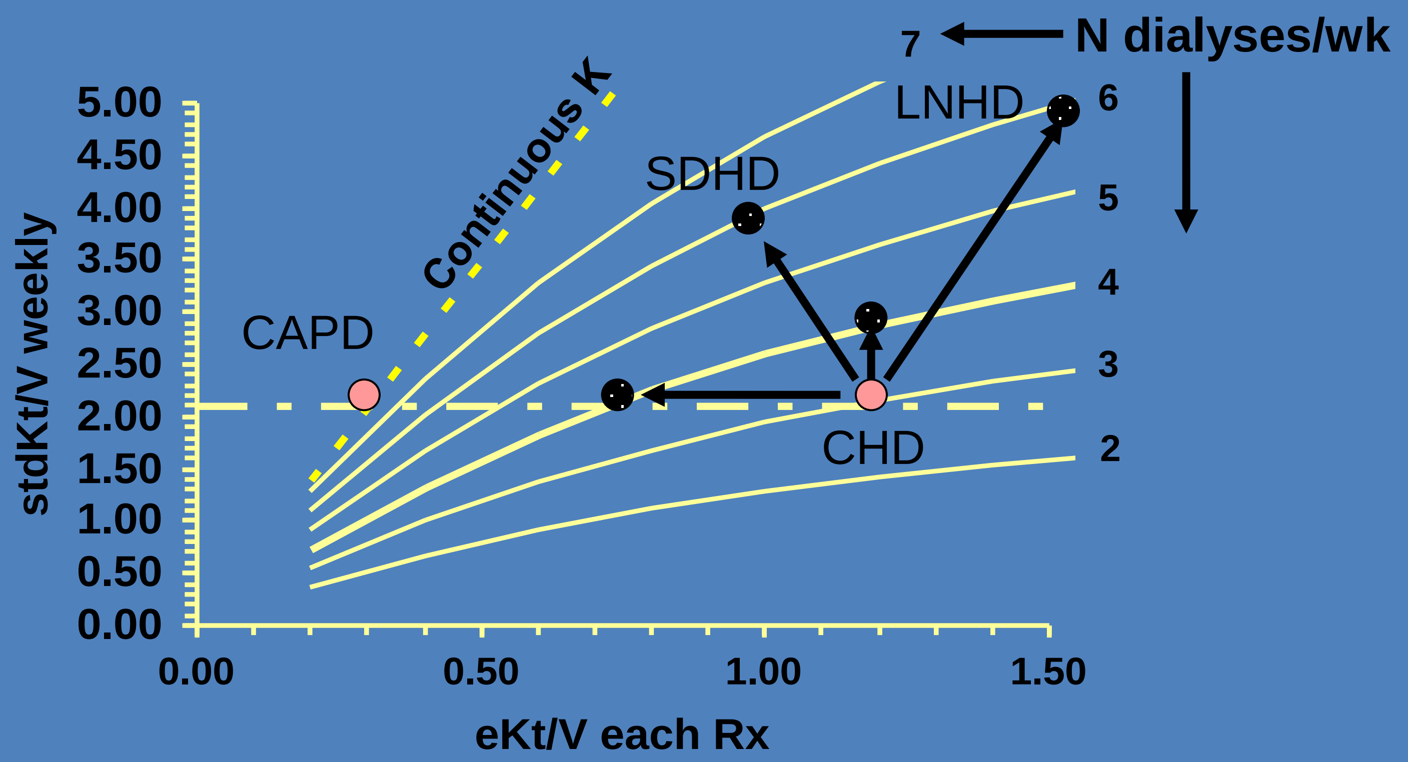
[2] Tests whether the RR for females equals the RR for males. A significant difference indicates that high dose is associated with a larger reduction in mortality for females than for males.

[3] Compares average eKt/V of 1.53 and 1.16, and average URR of 75.2% and 66.3% [1].

[4] Linear estimate of RR=0.94 per 0.1 eKt/V for females and RR=0.98 per 0.1 eKt/V for males applied to a difference of 0.37 eKt/V (equals average difference in HEMO Study groups).

DOPPS

Port FK et al. *AJKD* 43(6):1014-1023, 2004



The stdKt/V model provides a template to quantitatively describe dialysis treatment schedules over a wide ranges of intensity and frequency.

Bad Dialysis

- **Dialysis Times too short:**

This results in inability to remove intradialytic weight load causing hypertension, cardiac failure and increased hospitalization and mortality

High ultrafiltration rates result in intradialytic hypotension and cardiac, cerebral, gut and renal ischemia with loss of residual kidney function

Short times are selected ccurs because of need to control duration of shifts

INTRA DIALYTIC HYPOTENSION with organ ischemia

Bad Dialysis

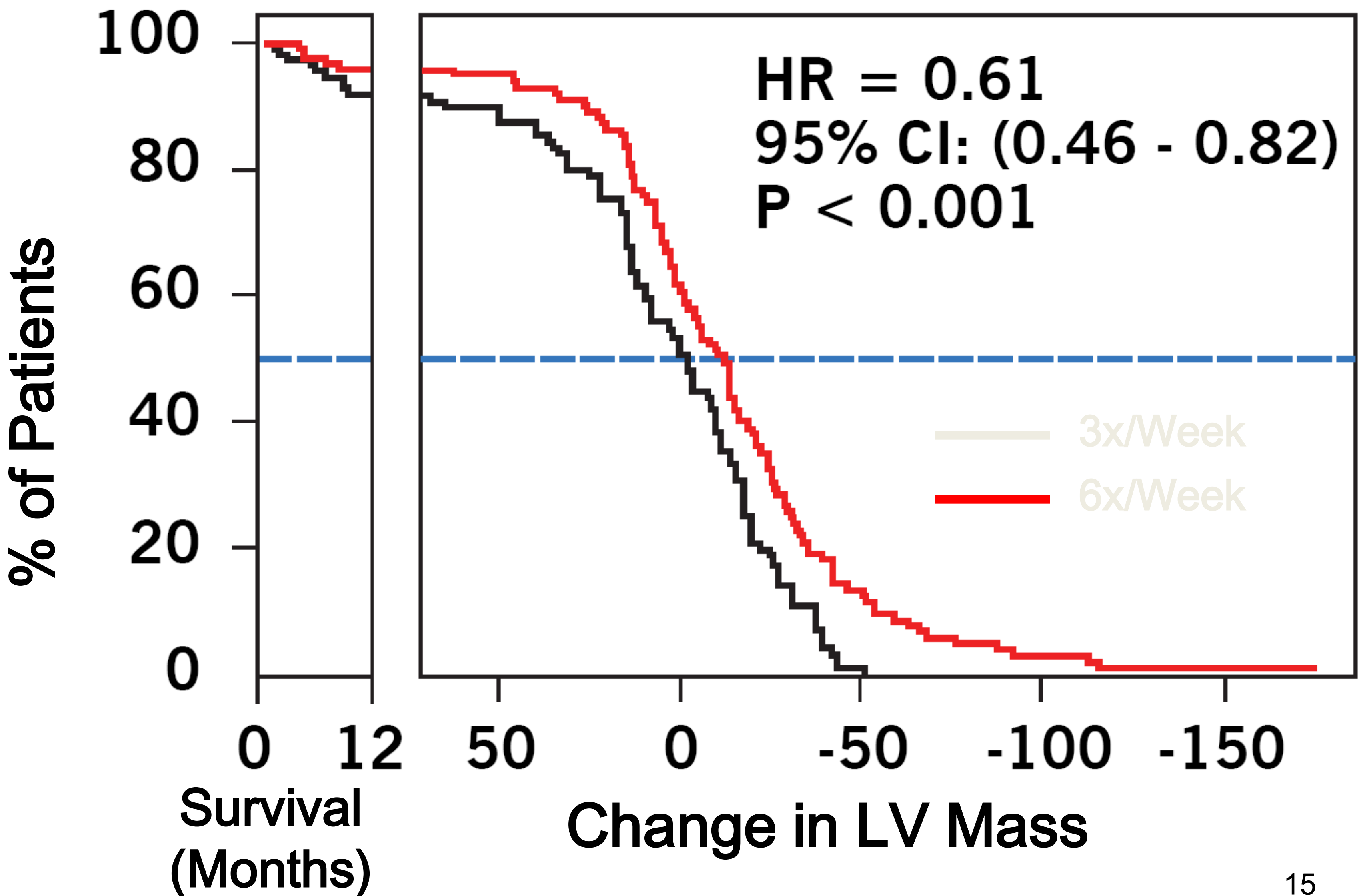
- **Dialysis not frequent enough**

Especially during the long interdialytic period, fluid accumulation and increased cardiac strain occur resulting in need for higher ultrafiltration rates

FHN showed improvement in left ventricular hypertrophy with daily dialysis

Death/LVM Composite Outcome

FHN Daily Trial



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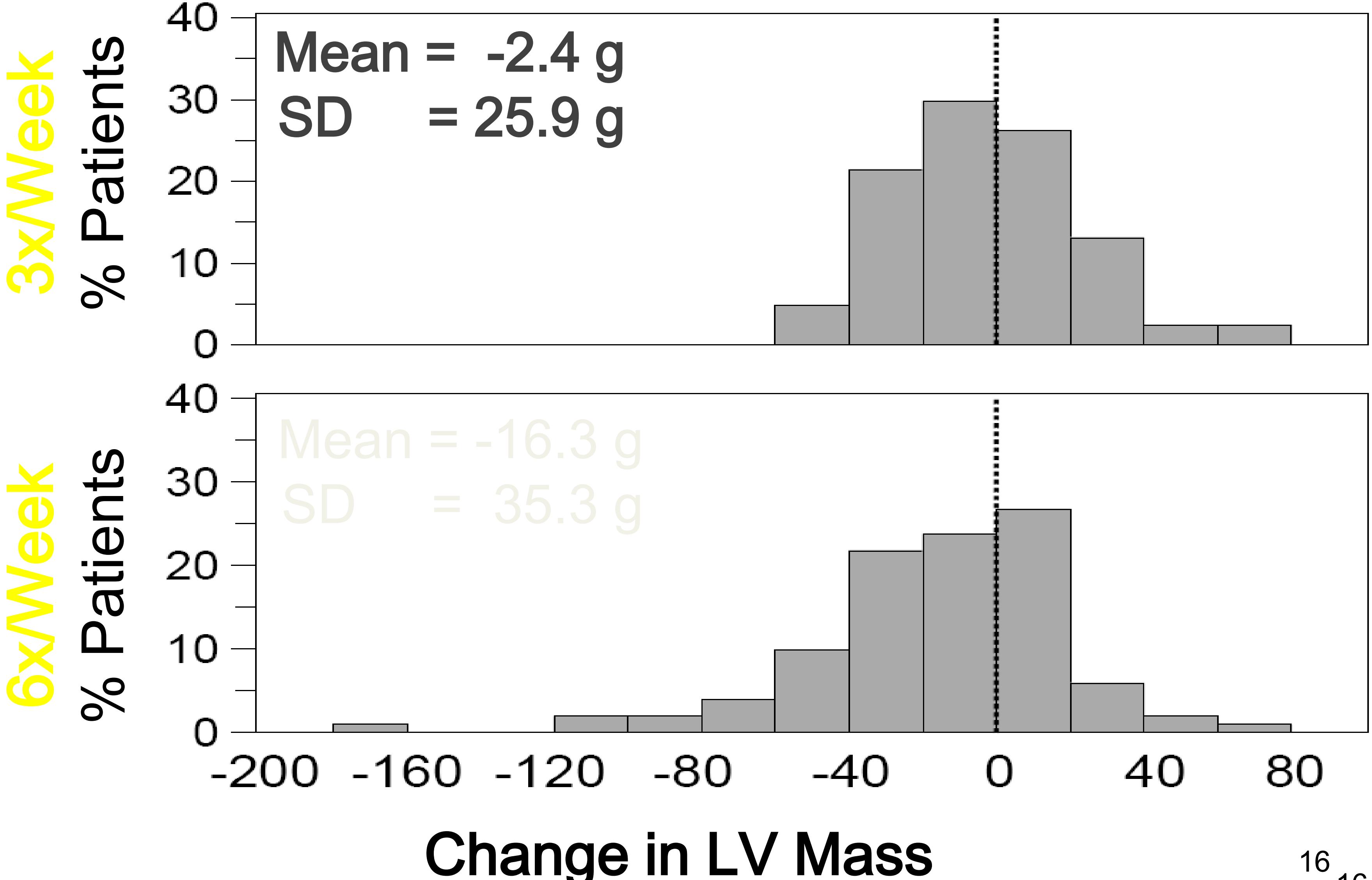
Change in LV Mass

FHN Daily Trial



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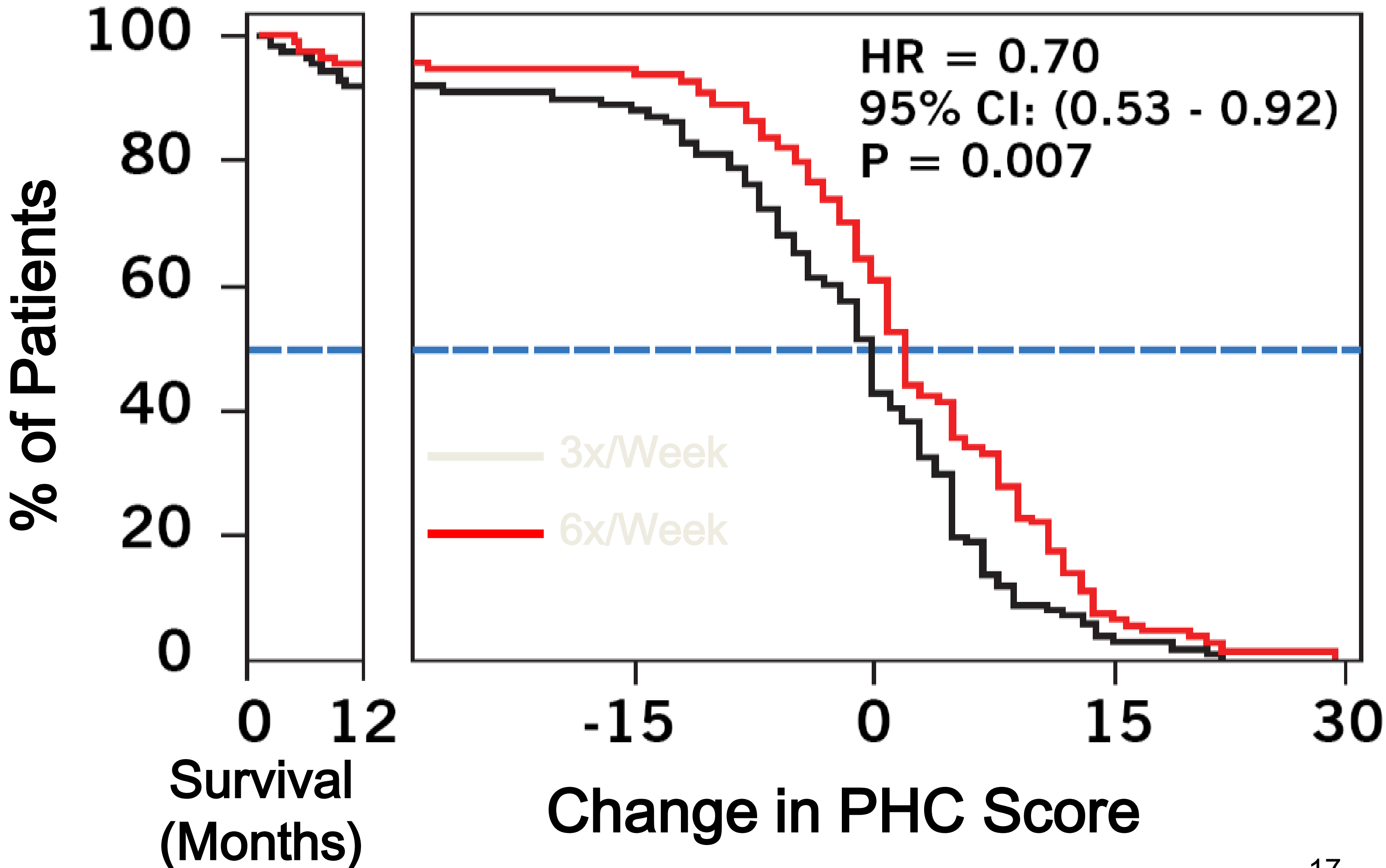
Death/PHC Composite Outcome

FHN Daily Trial



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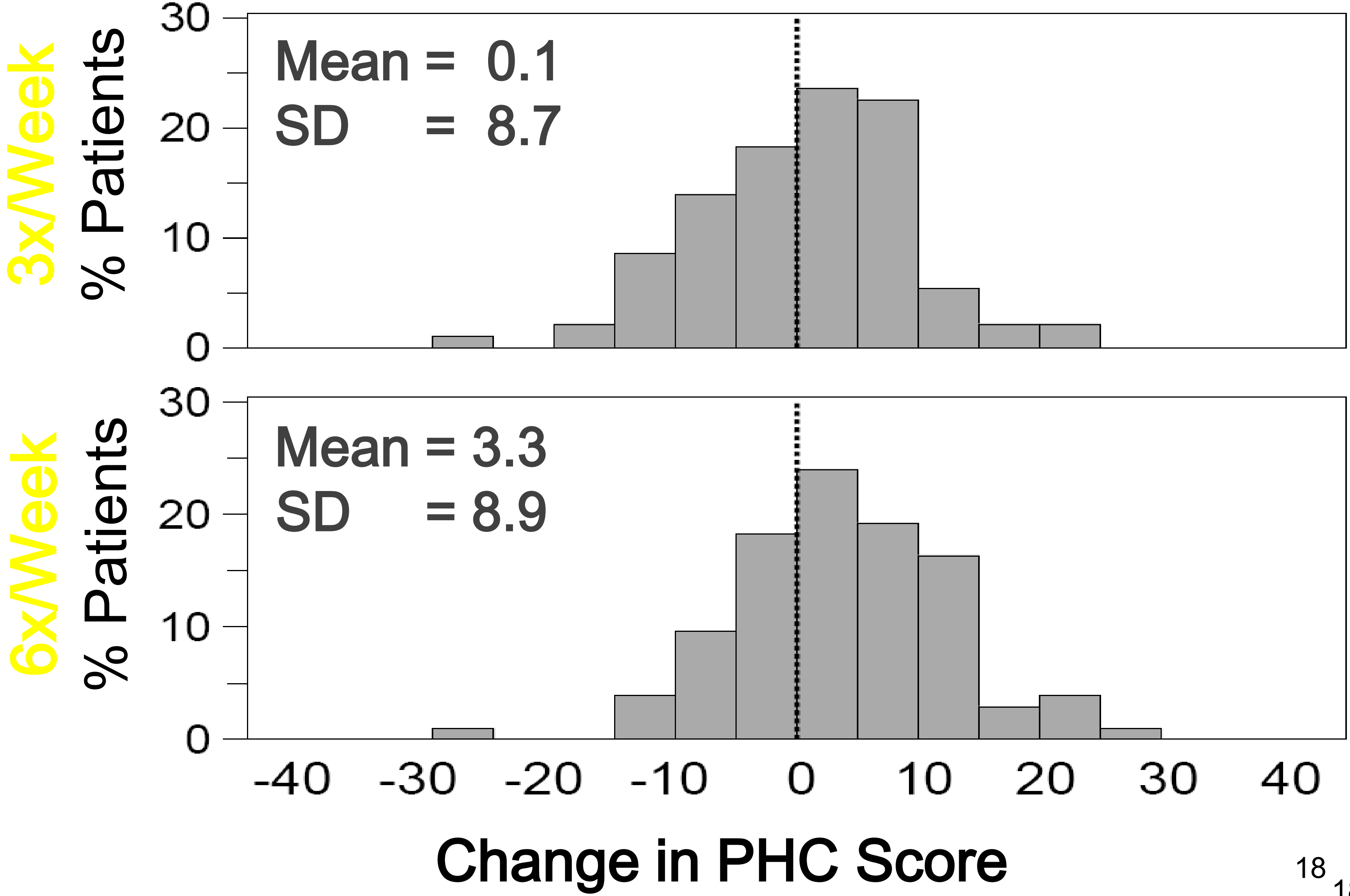
Change in PHC Score

FHN Daily Trial



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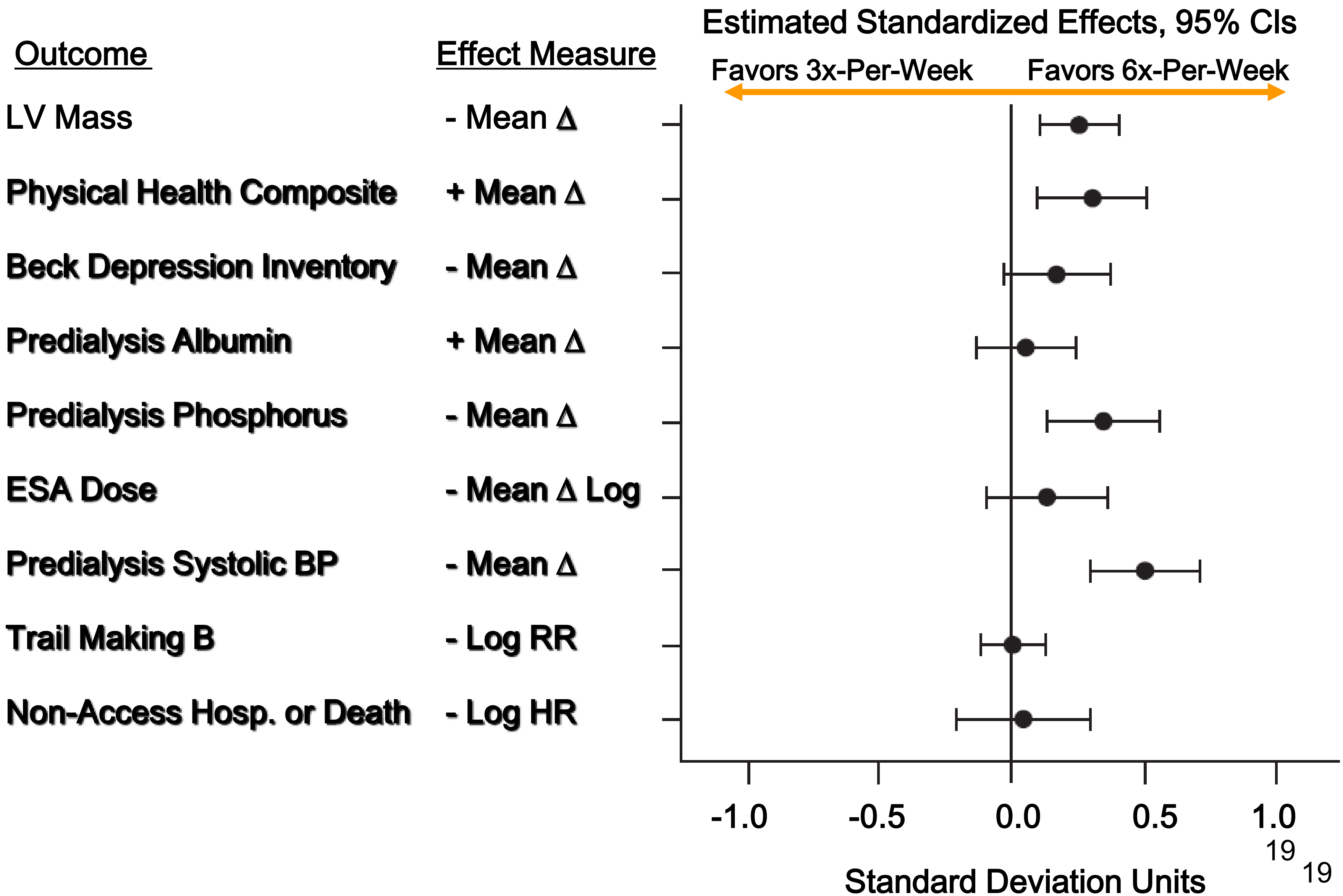
Main Secondary Outcome Results

FHN Daily Trial



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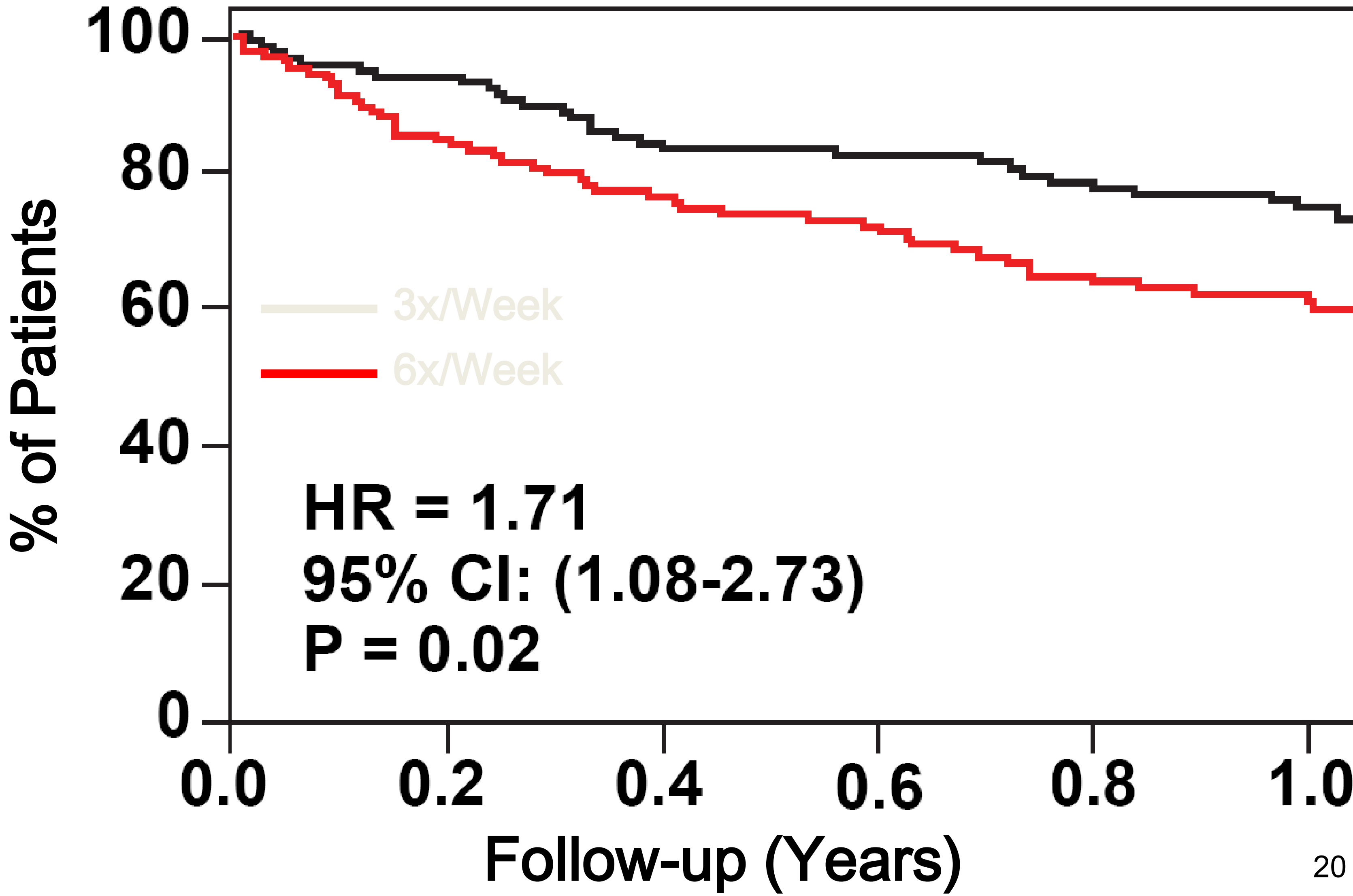
Time to First Vascular Access Intervention

FHN Daily Trial



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Adverse Events

FHN Daily Trial

Outcome	3x-Per-Week (n=120) [1]	6x-Per-Week (n=125) [1]	Hazard Ratio (95% CI)	P-value
Deaths	**9**	**5**		
All hospitalizations	**114 (47)**	**109 (58)**	**0.88 (0.60, 1.28)**	**0.50**
Non-access hospitalizations	**90 (44)**	**79 (47)**	**0.80 (0.53, 1.21)**	**0.30**
Cardiovascular hospitalizations	**15 (12)**	**17 (15)**	**0.83 (0.44, 1.59)**	**-**
Infection hospitalizations	**27 (20)**	**27 (23)**	**0.83 (0.49, 1.40)**	**-**
Access hospitalizations	**24 (14)**	**30 (20)**	**0.99 (0.54, 1.82)**	**0.97**
All vascular access interventions	**65 (29)**	**95 (47)**	**1.35 (0.84, 2.18)**	**0.22**
Failures	**23 (15)**	**19 (15)**	**0.71(0.35, 1.44)**	**0.35**
Other procedures	**42 (21)**	**76 (38)**	**1.71(0.98, 2.97)**	**0.058**
Hypotensive episodes	**470 (87)**	**724 (99)**	**-**	**-**
Hypokalemia (potassium <3.0 mEq/L)	**0 (0)**	**0 (0)**	**-**	**-**
(potassium <3.5 mEq/L)	**6 (5)**	**13 (8)**	**-**	**0.57**
Hypophosphatemia (phosphorus <2.17 mg/dL)	**9 (7)**	**15 (9)**	**-**	**0.80**

[1]Total numbers of events and (numbers of patients with events) during the follow-up the period.

FHN Daily Trial Summary

Compared to conventional 3x-per-week hemodialysis, more frequent hemodialysis resulted in:

- Statistically significant improvements in the co-primary composite outcomes of death/LVM and death/PHC
- Improved control of hypertension and hyperphosphatemia
- No significant effect on Trail Making B, Beck Depression Inventory, ESA dose and albumin
- Lower interdialytic weight gain
- More vascular access interventions

The overall benefit of daily dialysis was shown by satisfying the pre-study requirement for favorable effects on both co-primary outcomes. This was accompanied by more vascular access interventions.

Bad Dialysis

- **Cardiovascular disease is not well controlled despite being the major cause of mortality**

Left ventricular failure and diastolic dysfunction are very common in dialysis patients.

Problems include lack of sodium restriction and volume control withfluid overload. Use of cardiac drugs is often poor and in particular the underutilization of non-dialyzable beta-blockers. The poorer outcome with dialyzable beta-blockers may be due to the rapid reduction of the level of the drug in an environment which encourages the development of ventricular arrhythmias associated with increased sympathetic tone, large hemodynamic and electrolyte fluxes and marked ischemic heart disease with ventricular hypertrophy.

ACE inhibitors and ARBS appeared have more effect on dialysis patients.

Bad Dialysis

- **Uremic toxins are inadequately removed**
- **The adequacy of dialysis is usually assessed by the relationship of urea removal in relationship to body volume(Kt/V)**
- **The latter does correlate with outcomes, but the majority of uremic toxins is not removed by current dialyzers which are limited by the pore size of the membranes used.**
- **New approaches include interference with binding of small molecular weight compounds, thus allowing their removal by dialysis.**
- **In the future might be online plasma filtration with adsorption or binding of uremic toxins.**

Bad Dialysis

- Dialysis costs are high

To a larger degree then with most medical treatments chronic dialysis has been commercialized. The major proportion of the cost per patient is hospitalisation with infection and fluid overload being the most important factors. The alternatives, which are less costly, include transplantation, peritoneal dialysis and home dialysis, which all result in outcomes which are on average better then in center dialysis. Obviously personal preference is the most relevant factor once choices are possible

Bad Dialysis

- **Dialysis in chairs**

Countries such as China, Japan, France and Italy dialyze their patients in beds. These countries all have better survival/ Other countries such as, United States, Germany and to a large extent UK dialyze their patients in chairs which is associated with pooling of fluid in the legs and increased sympathetic tone.

It remains to be seen whether the lower mortality in bed dialyzed patients is due to position or because the patients are differentWhat do you think

Bad Dialysis

- **Inadequate referral to transplantation**

The percentage of readily transplantable patients on a list, should a donor become available, is a reflection of the competence and organization of the facility.

Success requires advocacy with patient and family, participation of transplant surgeons and efficient immunological services. Live donors need to be encouraged

Gebate exists concerning the use of paid donors. A recent challenge to current thinking is to pay suitable donors amounts of plus/minus $50,000 followed by life-long guaranteed insurance. The value to society according to its calculations is large with benefits to USA tax payers of 12 billion dollars a year

Bad Dialysis

- **Volume control in patients is generally poor with most patients being hypertensive (USA)**

Volume control is difficult because sodium restriction is not easily accepted by patients nor properly indoctrinated by dialysis staff. A target dry weight is often erroneous and based on clinical information such that patients are variously hypertensive, hypotensive in cardiac failure or dehydrated

New bioimpedance techniques provide dry weight information. Lengthening dialysis duration makes it easier to attain dry weight. Hypertension and hospitalization diminish and patients live longer.

Background

- We need an accurate method to estimate normal fluid status (NFS) in dialysis patients.
- Continuous calf bioimpedance techniques are accurate to estimate dry weight (DW) but requires constant body position during dialysis.
- The questions are

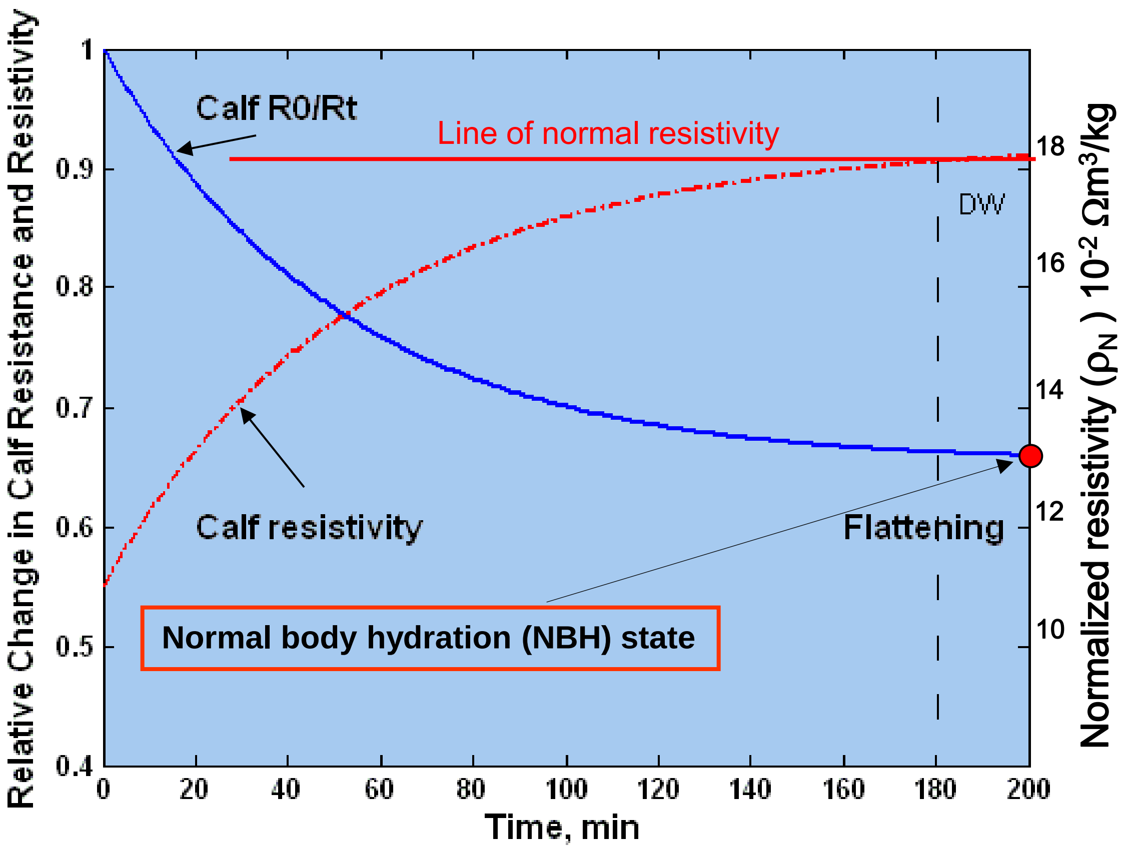
1. Can the calf present the total body in estimating fluid status and body composition;
2. Is it possible to predict DW with the calf method without continuous measurement ?

Calf bioimpedance measurement

- Resistance (R) represents fluid volume in the calf.
- Resistivity ($\rho = R*A/L$) is calculated by R times area of calf (A) within a distance L.
- Calf normalized resistivity (CNR) obtained by calf resistivity divided by BMI ($CNR = \rho/BMI$)
- BMI: body mass index

How to determine Dry Weight with cBIS

(a)



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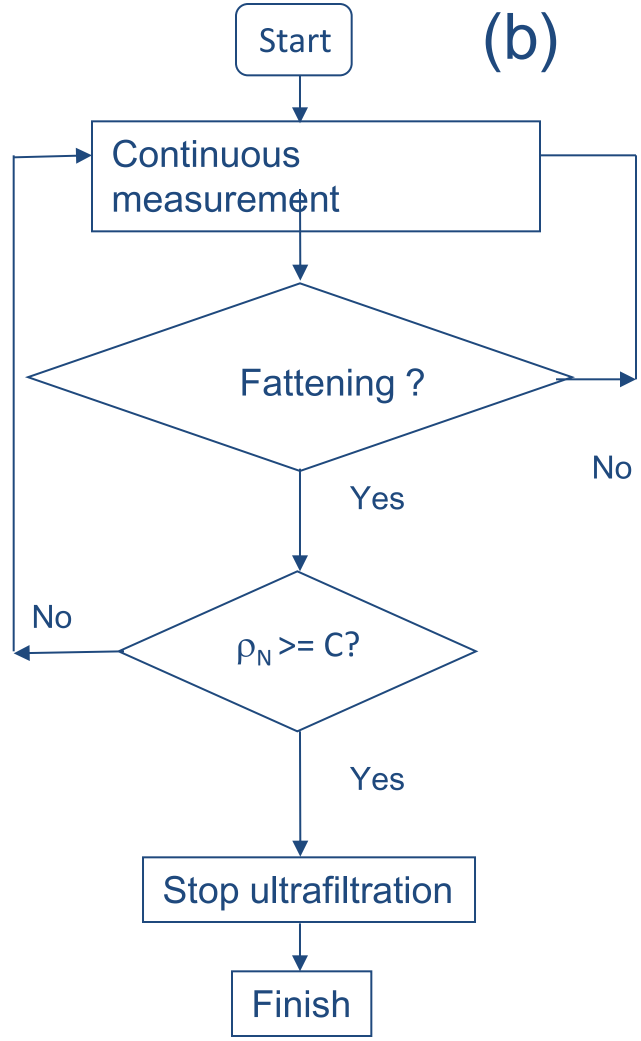
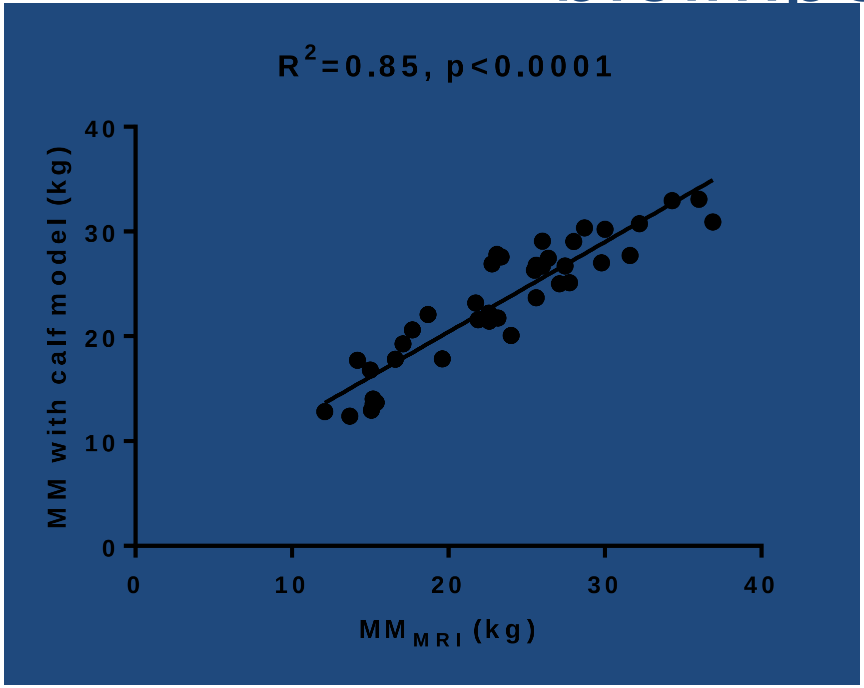
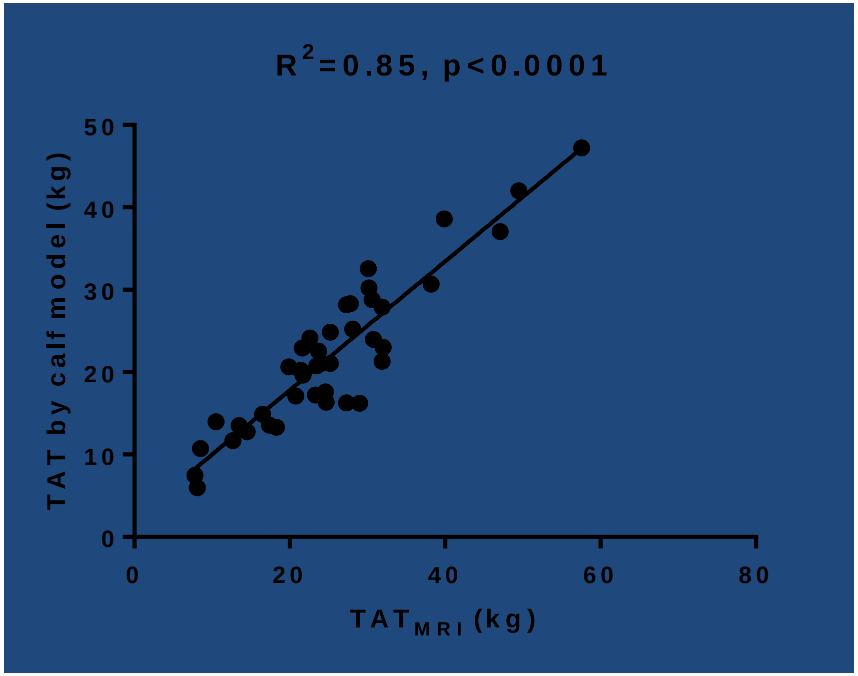


Estimation of muscle mass (MM) and total adipose tissue (TAT) with calf bioimpedance



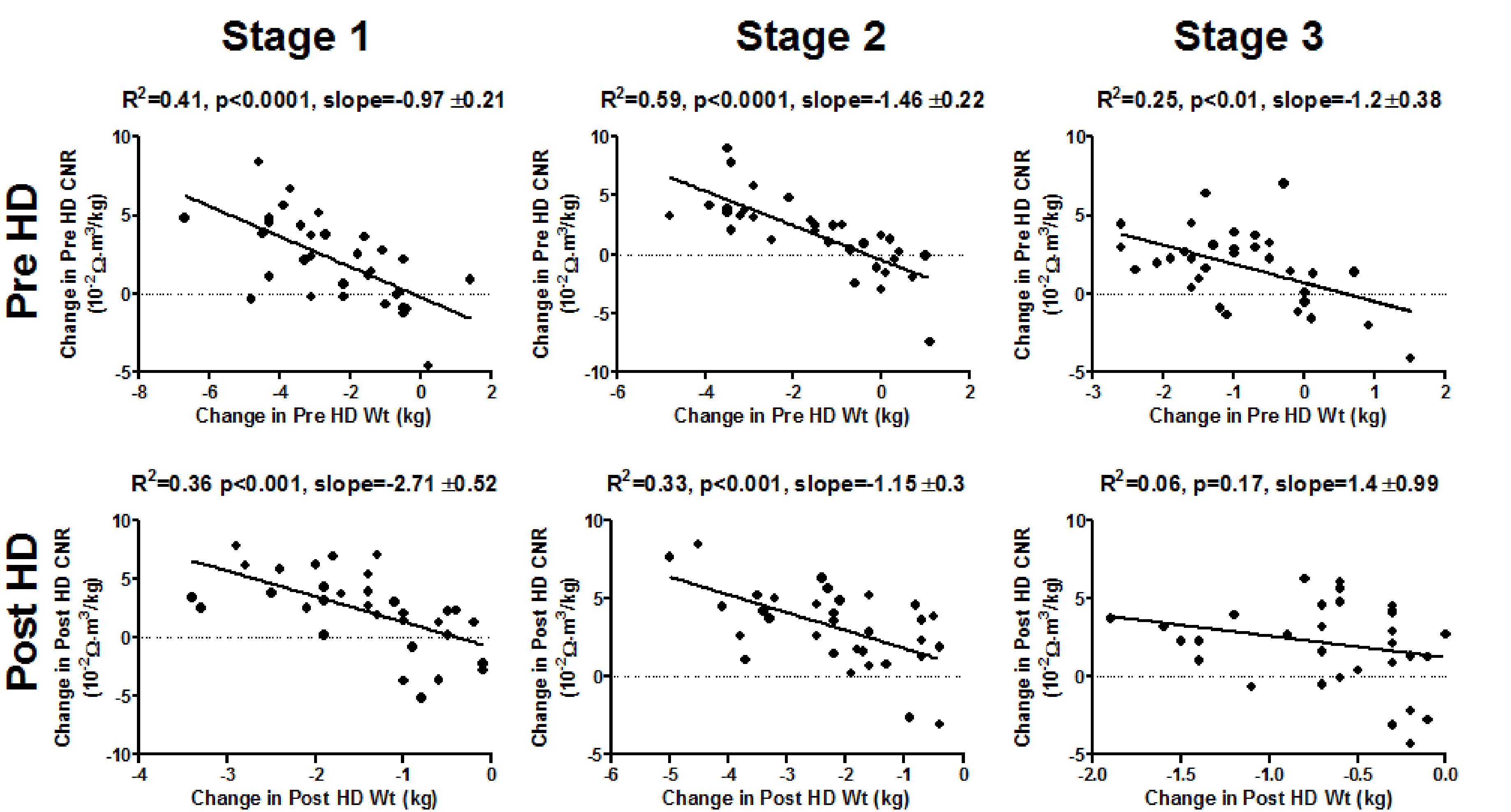


MM_{CBM} =-0.103*cRi+30.58*Height+0.159*weight-0.098*Age-28.736,

TAT_{CBM}= 0.13*cRi-0.142*CA +2.43*BMI+0.129*Age-44.33

17th International Conference on Dialysis Advances in Kidney 2015

Correlations of change in body weight and change in CNR in different stage of FO



BAD DIALYSIS

Not taking into consideration the dialyzability of drugs whether too much or too little

b-Blocker Dialyzability and Mortality in Older Patients Receiving Hemodialysis

Some β-blockers are efficiently removed from the circulation by hemodialysis ("high dialyzability") whereas others are not ("low dialyzability"). This characteristic may influence the effectiveness of the β-blockers among patients receiving long-term hemodialysis. To determine whether new use of a high-dialyzability β-blocker compared with a low-dialyzability β-blocker associates with a higher rate of mortality in patients older than age 66 years receiving long-term hemodialysis, we conducted a propensity-matched population-based retrospective cohort study using the linked healthcare databases of Ontario, Canada. The high-dialyzability group (n=3294) included patients initiating atenolol, acebutolol, or metoprolol. The low-dialyzability group (n=3294) included patients initiating bisoprolol or propranolol. Initiation of a high- versus low-dialyzability β-blocker was associated with a higher risk of death in the following 180 days (relative risk, 1.4; 95% confidence interval, 1.1 to 1.8; P<0.01). Supporting this finding, we repeated the primary analysis in a cohort of patients not receiving hemodialysis and found no significant association between dialyzability and the risk of death (relative risk, 1.0; 95% confidence interval, 0.9 to 1.3; P=0.71)

Table 2.

All-cause mortality (conditional logistic regression model)

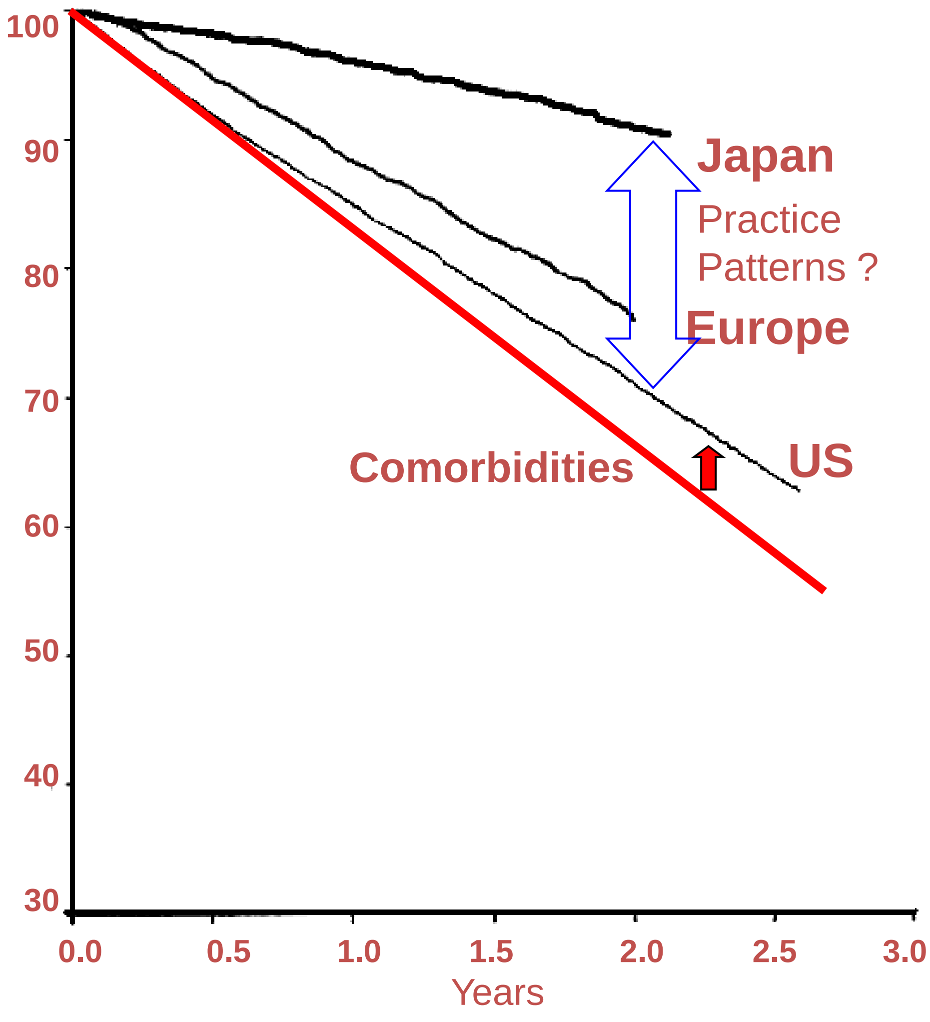
Variable	Patients	(n) No. of Events (%)	RR (95% CI)	P Value
Hemodialysis cohort				
High-dialyzability b-blockers	3294	182 (5.5)	1.4 (1.1 to 1.8)	<0.01
Low-dialyzability b-blockers	3294	135 (4.1)	1 (referent)	
Nondialysis cohort				
High-dialyzability b-blockers	13,586	186 (1.4)	1.0 (0.9 to 1.3)	0.71
Low-dialyzability b-blockers	13,586	179 (1.3)	1 (referent)	

Q:Why are outcomes different?

A:Patient characteristics

Dialysis technical problems

There must be more than "Practice Patterns"

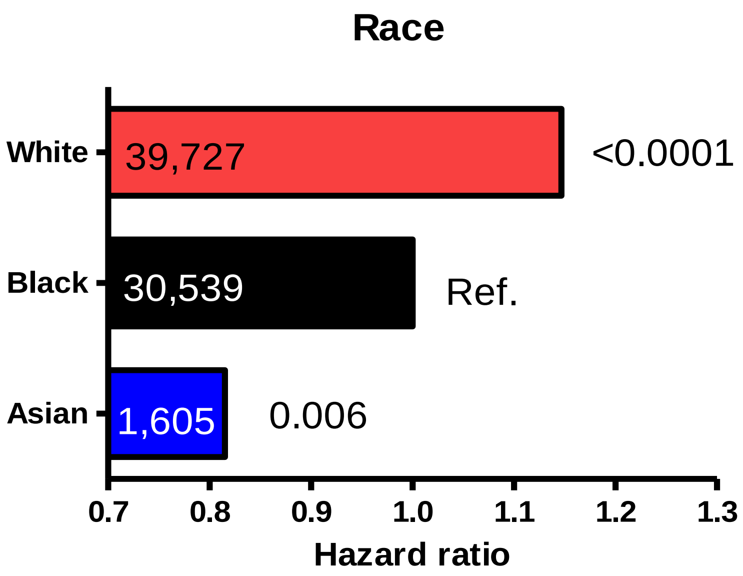


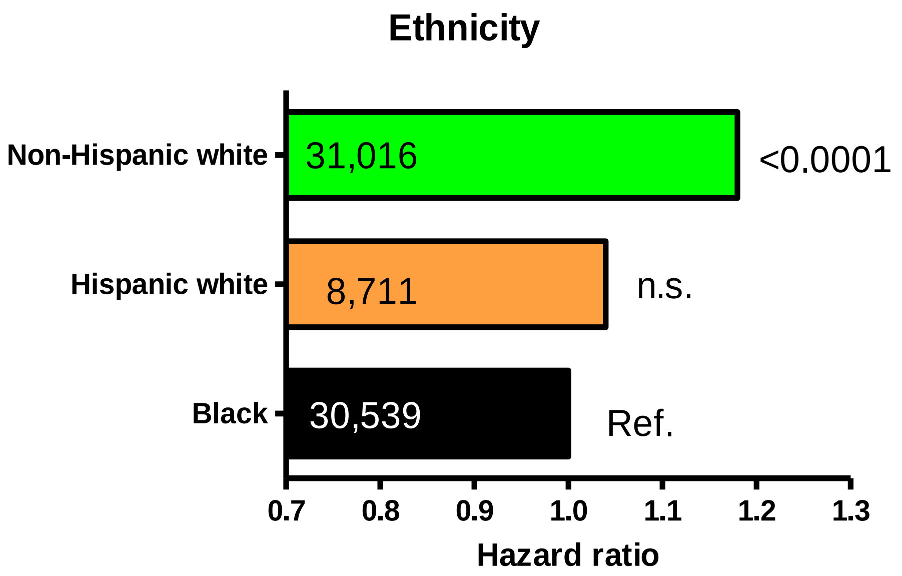
J Am Soc Nephrol **2003; 14:3270-3277**

All-cause Mortality by Race in USA

Cox Survival Model, 1 Year Follow-Up (01/03 - 01/04)

Adjusted for age, gender and diabetes



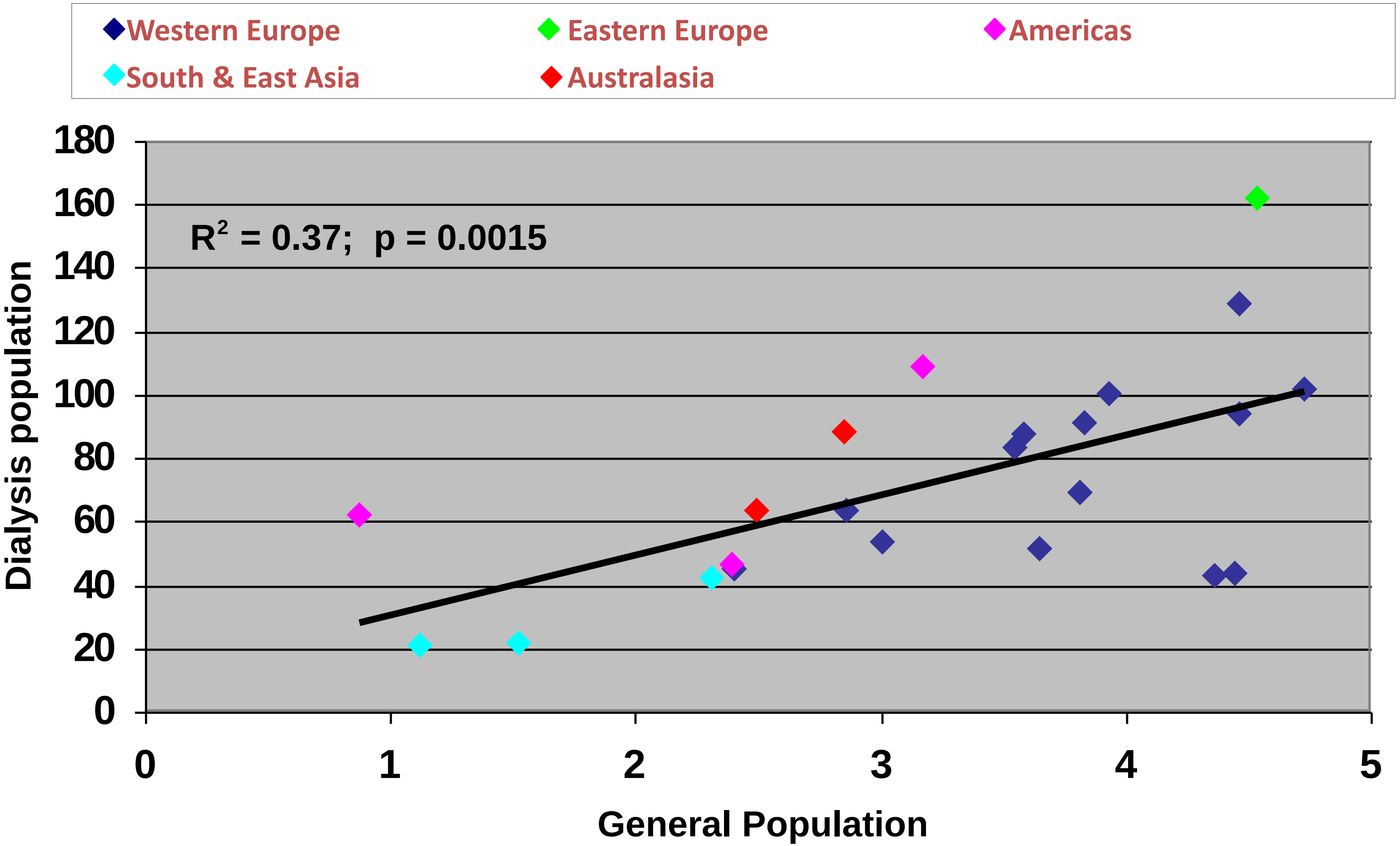


NS: not significant, p > 0.05

Unpublished data, FMCNA 2004

Atherosclerosis related CV death rate Dialysis vs. General Population

23 countries, per 1000 population year



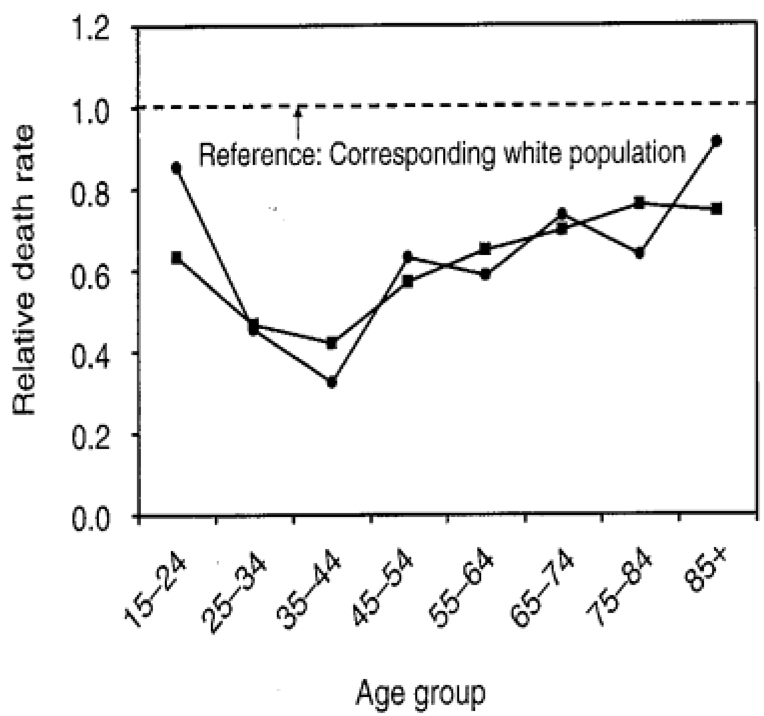
Lower Relative Death Rate in Asian Dialysis Patients

Age-adjusted relative risk of mortality for dialysis patients higher in USA (n=150.862) than Japan (n=66.244)

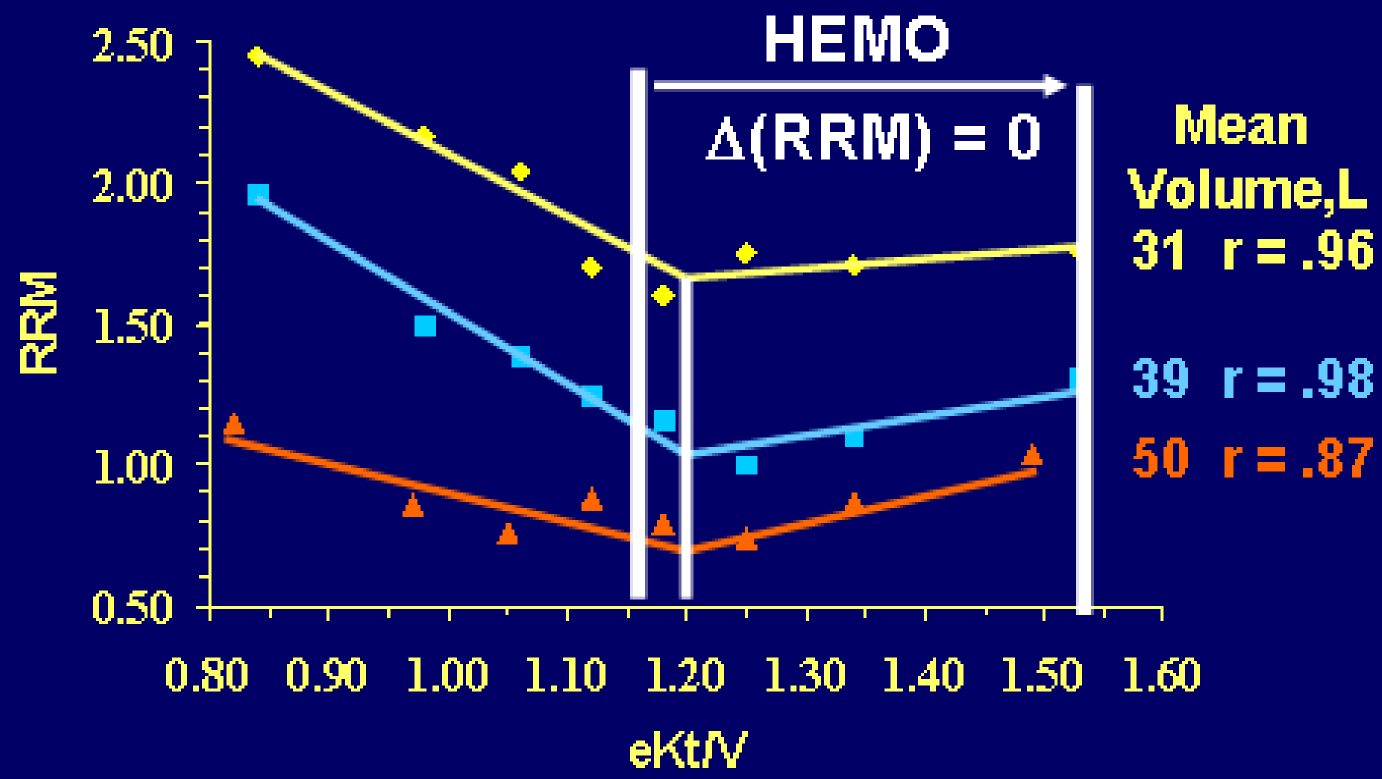
Are the differences in survival reported between Japanese and US populations accounted for by differences in the US delivery system?

Held et al Am J Kidney Dis 1990

25-35% lower mortality risk for Asian-American dialysis patients than for Caucasian-American



Wong et al. Kidney Int 55;2515-2523, 1999



Comparison of FMC data to HEMO Results


White
Black
Hispanic
Non-Hispanic
<60
60-<65
65-<70
70-<75
75+
Deaths per 1,000 patient years at risk
700
600
500
400
300
200
100
<20
20-<25
25-<30
30+
Body mass index (kg/m2)

BAD DIALYSIS

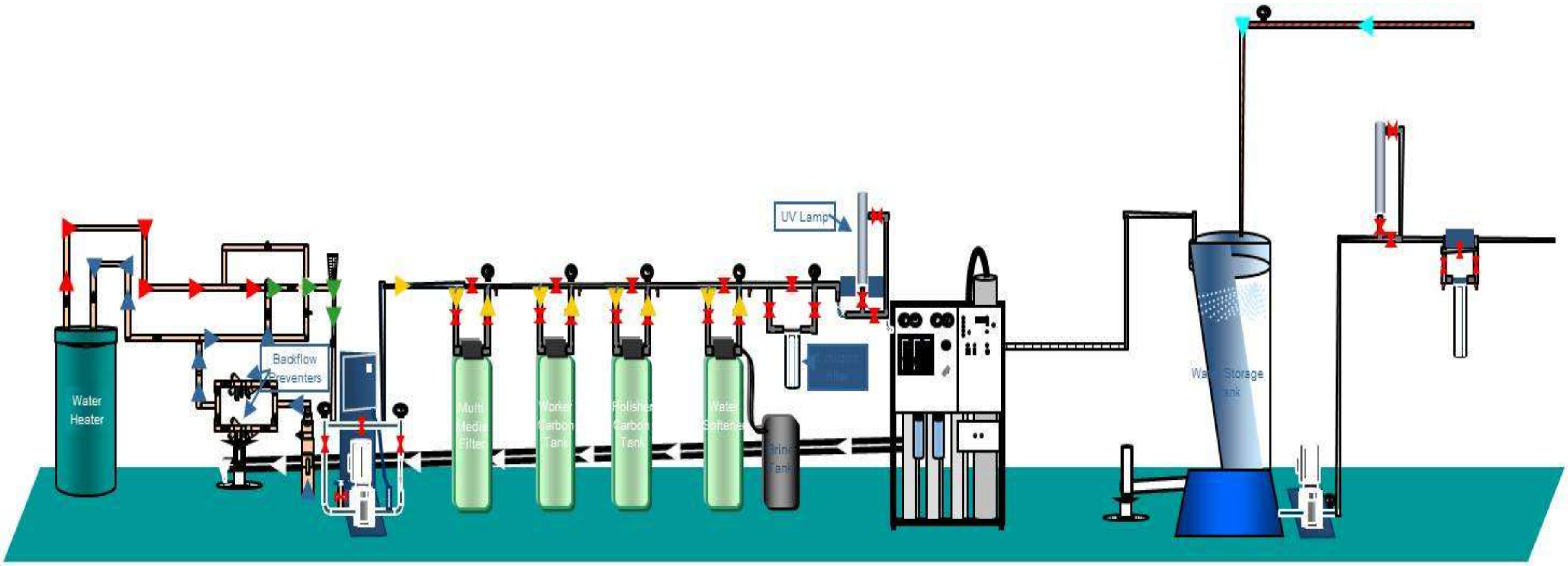
- Water systems that reliably have no chemical contaminants ,no bacteria or viruses

Water Treatment for Hemodialysis

"It is not exaggerated to state that inadequate water treatment is one of the gravest risks posed to the health of the patient on dialysis."

PR Keshaviah

Water Purification System



Overview

- Water
  - Water treatment- Why and How
  - Consequences of inadequate water treatment

Water contaminants

- Contaminants in ground or surface water
  - Chemical contaminants
    - Nitrates, sulphates, calcium, magnesium, trace metals, heavy metals, pesticides
  - Bacterial contaminants
    - Excreted bacterial pathogens
      - e.g faecal bacteria from animals
    - Pathogens growing in water supplies
      - e.g cyanobacteria
- Chemicals added during municipal treatment

Water delivered to the consumer complies with EPA requirements in respect of contaminant levels but is unsuitable for use in dialysate preparation unless subjected to further treatment

Why treat water further?

- Typically a dialysis patient is exposed to 360 liters of water per week, i.e 25 times more than the average person drinks in a week
- A dialysis patient is exposed to more water in three years than the average person in a lifetime
- Transfer of contaminants from drinking water is prevented in the gut, but for dialysis patients blood is separated from water used in the preparation of dialysis fluid by a semi permeable membrane.

Regulatory aspects of water quality

- Standards define the acceptable contaminant levels within the water used for dialysate preparation
  - AAMI water quality standards RD 62: 2001
  - CMS (HCFA) conditions for coverage of ESRD services require compliance with 103 V tags

Consequences of inappropriate water quality

- Nearly every water contaminant has the ability to cause problems in ESRD patients. Over a long period it may not be easily distinguishable from problems arising from ESRD
- Chemical contaminants
  - Aluminium
  - Chlorine and chloramine
- Bacterial contamination

Three Deaths Associated With Excess Aluminum in Dialysate

Three recent deaths among patients on dialysis have been tied to excessive serum aluminum levels leached in through a dialysis unit's dialysate delivery system, according to the Food and Drug Administration (FDA).

FDA SAFETY ALERT: ALUMINUM AND OTHER TRACE ELEMENT CONTAMINATION DISCOVERED IN DIALYSIS FACILITIES

This is to alert you to a pot… tially hazardous situat… which dialysis patients h… exposed to dialysate… sive aluminum le… levels were lea… component… ery syst… (e.…

Cover-up alleged at dialysis clinic

Contamination danger hidden, suits say

Tests Show Water Quality At Unit Below Standards

R.O. System Bypassed, D.I. Tanks Exchanged on Same Day as Reactions Seen

Overexposure to Fluoride Blamed in Chicago Deaths

by Mark E. Neumann

…Chicago Medical Center officials and investigators from the …liminary findings show that acute …University-

__Deaths in Chicago__

FDA Says Unit Staff May Have Misread Warning on Water Treatment System

Agency Issues Alert Recommending Audible Alarms for all Dialysis Units

by Mark E. Neumann

…f Public Health in in… …ad some symptoms similar to the patients… …at the unit were hospitalized for observation and discharged the nex… While not all the patients… …ift, they all experienced… …rs said. Some of the eight

__Controversies in Water Treatment__

More Deaths Reported From Algae in Brazil; High Aluminum Concentrate Kills Patients in The Netherlands

Water Systems

Glycol Int…

Patient Injury in Hemodialysis

1992 – 3 Patients die in Chicago.

Fluoride poisoning

1996 - 60 patients die in Caruaru, Brazil.

Water system contaminated with high levels of blue green algae

Patient Injuries in Hemodialysis

1996 - 9 patients die in the Netherlands Antilles.

High levels of aluminum in water

1998 - 3 patients die in Hong Kong

Disinfectant contaminated water.

Patient Injuries in Hemodialysis

2000 - 2 patients die, 17 injured in Youngstown, Ohio.

High levels of bacteria found in the water distribution loop

Dialysate

1992 - 3 deaths associated with excess aluminum in dialysate

1995 - Patient dies hours after dialysate accident

2008 – 22 Patients hospitalized with anemia after undetected chloramine breakthrough

No matter how good the source water supply is, it cannot be considered suitable for dialysis without further purification.

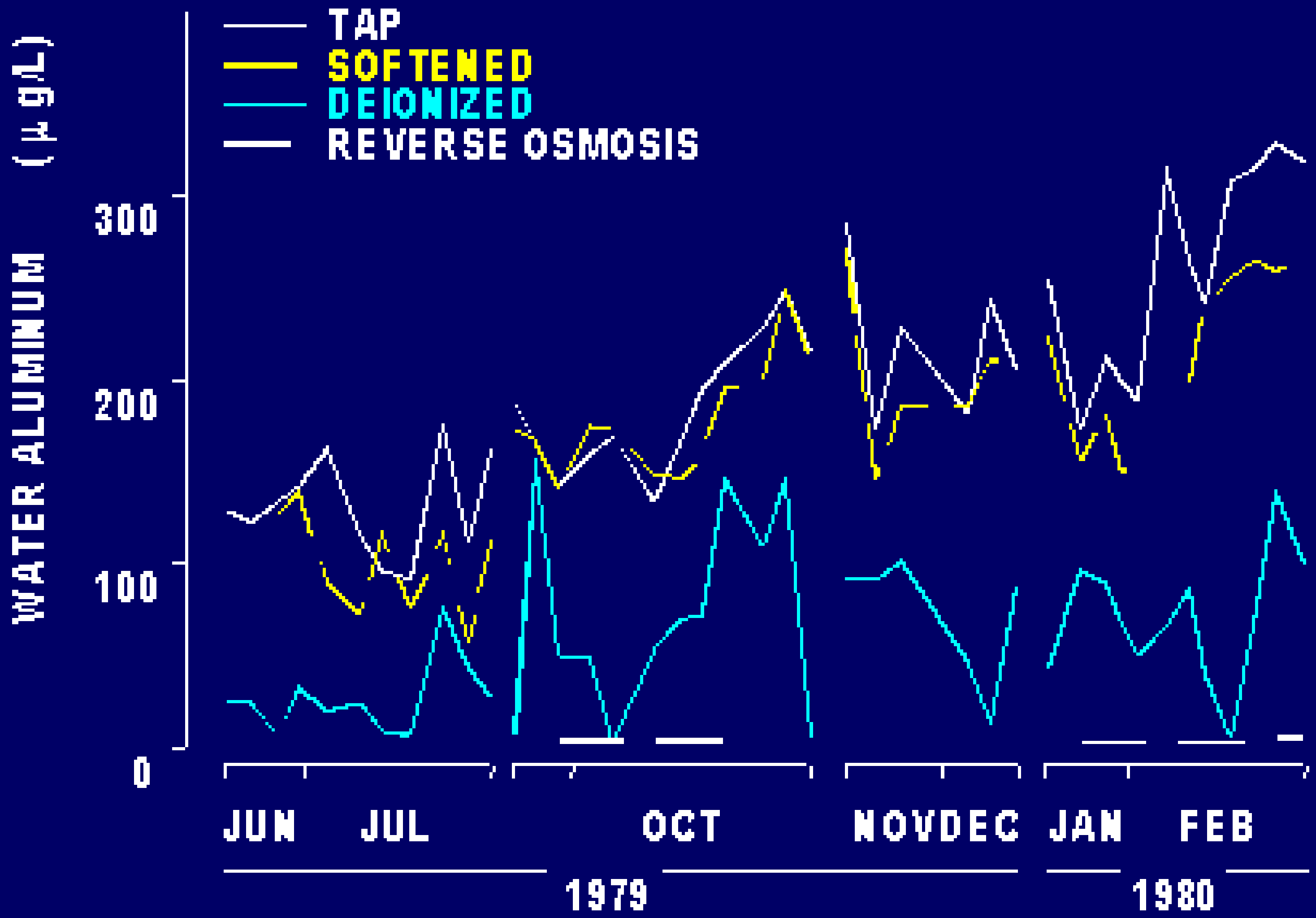
Aluminium

Aluminium

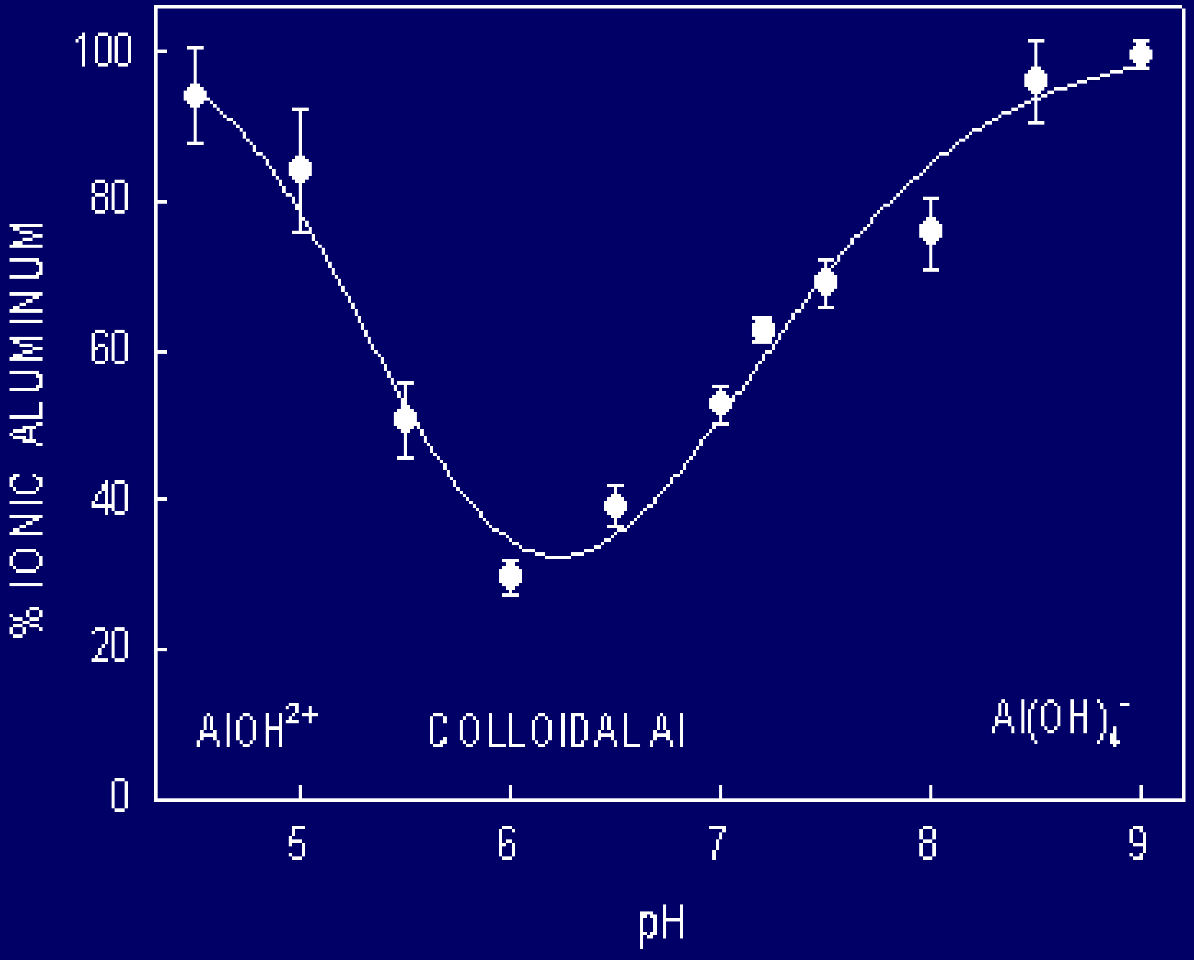
- Regulatory standard for drinking water
  - 0.2mg/l [0.2ppm]
- Desirable level in water used for the preparation of haemodialysis fluid
  - 0.01 mg/l [0.01 ppm]
- Principal mode of removal
    - Reverse osmosis
    - Some may also be removed by deionizer

EFFECT OF TREATMENT ON WATER Al CONTENT

Parkinson IS et al. J Clin Pathol 34:1285-1294, 1981



EFFECT OF pH ON ALUMINUM IN WATER



Parkinson IS et al. J Clin Pathol 34:1285-1294, 1981

Chlorine and Chloramine

Chlorine and chloramine

- Chlorine (Cl)
- Chloramine ($C_7H_8ClNO_2S.Na$)
  - Condensation products of chlorine and ammonia
- By products
  - Trihalomethanes (THM) and Haloacetic Acids (HAA5) are formed when chlorine or other disinfectants react with naturally occurring organic and inorganic matter in water.
  - Their presence in water is regulated as both have demonstrated carcinogenic activity in laboratory animals and linked to an increased risk of miscarriage.


Carbon
Filter
Carbon
Filter

Three Deaths Associated With Excess Aluminum in Dialysate

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Contamination danger hidden, suits say

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Glycol Intox
Water Systems

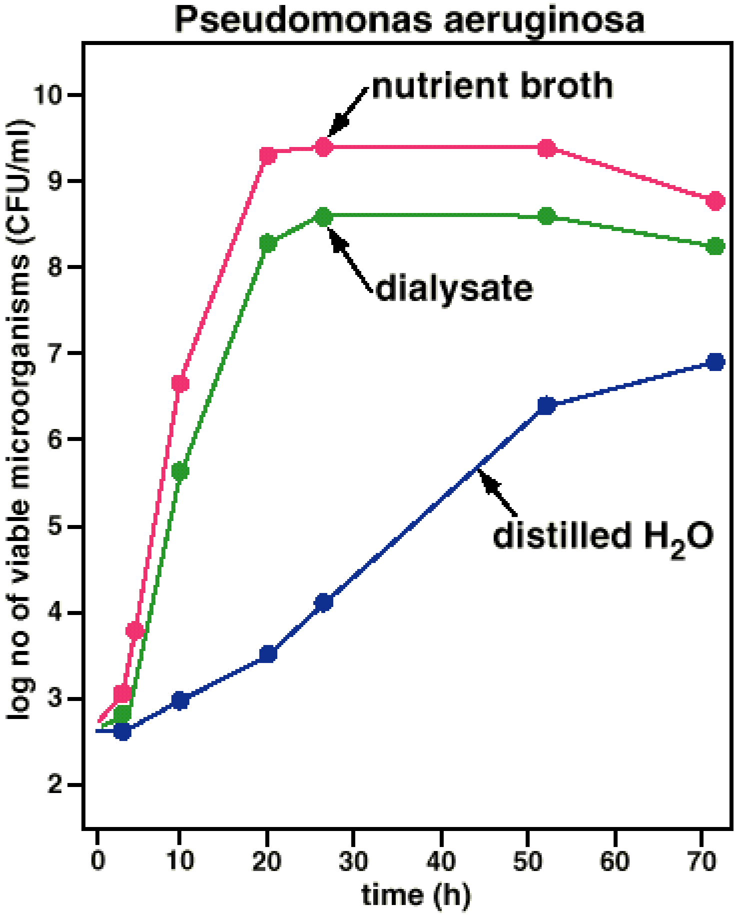
Chloramine and chlorine removal from water

- Carbon filtration is the only effective method for the removal of chlorine and chloramines
- Desirable features of carbon used
  - Empty bed contact time [EBCT] 10 minutes minimum
  - Adsorptive capacity [Iodine number] 900-1000
- Requires worker polisher configuration for optimum effect
- Effectiveness of carbon is dependent on a range of factors, but it is estimated that 200kg of carbon is required for 1000liters of water

Factors that Promote Bacterial Growth in Dialysis Fluid Systems

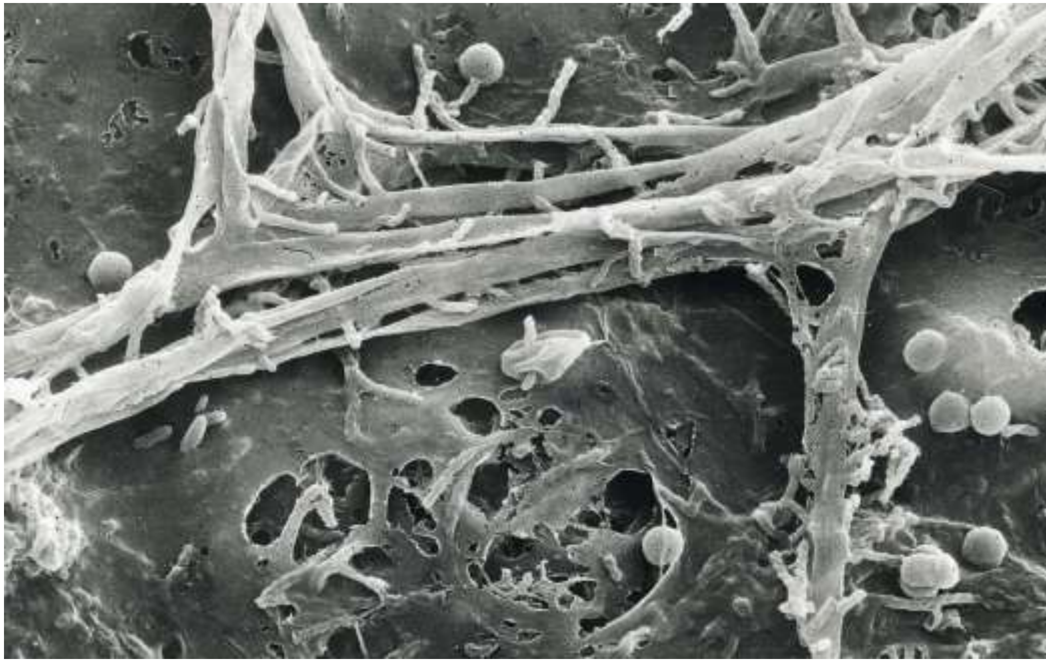
Favorable environment

- Nutrients
- Water
- Room temperature
- No flow
- No disinfection
- Uneven surfaces/joints (biofilm formation)



Development and consequences of biofilm within the pipework

- Bacteria enters system
- Attaches to surface
- Multiplies and spreads
- Protective surface layer develops
- Fragments released
- Inflammatory response in patients



Minimization of bacterial products in the dialysis fluid

- Prevention of the formation of biofilm
- Monitoring
- Introduction of bacterial filters

Monitoring and control

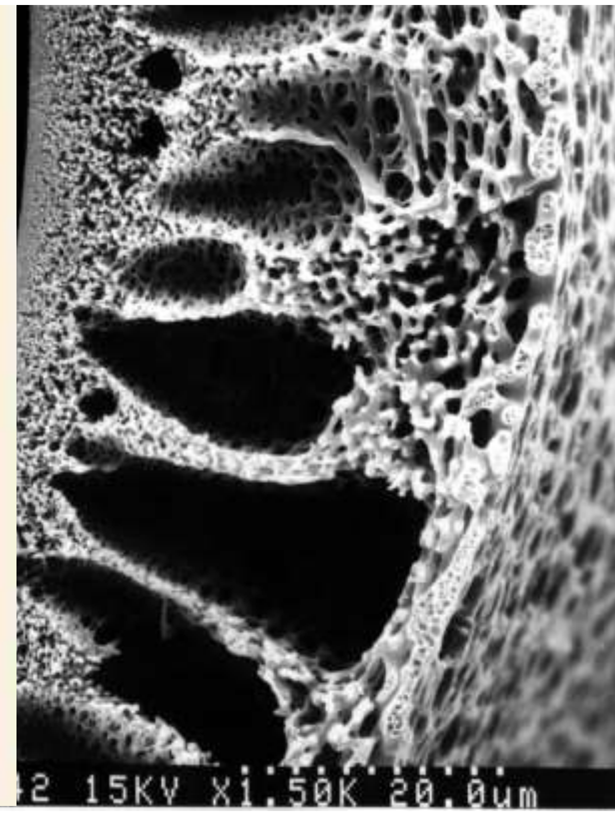
- Disinfect regularly
  - Prevents the development of bacterial growth
- Monitor regularly
  - Use appropriate methods
- Maintain records and QA charts

Monitoring Frequency

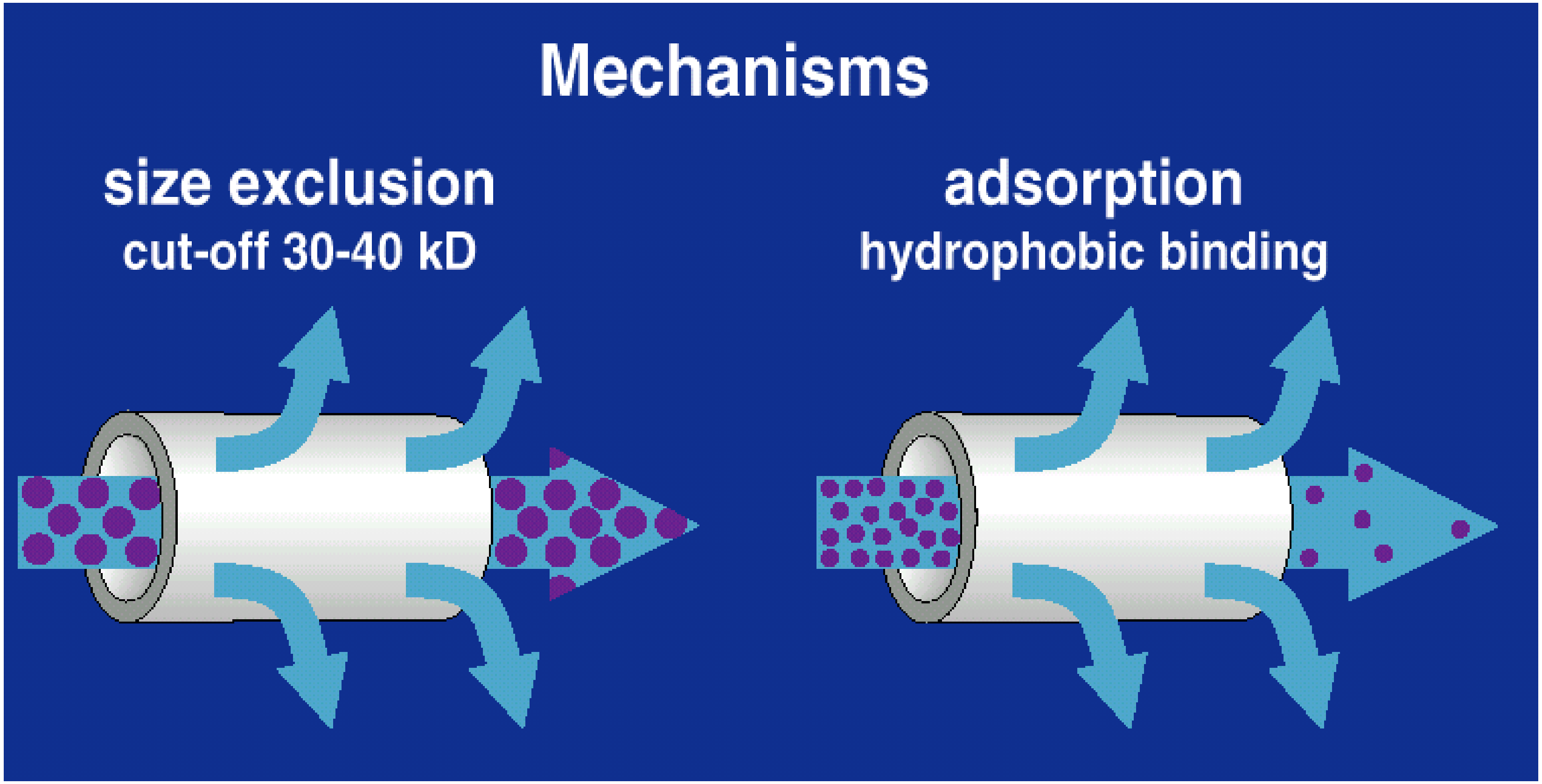
- Daily
  - Chlorine and chloramine (every shift)
  - Water softener
  - RO
- Weekly
  - Cultures for bacteria
  - LAL for endotoxin
- Monthly
  - All dialysis machines
- 6 monthly
  - Feed water quality

Filtration

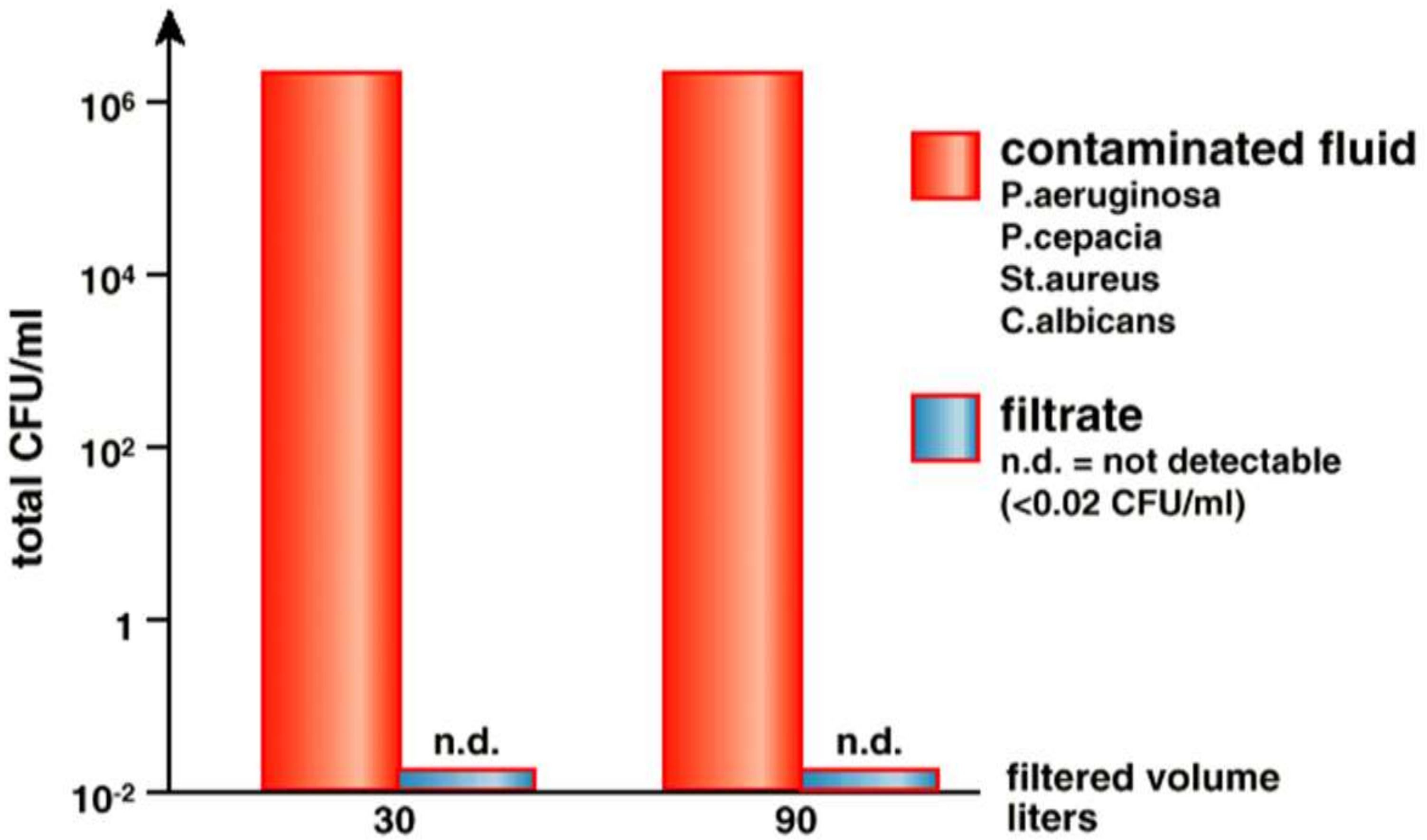
Filters incorporated into new generation of proportionating systems to minimize endotoxin exposure



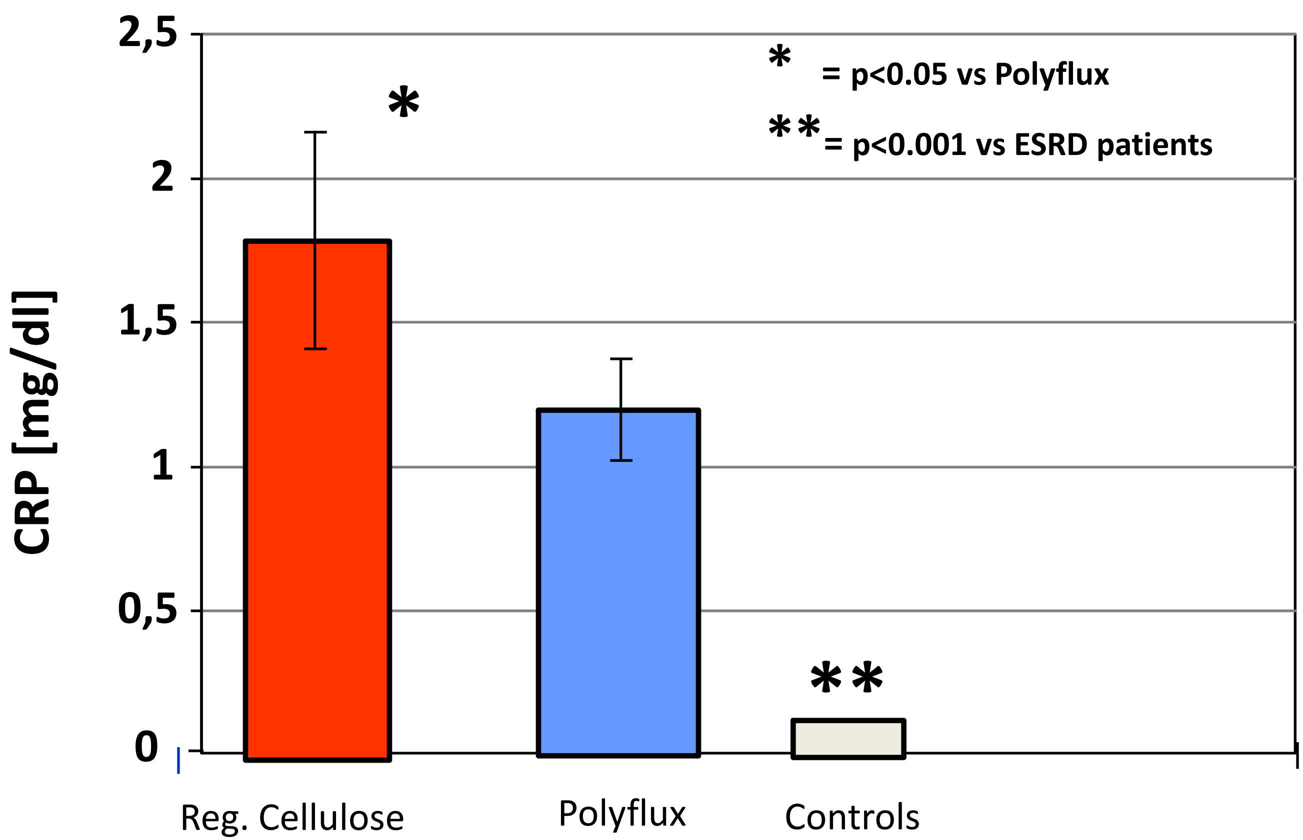
Ultrafilters Remove Bacterial Products by Size Exclusion and Adsorption



Ultrafilters Reduce Bacterial Counts



Reduced Microinflammation prospectively assessed in vivo by analysis of CRP



Schindler et. al, Clin Nephrol 2000

Filtered Fluid Reduces Inflammation

	standard fluid	filtered fluid	p<0.05
fluid quality (CFU/ml)	85 → 93	90 → 0	#
IL-6 (pg/ml)	34 → 40	38 → 18	#
CRP (mg/dl)	1.2 → 1.0	1.3 → 0.6	#
Hb (g/dl)	10.0 → 10.1	10.1 → 10.2	
rHuEPO (U/kg/week)	96 → 92	92 → 64	#

Filtered Fluid Reduces Inflammation and Improves Nutritional Markers

	standard fluid	ultrapure fluid	$p<0.05$
fluid quality (CFU/ml)	60 ⇨ 42	63 ⇨ 0	* #
IL-6 (pg/ml)	21 ⇨ 24	19 ⇨ 13	* #
CRP (mg/dl)	0.9 ⇨ 1.1	1.0 ⇨ 0.5	* #
dry weight (kg)	73.5 ⇨ 74.1	72.1 ⇨ 76.3	*
circumference (cm)	26.9 ⇨ 26.5	26.3 ⇨ 27.5	*
albumin (g/dl)	3.5 ⇨ 3.6	3.6 ⇨ 3.9	*

Summary for water

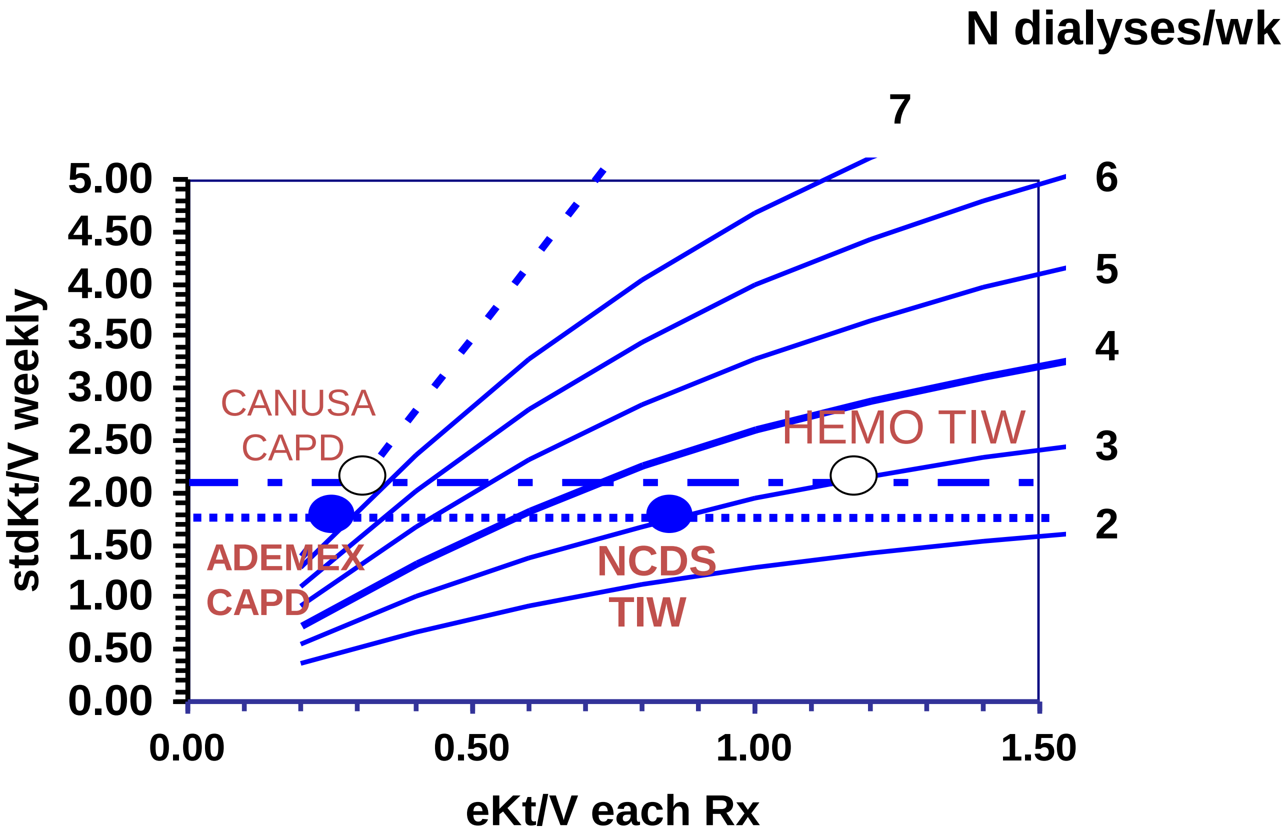
- Water quality is an important contributor to morbidity and outcomes in ESRD patients
- Detailed attention to these aspects needs to be paid to ensure optimal outcomes associated with treatmens

Effect of body size

Standard Kt/V

A Fable
The Hare and the Tortoise
(Aesop, 650 BC)

Aesop's message: The slow but continuously moving turtle can travel as far and as quickly as the very much faster but intermittently sleeping rabbit.



The model fits the adequate dose for CAPD equal to the adequate dose for thrice weekly HD.

Case History – for discussion only

The KoA of a dialyzer is 1200 ml/min; the blood flow prescribed is 350 ml/min; treatment time is 210 min; dialysate flow is 500 min/min. The patient urea distribution volume is 30 liters

UKM results are:

eKt/V = 0.8

Urea distribution volume 36 l

Access flow 450 ml/min

The arterial pre-pump pressure is – 368 mmHg

Describe the situation in one sentence.

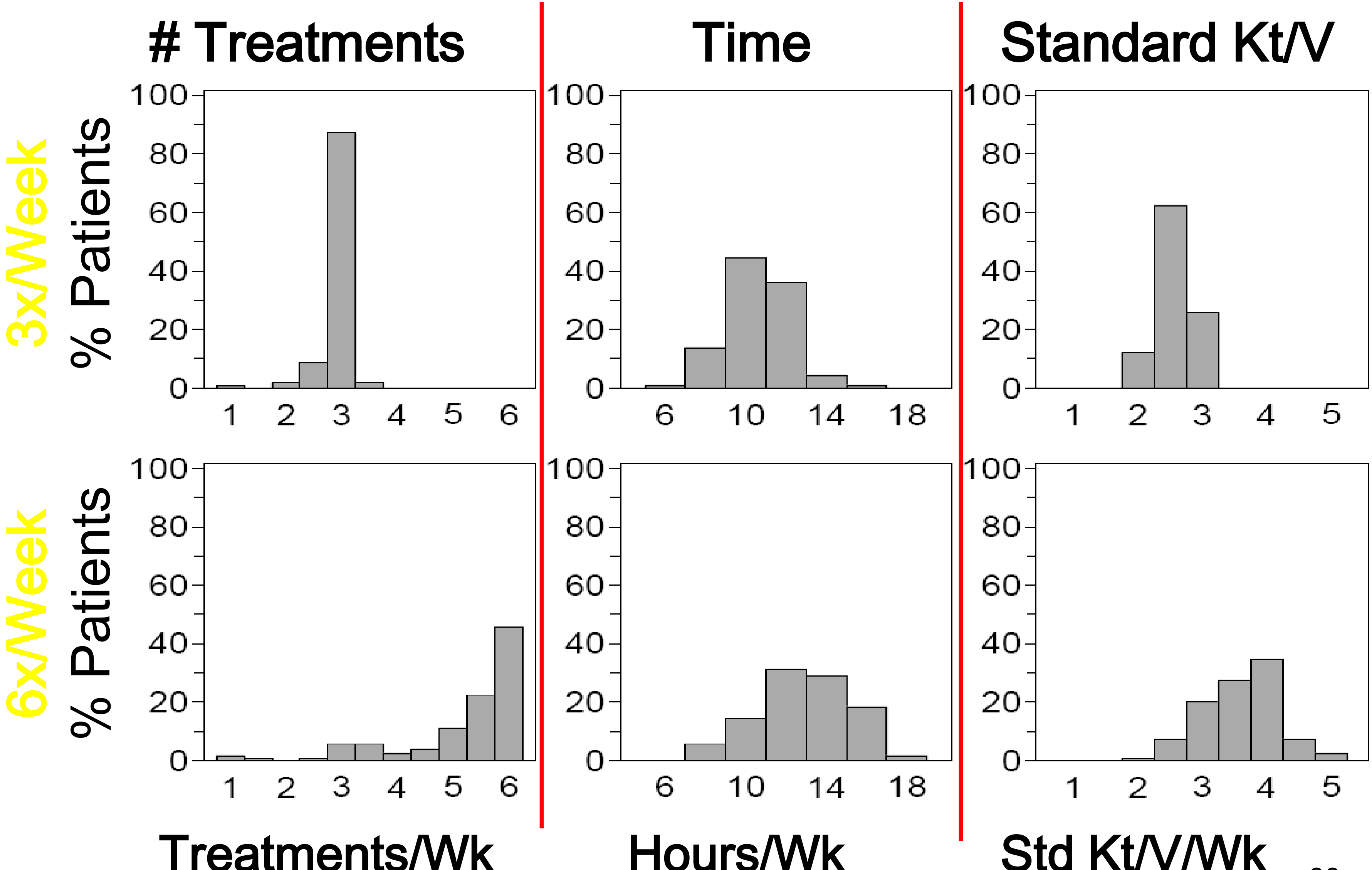
Baseline Characteristics

FHN Daily Trial

Factor	All Patients (n=245)	3x-Per-Week (n=120)	6x-Per-Week (n=125)
Age (years) (mean ± SD)	**50.4 ± 13.9**	**52.0 ± 14.1**	**48.9 ± 13.6**
Female (%)	**38**	**39**	**38**
Race			
Black (%)	**42**	**44**	**39**
White (%)	**36**	**38**	**34**
Other (%)	**22**	**18**	**26**
Diabetes (%)	**41**	**42**	**40**
ESRD vintage (years)			
< 2 (%)	**16**	**17**	**16**
2 – 5 (%)	**39**	**42**	**35**
> 5 (%)	**45**	**41**	**49**

Separation in Treatment Parameters between Groups

FHN Daily Trial



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Urea Kinetic Modeling (UKM) is simply the formal mathematical description of urea mass balance

Urea Input = Urea Removal

In steady state, ie, chronic renal failure,

Generation of Urea = Removal of Urea

Rarely measure Generation

Rarely measure Clearance

$$\frac{\text{Generation}}{\text{Clearance}}$$

Always measure BUN