MyTEMP Some Reflections

- We practice without high-quality evidence for > 90% of interventions used in hemodialysis, which is <u>not</u> in the best interests of patient care. We also want creative solutions to improve the current status quo.
- Large, well-done, multi-centre RCTs generate reliable estimates of intervention effects, so we can understand and use what improves outcomes and care.
- Individual-level, parallel-group RCT done traditionally.

  ~ **5000** patients, $**4000** per patient = $**20** million

  the major barrier why we lack evidence [most interventions no private sector partner]
- Can we advance <u>responsible</u>, <u>streamlined approaches</u> to:
  - methods,
  - the informed consent process (notification/disclosure, comprehension, choice),
  - promoting adherence to the randomly allocated intervention,
  - data requirements

  to make large trials testing solutions to improve hemodialysis care possible?
- "Democratic" allowing community sites to participate

For each hemodialysis treatment we set the temperature of dialysate on the machine

photo by Anna Frodesiak/Wikimedia

typically done

standard temperature

36.5 ºC

or **37.0**

for all patients and all treatments in a centre

historical reason for this is unclear,
likely represents what was considered
the average body temperature of most patients

in a recent international survey of over 270 centres
nearly half now use

cooler temperature

dialysate in patient care

≤ 36.0 ºC

In Ontario, before MyTEMP ≥ 8 centres set a centre-wide policy
of 35.5ºC (individualized care left with MD/patient)

Before MyTEMP, 3 cohort studies

Study	Outcome	Effect	Intervention	Control
Hsu et al.	Cardiac death	0.65 HR (95%CI: 0.44 to 0.97)	<35.5°C	35.5 to 37°C
	All-cause Death	0.75 HR (95%CI: 0.57 to 0.98)		

Hsu HJ, Yen CH, Hsu KH, et al. Association between cold dialysis and cardiovascular survival in hemodialysis patients. Nephrol Dial Transplant 2012; 27: 2457–64. **910** patients from Taiwan.

Effect of Lowering the Dialysate Temperature in Chronic Hemodialysis: A Systematic Review and Meta-Analysis

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Clin J Am Soc Nephrol 11: 442–457, 2016. doi: 10.2215/CJN.04580415

Cochrane Library

Cochrane Database of Systematic Reviews

Dialysate temperature reduction for intradialytic hypotension for people with chronic kidney disease requiring haemodialysis (Review)

Tsujimoto Y, Tsujimoto H, Nakata Y, Kataoka Y, Kimachi M, Shimizu S, Ikenoue T, Fukuma S, Yamamoto Y, Fukuhara S.
Dialysate temperature reduction for intradialytic hypotension for people with chronic kidney disease requiring haemodialysis.
Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD012598.
DOI: 10.1002/14651858.CD012598.pub2.

Research in Context

Evidence before this study

- 26 RCTs
- 20 trials fixed temp cooling, most often 35 or 35.5°C
- Standard dialysate most often 37°C
- 484 patients
- 24 of 26 trials < 20 patients
- 25 of 26 trials single centre
- 8 trials restricted to IDH, 10 were not, 8 were unclear
- Quality of methods rated to be low
- 18 of 26 trials cross-overs of only 2 treatments
- 3 trials with > 6 treatments; these trials had a high drop-out rate

Fixed reduction of dialysate temperature may reduce the rate of intradialytic hypotension compared to standard temperature dialysate, but the conclusion is uncertain

Nephrol Dial Transplant (2007) 22 [Suppl 2]: ii22–ii44
doi:10.1093/ndt/gfm019

2007

NDT
Nephrology Dialysis Transplantation

EBPG guideline on haemodynamic instability

Jeroen Kooman[1], Ali Basci[2], Francesco Pizzarelli[3], Bernard Canaud[4], Patrick Haage[5], Denis Fouque[6], Klaus Konner[7], Alejandro Martin-Malo[8], Luciano Pedrini[9], James Tattersall[10], Jan Tordoir[11], Marianne Vennegoor[12], Christoph Wanner[13], Piet ter Wee[14] and Raymond Vanholder[15]

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3.4 Dialysate and body temperature

- **Guideline 3.4.1 Cool dialysate temperature dialysis (35–36°C) or isothermic treatments by blood temperature controlled feedback should be prescribed in patients with frequent episodes of IDH (Evidence level I).**
- **Guideline 3.4.2 With cool temperature dialysis, dialysate temperature should be gradually reduced in steps of 0.5°C from 36.5°C until symptoms are controlled (Opinion).**
- **Guideline 3.4.3 Dialysate temperatures <35°C should not be used (Opinion).**

MyTEMP trial

to determine if

adopting a centre-wide protocol of

personalized cooler dialysate

superior

standard temperature dialysate 36.5 °C

↓ rate of CV related deaths or CV hospital admissions

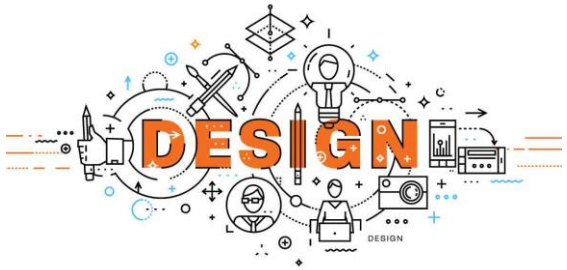
↓ drop in SBP during hemodialysis

cluster RCT 84 HD centres in the province of **Ontario**, Canada

randomly allocated

n=42
Personalized cooler dialysate

n=42
Standard temperature dialysate



~ 8000 patients ~ hemodialysis treatments ~ 7400 patients

during
4 yr
trial period
there were

- innovative & pragmatic, implemented as part of a learning health care system
- covariate constrained randomization
- registry-based (most baseline + outcome information came from existing databases)
- embedded in routine care
  - .. no research coordinators at the 84 centres
  - .. rather we trained over 2000 nurses to deliver personalized cooler dialysate
- approved to use opt-out consent process (default protocol, still individual care)
- both the protocol and statistical analytic plan were published
- research was authored with patient partners
- generated high-quality information in a feasible budget

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3.1.3. Risk of Bias

Intention-to-treat	Unique ID	Study ID	Experimental	Comparator	Outcome
	MyTEMP	1	Personalized cooler dialysate	Standard temperature dialysate	CV-mortality or major CV hospitalization

D1a Randomisation process
D1b Timing of identification or recruitment of participants
D2 Deviations from the intended interventions
D3 Missing outcome data
D4 Measurement of the outcome
D5 Selection of the reported result

+ Low Risk
! Some Concerns
- High risk

	D1a	D1b	D2	D3	D4	D5	Overall
	+	+	+	+	+	+	+

On behalf of the investigators

MyTEMP

Thank you for listening