Do advances in hemodialysis technology (e.g. the use of biofeedback, blood volume and clearance monitoring) offer better outcomes?
- NO -

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As Elton John said:
“I’ve got nothing to say, I’ve got nothing to say…..”

Types of Add-ons

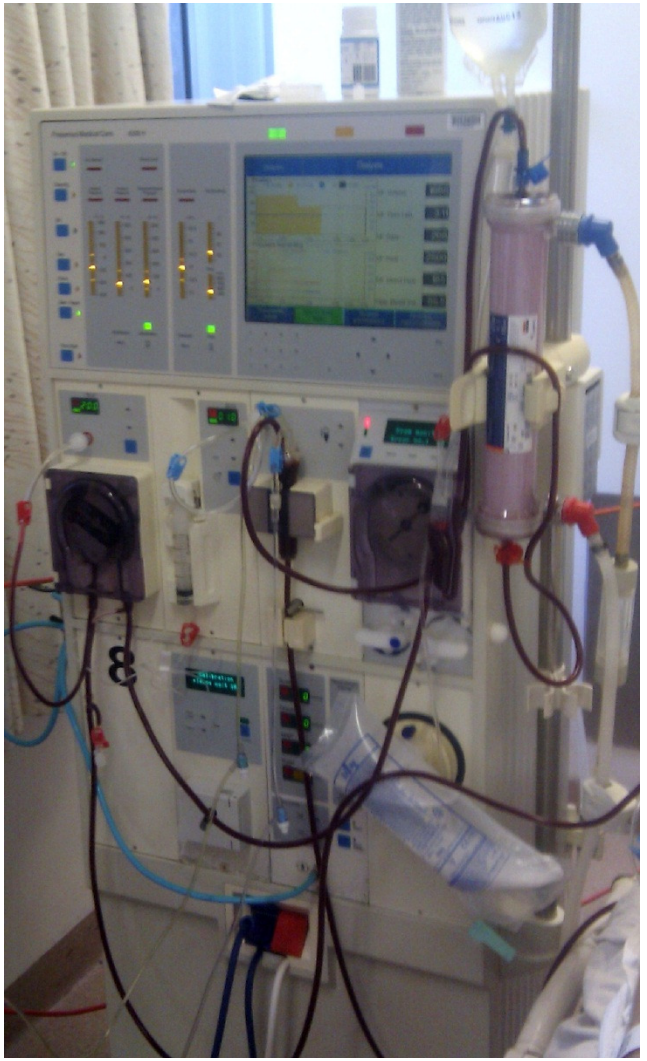
- Blood volume – predominantly hematocrit based
- Hydration status (TBW) – bio-impedance
- Blood temperature – also useful to measure AV access flow
- Sodium profiling
  - Main use for preventing intradialytic hypotension
- Clearance monitors – dialysate based Kt/V

All add-ons have some purpose.

- Less hypotensive episodes
- Better tolerance of dialysis sessions
- More patients at Kt/V target
- More patients at true dry weight
- Better BP control

BUT…….

- In short…..
  - No evidence of improved hard outcomes
  - No improvement in mortality
  - No improvement in major events
- In reality….
  - No evidence that they do help
  - Little evidence that they don’t help



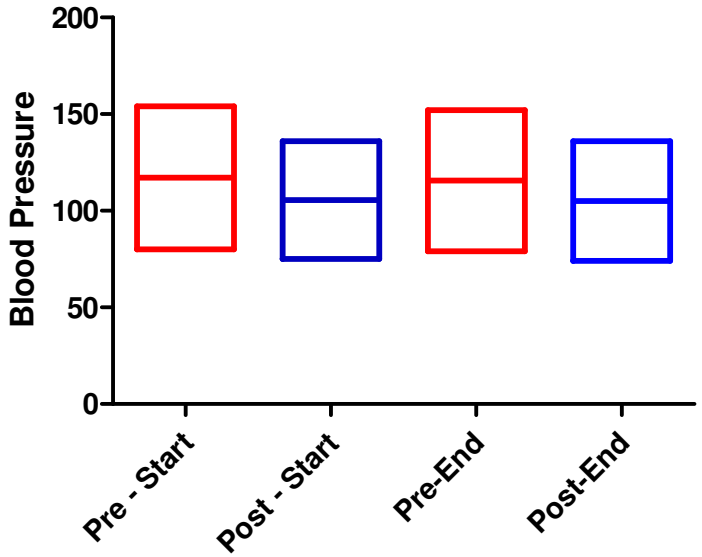
Intradialytic Hypotension

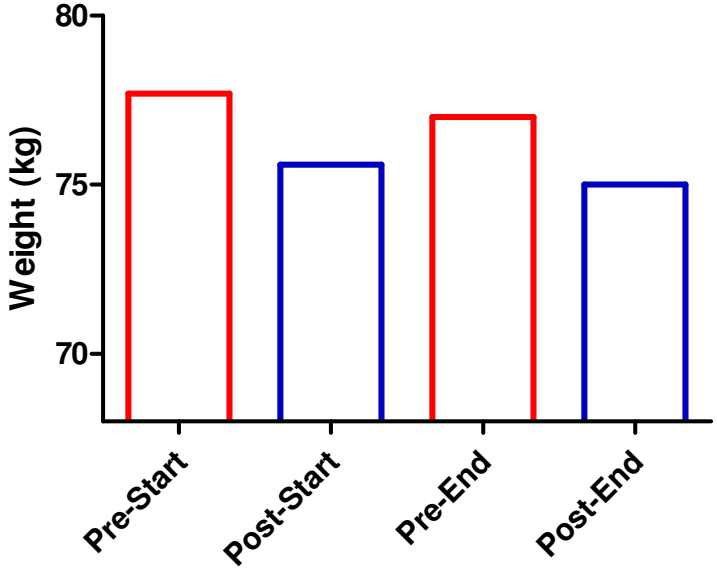
- Balance of fluid removal (rate) and vascular refilling
- Common – variably reported but some report rates of 7-10% of all dialysis sessions
- May depend on the definition – symptoms, requirements for resuscitation, IV fluids etc

Blood Pressure

- 3 month period, > 3500 dialysis sessions
- Mean Pre-HD: 151 ± 16 / 78 ± 11
- Mean Post-HD: 135 ± 10 / 74 ± 17

- Mean wt gain (weekday): 1.8 kg ± 0.8
- Mean wt gain (weekend): 2.7 kg ± 1.1



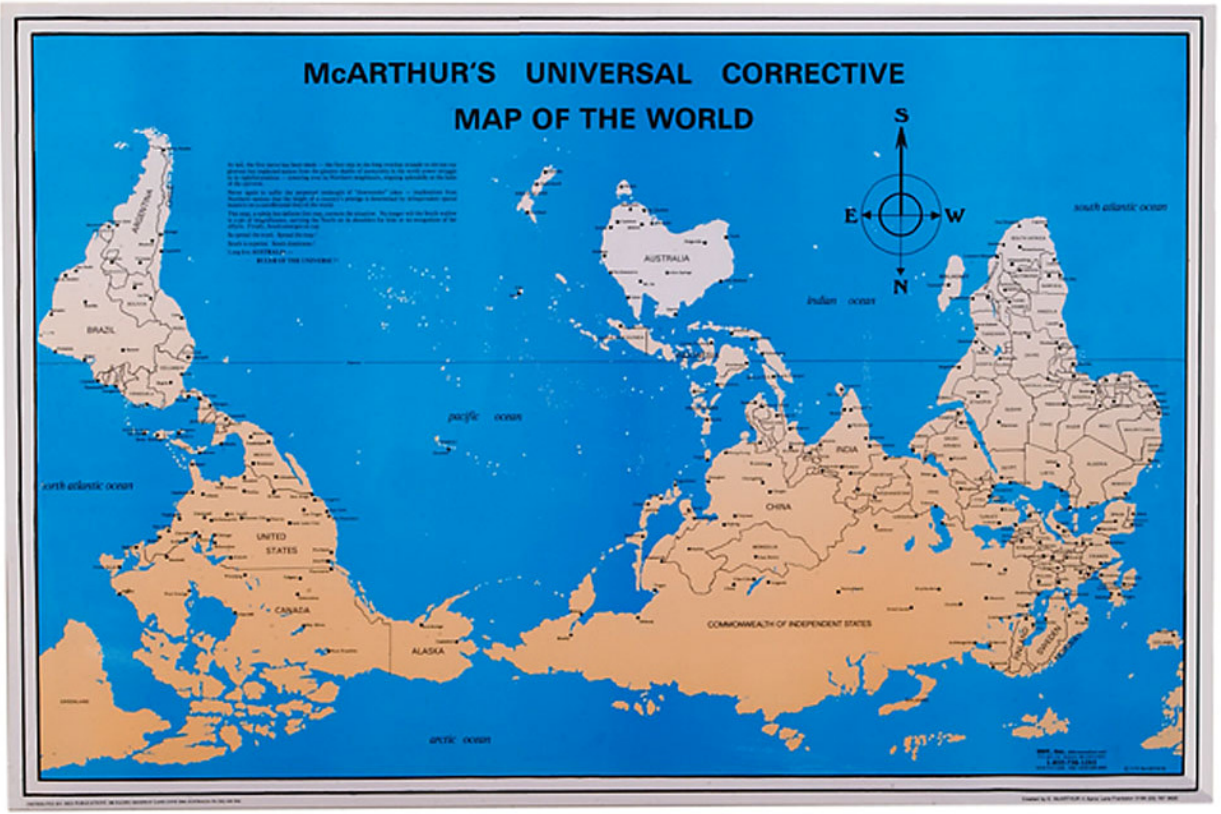


Hypotensive Episodes

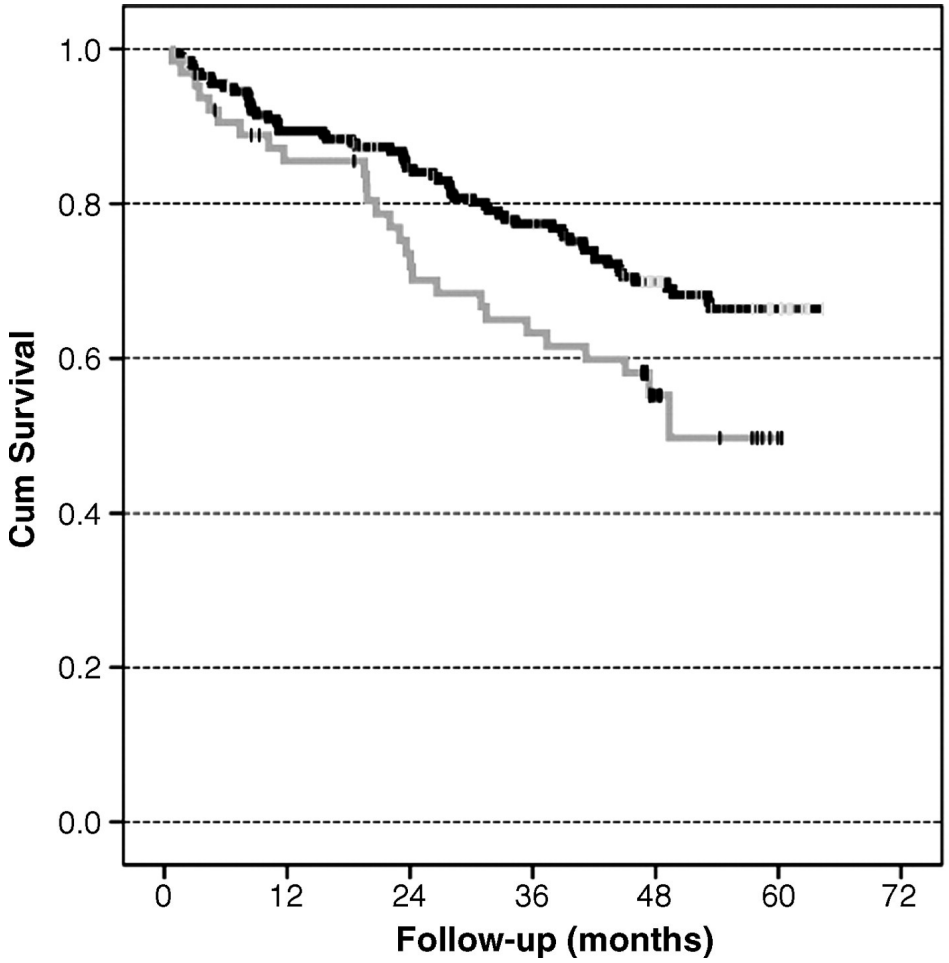
- **Hypotension (on M/T): 8 episodes (7 pts); 8/1209 or 6.6/1000 sessions**
- **Hypotension (on W/Th/F/S): 22 episodes (18 pts); 22/2418 or 9.1/1000 sessions**
- **Extra sessions for excess fluid: 7 (7.5% of patients); 3 on weekdays, 4 on weekends.**

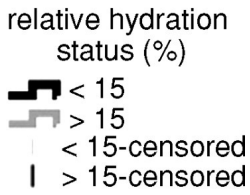
Down Under View

- **Dialysis for longer - Median 4.5 hours**
- **Slower rate of fluid removal**
- **Less hypotension**

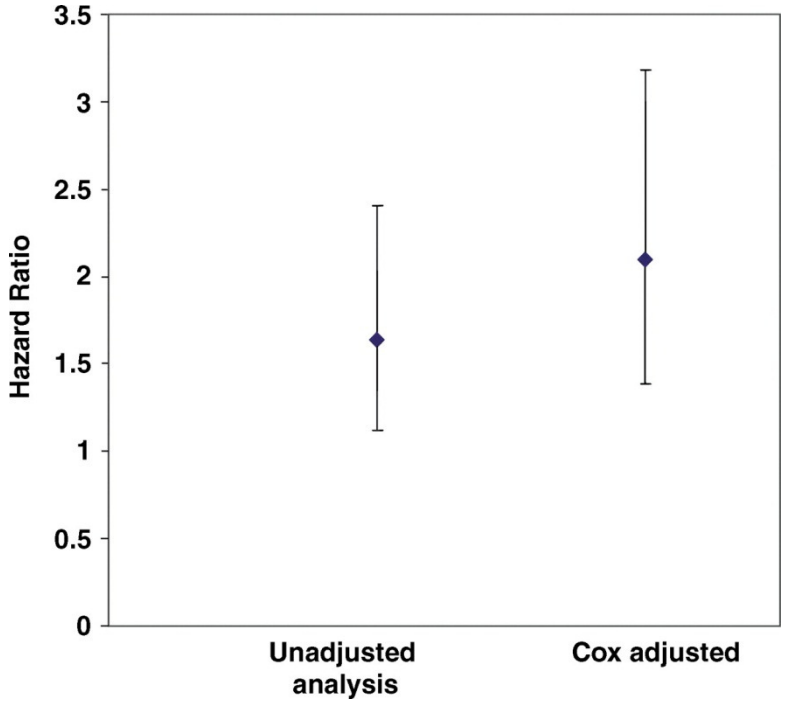


Kaplan–Meier curve separating the patients for the relative hydration status (ΔHS >15%), as detected by BIA (using Fresenius BCM).





n=269
Not a trial – just observation. Patients categorised into hydration status.



Wizemann V et al. Nephrol. Dial. Transplant. 2009;24:1574-1579

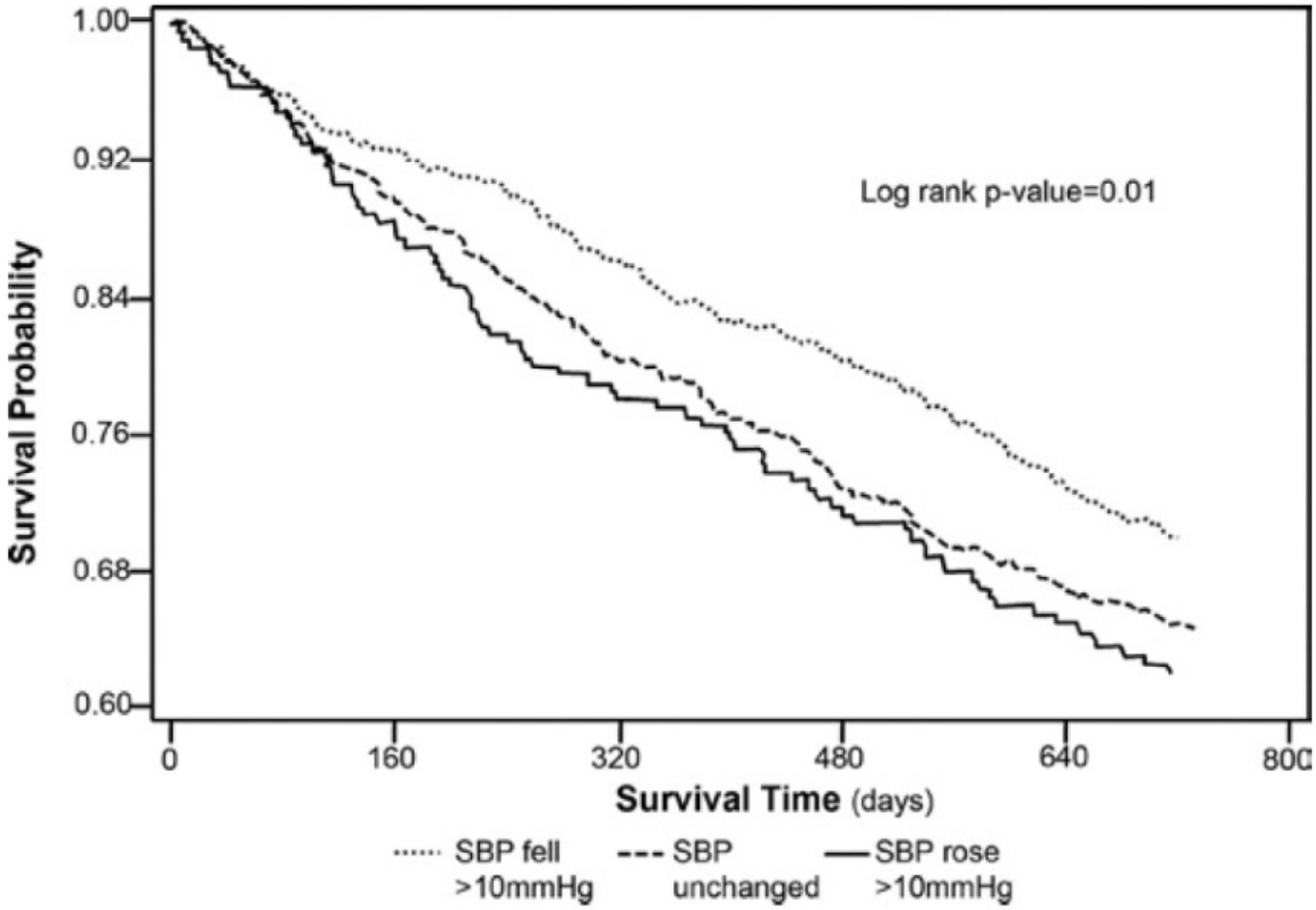
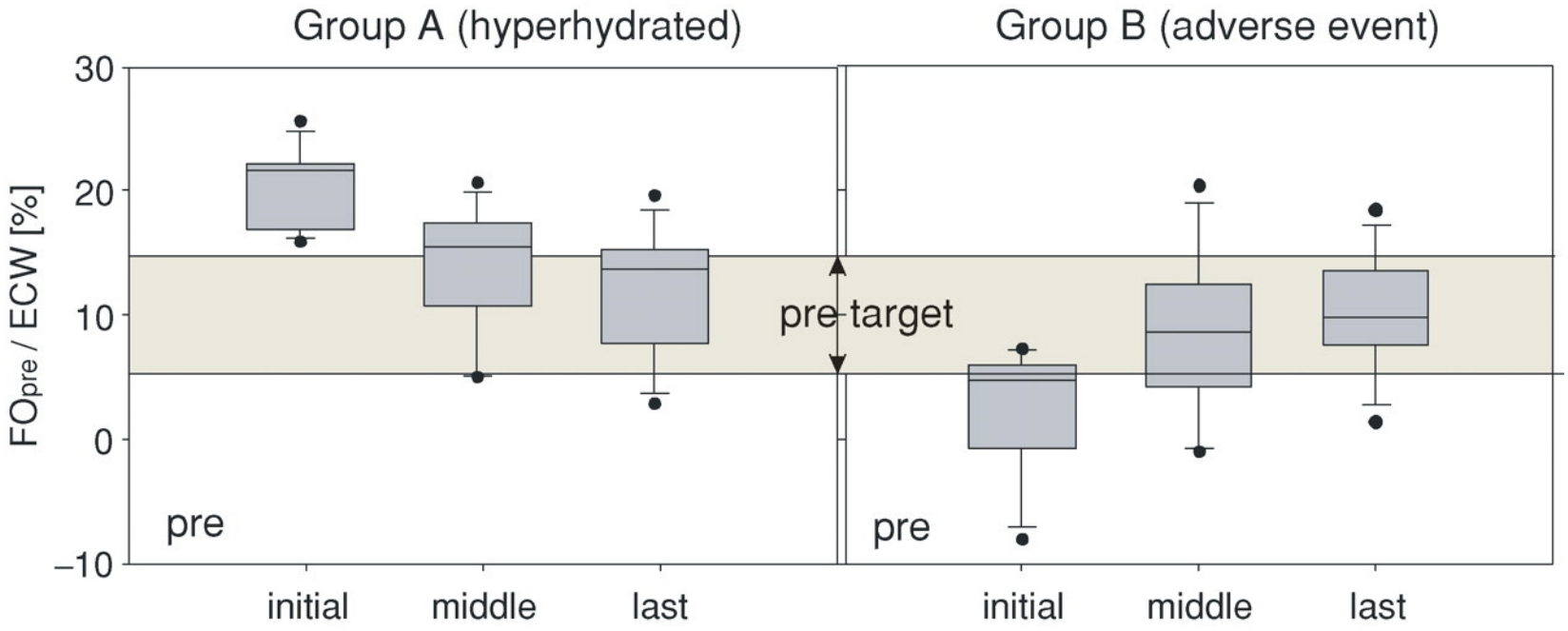


Figure 2. Kaplan-Meier survival curves of time to death over 2 years in a national cohort of incident hemodialysis (HD) patients stratified by changes in systolic blood pressure (SBP) during HD.

Inrig et al, AJKD, 2009

Fluid status changes over 12 months
– monthly assessment of hydration status using Fresenius BCM



No increase in intra-dialytic hypotension in Group A (n=13), no increase in BP in Group B (n=12).

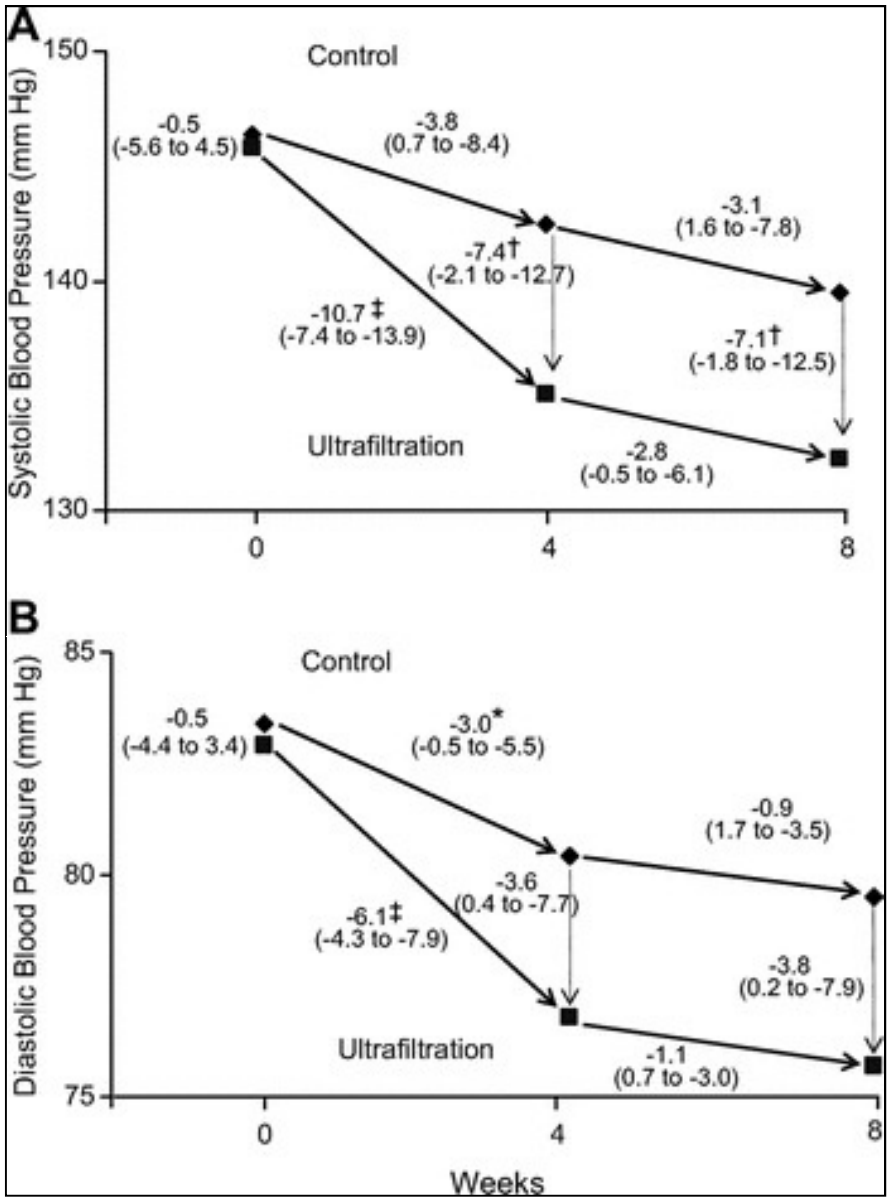
Machek P et al. Nephrol. Dial. Transplant. 2010;25:538-544,
Conflict of interest statement. All authors are employees of Fresenius Medical Care.

Improving hydration status

- Might improve BP
- Might improve survival

- But no-one has done the trial

Do you need a machine to do this for you?



Dry-Weight Reduction in Hypertensive Hemodialysis Patients (DRIP): A Randomized, Controlled Trial.
Agarwal, Rajiv; Alborzi, Pooneh; Satyan, Sangeetha; Light, Robert

Hypertension. 53(3):500-507, March 2009.

The effect of dry-weight reduction by repeated probing by the attending physician on interdialytic ambulatory systolic (A) and diastolic BP (B) in hypertensive hemodialysis patients. The mean systolic and diastolic BPs are shown for the control and ultrafiltration groups. The numbers next to the dotted lines connecting the data points are the mean changes in BP between groups at 4 and 8 weeks after randomization.

Onofriescu M et al, Int Urol Nephrol 2011.
135 HD patients randomized to clinical care (Group A) or BCM controlled volume assessment (Group B).

Table 2 Changes in BP, BMI, and body water

	Baseline	3 months	6 months	9 months	12 months
(a) Group A					
TBW (L)	34.1 ± 6.3	34.5 ± 6.3	34.1 ± 6.7	34.2 ± 6.6	34.2 ± 6.2
ECW (L)	16.4 ± 3.1	16.5 ± 3	16.5 ± 3.1	16.4 ± 3	16.5 ± 2.8
SBP (mm Hg)	146.6 ± 16.3	145.6 ± 14.9	146.3 ± 16.8	140.1 ± 14.5*	142.8 ± 13
DBP (mm Hg)	77.7 ± 11.5	82.7 ± 9.6*	79.7 ± 11.7	77.2 ± 10.5	75.3 ± 9.6
(b) Group B					
TBW (L)	33.3 ± 5.4	33.4 ± 5.4	32.9 ± 5.7	33.3 ± 5.6	33.5 ± 6
ECW (L)	15.7 ± 2.9	15.8 ± 2.7	15.9 ± 2.7	15.9 ± 2.6	16 ± 2.7
SBP (mm Hg)	144.3 ± 14.5	144.9 ± 13.3	143.1 ± 14.5	141.5 ± 13.8	135.4 ± 17.8*#
DBP (mm Hg)	79.3 ± 9.5	82.5 ± 9.2	79.9 ± 9.5	77.3 ± 8.9	73.2 ± 11.1*#

Table 3 Changes in PWV, AIx, and NT-proBNP during follow-up: comparison between the two groups

Data	Group A ($n = 64$)		Group B ($n = 71$)	
	Baseline	End of study	Baseline	End of study
PWV (m/s)	7.9 ± 2.5	9.2 ± 3.6*	8.2 ± 2.3	6.9 ± 2.3*
AIx (%)	37.5 ± 26.1	35.6 ± 10.7	33.1 ± 11.5	30.9 ± 13.3
NT-proBNP (pg/ml)	5,238 (2,550–14,841)	3,883 (2,009–10,119)*	7,552 (3,591–15,429)	4,561 (2,815–10,269)*

Reddan DN et al, JASN, 2005. CLIMB Study
RCT of Blood Volume Monitoring using Crit-Line vs usual care – n=433, 6 months

Table 2. Risk ratios for hospitalization (unadjusted)[a]

Hospitalization Type	Annual Event Rate		Risk Ratio		*P* Value
	Conventional	Crit-Line	Estimate	95% CI	
Non–access-related	0.77 (81)	1.15 (120)	1.49	1.07 to 2.08	0.017
cardiovascular	0.21 (22)	0.31 (32)	1.47	0.94 to 2.29	0.088
other	0.56 (59)	0.84 (88)	1.50	1.06 to 2.14	0.022
Access-related	0.26 (27)	0.36 (38)	1.42	0.93 to 2.16	0.10

Table 3. RR for hospitalization (adjusted[a])

Hospitalization Type	RR		
	Estimate	95% CI	*P* Value
Non–access-related	1.61	1.15 to 2.25	0.01
cardiovascular	1.85	1.19 to 2.86	0.006
other	1.53	1.07 to 2.19	0.02
Access-related	1.52	1.02 to 2.28	0.04

[a]Adjusted for dialysis site, race, gender, cause of ESRD (diabetes, hypertension, other), age, peripheral vascular disease, chronic obstructive pulmonary disease, and cardiac disease.

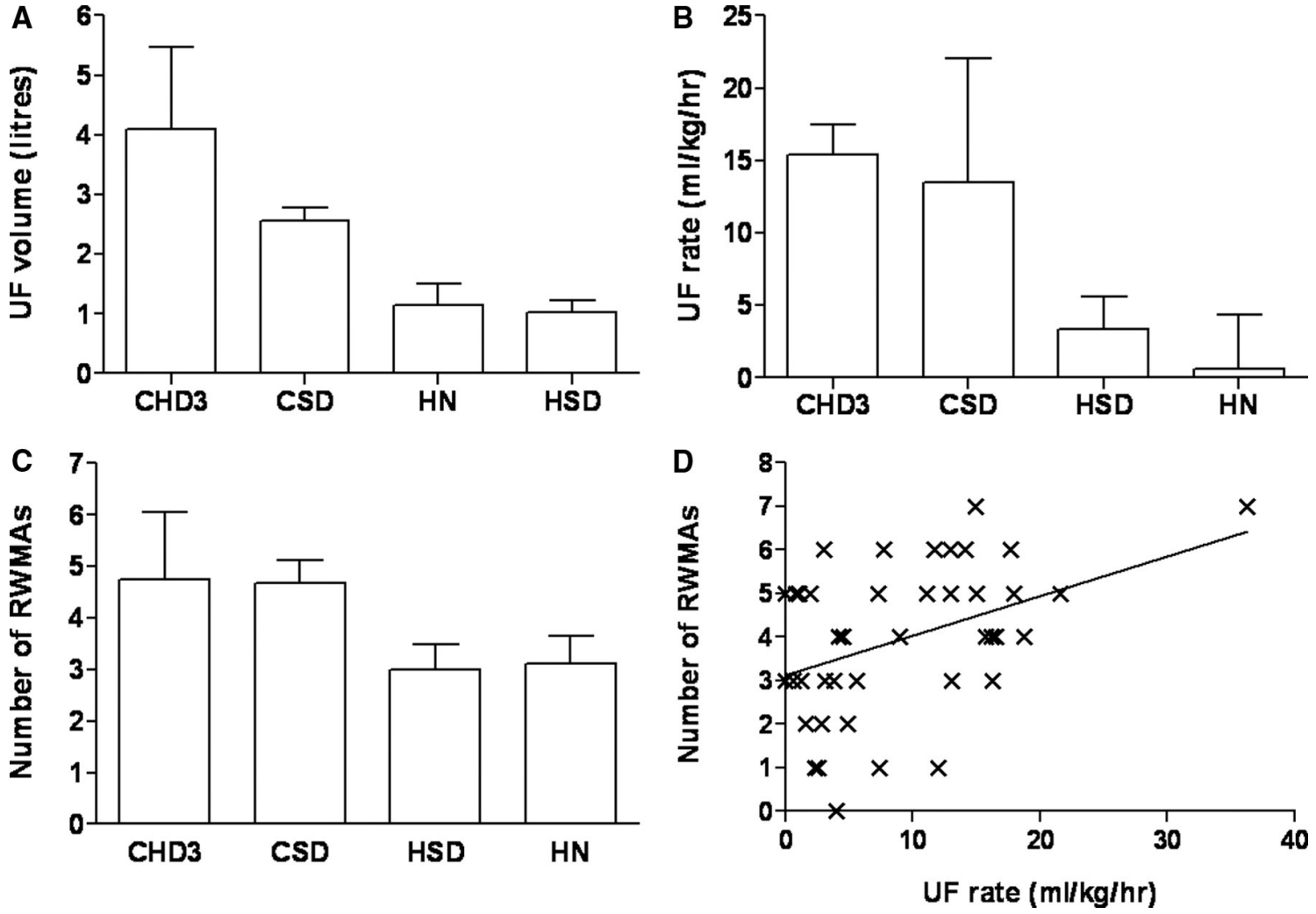
Reddan DN et al, JASN, 2005. CLIMB Study
RCT of Blood Volume Monitoring using Crit-Line vs usual care – n=433, 6 months

Table 7. Comparison of mortality by treatment groups with US Renal Data System data

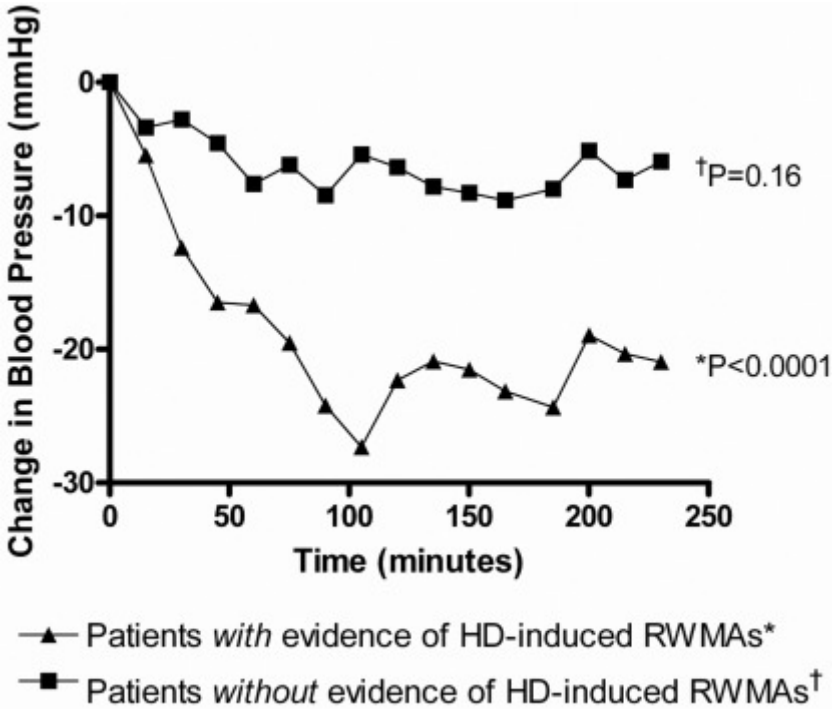
	Crit-Line Group	Usual Care Group
Patients	227	216
Deaths		
observed	19	7
expected	24.7	26.8
Deaths/100 patient-years at risk		
observed	17.4	6.4
expected	22.6	24.6
Standardized mortality ratio	0.77	0.26
χ^2	1.3	14.6
P value	NS	<0.001

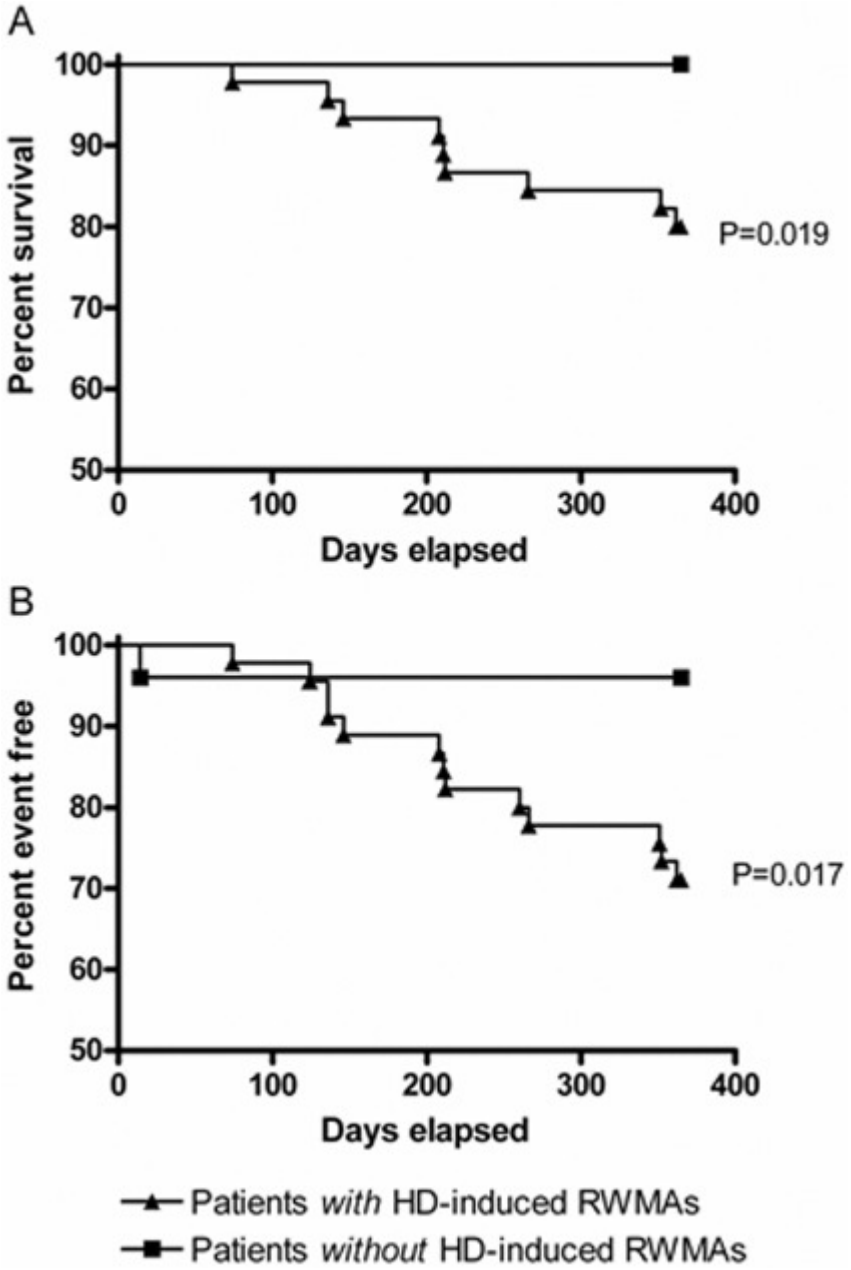
Ultrafiltration characteristics and regional wall motion abnormalities.

Jefferies H J et al. CJASN 2011;6:1326-1332



CHD3 = conventional, n=12; CSD = short daily in-centre, n=12; HSD = home short daily, n=12; HN = home nocturnal, n=10





Burton JO et al, *CJASN 2009; 4:914*

Speculation

- Some of these advantages might result from improved volume control and less intradialytic hypotension; given that the reason for the benefits postulated were reduced myocardial stunning.

- No trials!

Clearance monitors

- More patients at target?
- Does this matter in the range we tend to operate in?
- No outcome data

- Need to avoid minimalist approach – allowing reductions (in time) if target will be met

Summary

- Machine add-ons undoubtedly reduce intradialytic hypotension
- May result in more patients achieving Kt/V

- Are expensive
- Haven’t been translated into improved survival
- Like everything in Nephrology – we need trials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