Baxter

hemocontrol
Modality

WITH THE HEMOCONTROL MODALITY, YOU CAN START TO DECREASE THIS NUMBER

31%

OF IN-CENTRE HD PATIENTS EXPERIENCE INTRADIALYTIC HYPOTENSION (IDH)[1]

SEE HOW HEMOCONTROL TREATMENT CAN HELP PATIENTS LIKE MARY

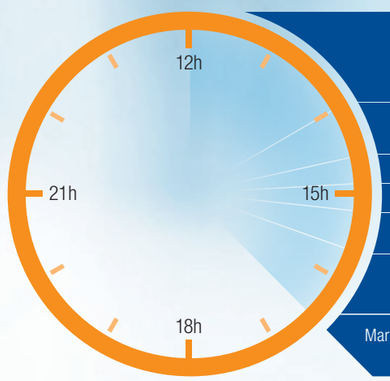
Making possible personal.

MARY SUFFERS FROM FREQUENT IDH EPISODES AND HAS CHRONIC **FLUID OVERLOAD COMPLICATIONS***

- 71 years old with chronic kidney disease from diabetic nephropathy
- Receiving in-centre HD treatment for 2 years
- Developed progressive problems with fluid overload and has needed inpatient assessment and care twice in the last 6 months
- Suffers frequent fluid overload with peripheral oedema, raised jugular venous pressure and occasional breathlessness
- Frequently attends for in-centre HD sessions 3-4kg above her prescribed post-dialysis weight
- Prone to IDH episodes and often leaves in-centre HD above her target post-dialysis weight and still fluid-overloaded

IDH is a common problem for patients like Mary, occurring in 31% of patients during in-centre HD sessions.[1†]

MARY'S TYPICAL SESSION WITH STANDARD IN-CENTRE HD



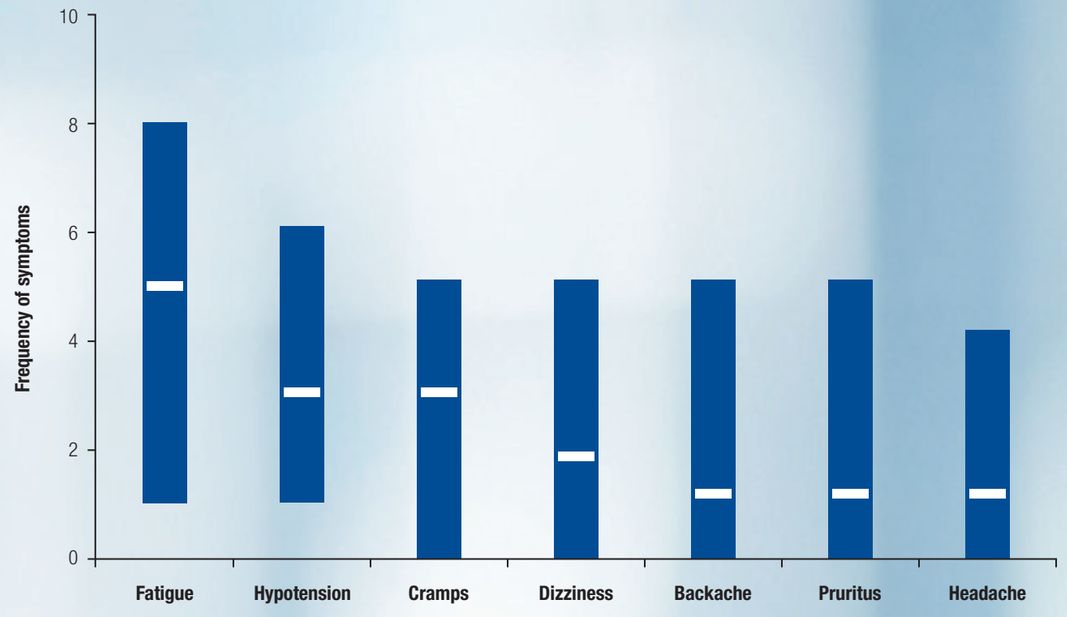
Starts standard HD treatment	**12:00**
Mary is yawning and her BP is low – UF is stopped and Mary is put into the Trendelenburg position	**14:00**
Mary's BP is still low – 50ml saline bolus is administered	**14:10**
Mary is given another 100ml of saline	**14:20**
UF restarted but at a lower rate	**14:35**
Mary is dizzy but her BP is unaffected – UF rate decreased slightly	**15:45**
Mary's BP is OK but her UF target has not been achieved due to periods of no/reduced UF and a gain of 150ml in saline boluses. Mary feels tired	**16:30**

* Based on a typical patient with IDH – names have been changed to retain anonymity.
† Based on 39,497 HD patients during a 90-day exposure assessment period.

Reference:
1. Stefánsson BV, et al. Intradialytic hypotension and risk of cardiovascular disease. Clin J Am Soc Nephrol. 2014;9:2124-2132.

UP TO 76.4% OF HD PATIENTS **REPORT SYMPTOMS OF IDH[2]**

SYMPTOMS FREQUENTLY REPORTED BY HD PATIENTS[2*]



Adapted from Caplin, 2011[2]

- Hypotension is the second most common patient-reported symptom during HD[2]
- Correcting fluid overload may lead to frequent IDH episodes and development of IDH symptoms such as cramps and fatigue[2]

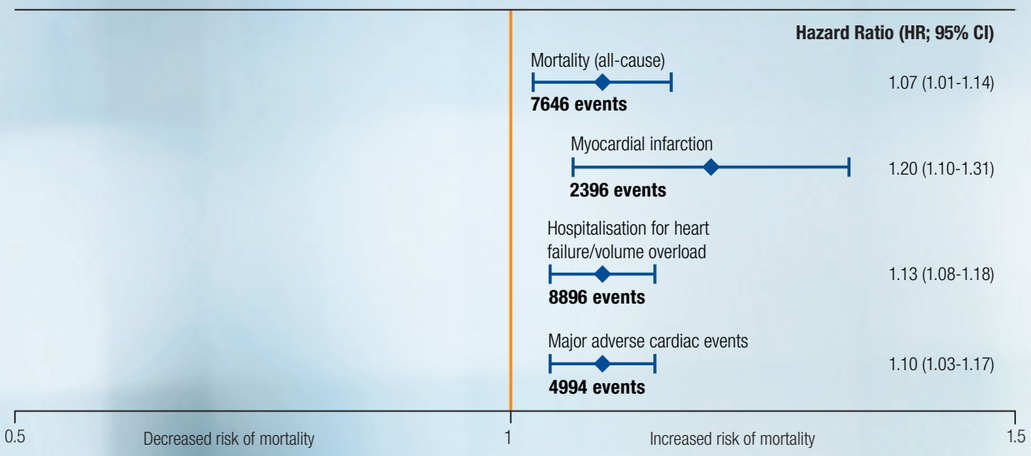
IDH IS A COMMON PROBLEM[2]

* Study based on patient questionnaires of 550 HD outpatients. The frequency of symptoms was analysed using a visual analogue scale (Score 10 = symptom present during each HD session and Score 0 = symptom always absent). Values expressed as medians (white bar) and 25-75% confidence limits (blue box)[2].

Reference:
2. Caplin B, et al. Patients' perspective of haemodialysis-associated symptoms. Nephrol Dial Transplant. 2011;0:1-7.

IDH IS ASSOCIATED WITH INCREASED **CARDIOVASCULAR (CV) MORTALITY AND MORBIDITY**[1]

IDH, CV OUTCOMES AND DEATH[1]

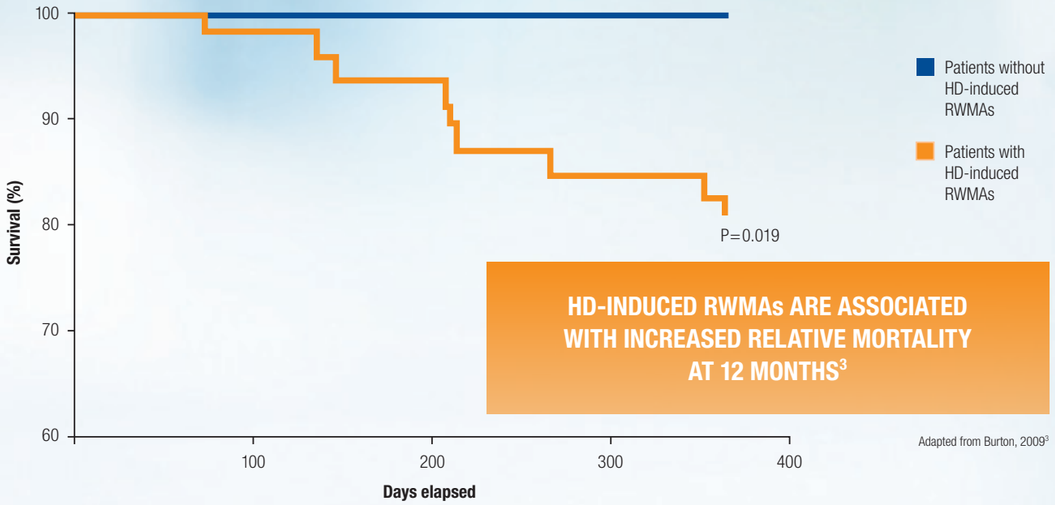


Adapted from Stefánsson, 2014[1]

HD-INDUCED MYOCARDIAL STUNNING IS A RISK FACTOR FOR CV EVENTS AND DEATH[3]

Myocardial stunning with regional wall motion abnormalities (RWMA) is common in HD sessions and associated with higher UF rates, which are also key risk factors for other CV events and death[3]

PATIENT SURVIVAL AND RWMAs[3*]



HD-INDUCED RWMAs ARE ASSOCIATED WITH INCREASED RELATIVE MORTALITY AT 12 MONTHS[3]

Adapted from Burton, 2009[3]

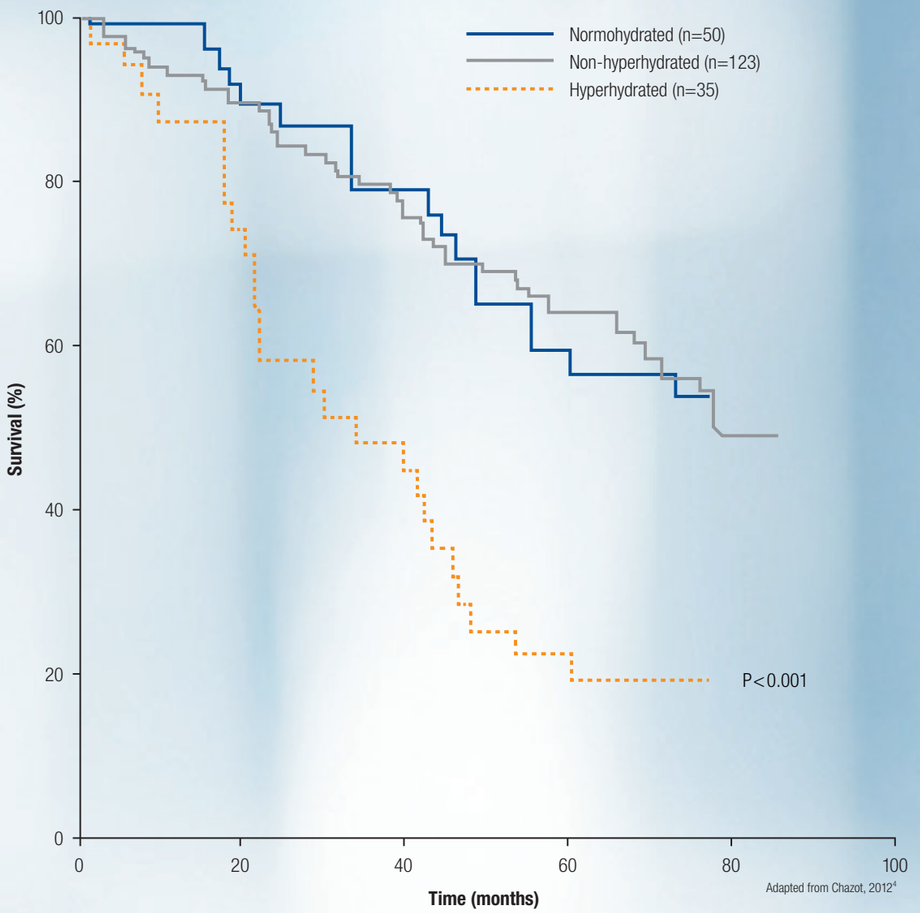
* For this 12-month observational cohort study, 70 standard HD patients were recruited.

References:
1. Stefánsson BV, et al. Intradialytic hypotension and risk of cardiovascular disease. Clin J Am Soc Nephrol. 2014;9:2124-2132.
3. Burton JO, et al. Hemodialysis-induced cardiac injury: determinants and associated outcomes. Clin J Am Soc Nephrol. 2009;4:914-920.

FLUID OVERLOAD IS ASSOCIATED WITH **INCREASED ALL-CAUSE MORTALITY**[4,5]

28.3% of patients have been reported to have severe pre-dialysis fluid overload[5]

HYDRATION STATUS AND PATIENT SURVIVAL[4*†]



Adapted from Chazot, 2012[4]

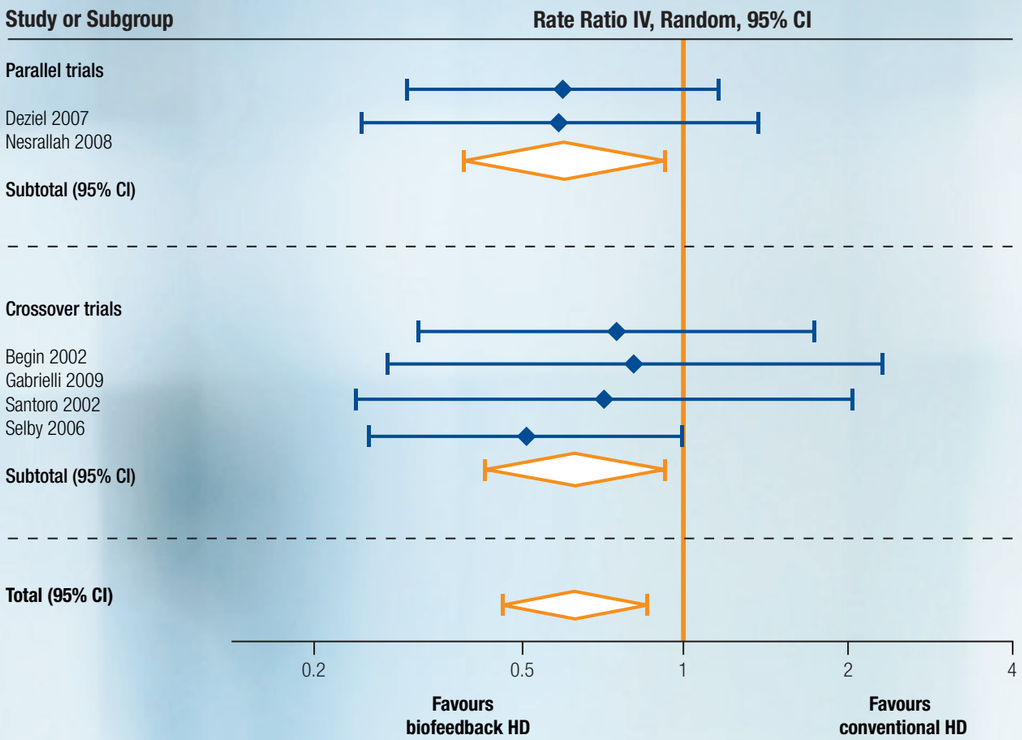
HYPERHYDRATION SIGNIFICANTLY INCREASED ALL-CAUSE MORTALITY OVER 6.5 YEARS (P<0.001)[4]

* Unadjusted Kaplan-Meier analysis: all-cause mortality, n=208.[4]
† Hydration status (ΔHS) of all patients was objectively measured with whole-body bioimpedance spectroscopy. Normohydration = -7%<ΔHS[rel]<7%. Non-hyperhydrated and hyperhydrated groups were separated retrospectively based on body composition monitor measurement.[4]

References:
4. Chazot C, et al. Importance of normohydration for the long-term survival of haemodialysis patients. Nephrol Dial Transplant. 2012;27:2404-2410.
5. Wabel P, et al. Prevalence of fluid overload in European HD patients. NDT Plus. 2010;3(suppl3):iii191-iii192.

BIOFEEDBACK DIALYSIS SIGNIFICANTLY REDUCES THE NUMBER OF **HYPOTENSIVE EPISODES BY 39%**[6]

META-ANALYSIS OF IDH REDUCTION (6 STUDIES)[6*]



Adapted from Nesrallah, 2013[6]

- The **HemoControl** modality on the **Artis Physio** system is a biofeedback control of blood volume[6] – it significantly reduced the number of IDH episodes in HD patients (risk ratio 0.61; 95% CI, 0.44-0.86; I^2=0%)[6]
- The **HemoControl** modality was shown to be the favoured HD treatment versus conventional HD in a meta-analysis of 6 studies[6]

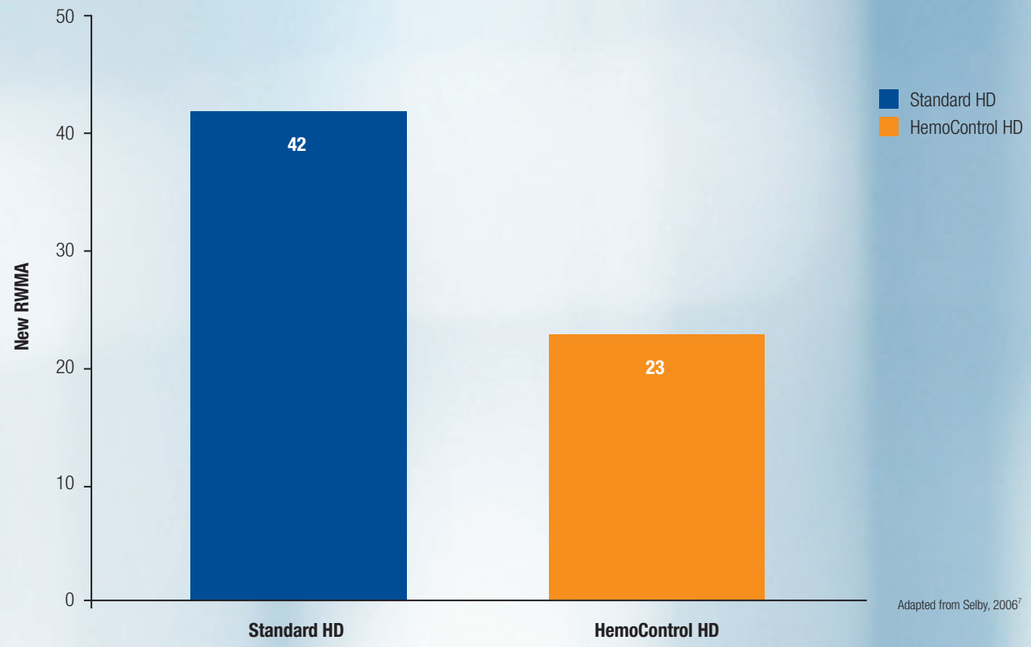
WHAT COULD THIS MEAN FOR PATIENTS LIKE MARY?

* Results from a meta-analysis of 6 clinical studies (2 randomised, parallel-arm, controlled; 4 randomised, crossover) which reported IDH frequency. Patients were aged >18 years; n ranged from 7 to 60; duration ranged from 4 to 24 weeks. Important sources of bias within studies included lack of blinding of all participants, study personnel and possibly outcome adjudicators and analysts. Data from published randomised studies of biofeedback dialysis lacked sufficient power to evaluate its impact on major outcomes such as survival and hospitalisation rates.[6]

Reference:
6. Nesrallah GE, et al. Biofeedback dialysis for hypotension and hypervolemia: a systematic review and meta-analysis. Nephrol Dial Transplant. 2013;28:182-191.

HEMOCONTROL TREATMENT REDUCES CARDIAC EFFECTS FREQUENTLY **OBSERVED DURING HD SESSIONS**[7]

IMPACT OF USE OF THE HEMOCONTROL MODALITY ON RWMA[7*]



Adapted from Selby, 2006[7]

- **HemoControl** treatment reduces the number of RWMAs developed during HD sessions (OR, 1.8; 95% CI, 1.1-3.0)[7]

HEMOCONTROL TREATMENT MAY HELP ALLEVIATE IDH-RELATED CV RISK IN PATIENTS LIKE MARY

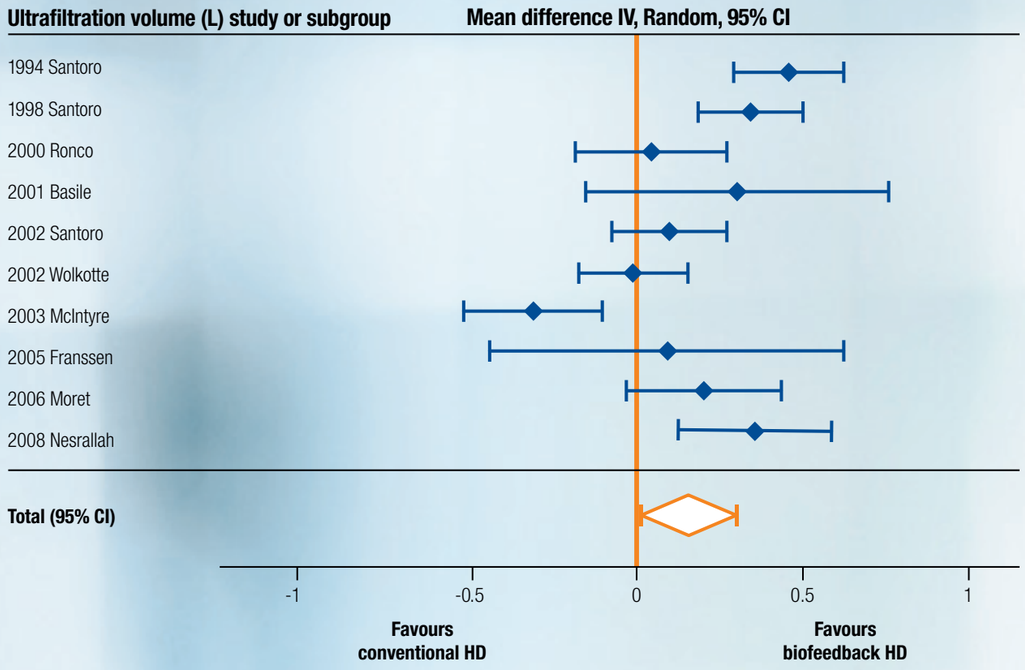
* Results from a 2-week, randomised, crossover clinical study in 8 male patients; all were long-term HD patients (>12 months), were prone to IDH, and had LV hypertrophy.[7]

Reference:
7. Selby NM, et al. Occurrence of regional left ventricular dysfunction in patients undergoing standard and biofeedback dialysis. Am J Kidney Dis 2006;47:830-841.

HEMOCONTROL TREATMENT MAY MAKE CLINICAL TARGETS SUCH AS **FLUID BALANCE MORE ACHIEVABLE**[8]

Achieving the prescribed post-HD weight is a critical goal for doctors, nurses and patients

META-ANALYSIS OF UF DURING HD[8*]



Adapted from Winkler, 2011[8]

Fluid balance is better achieved with **HemoControl** HD versus standard HD:[8,9]

- **HemoControl** treatment allows a higher UF volume without IDH
- Fluid balance achieved due to decreased symptomatic IDH episodes and increased patient tolerance of HD

HEMOCONTROL TREATMENT MAY HELP PATIENTS LIKE MARY ACHIEVE THEIR PRESCRIBED POST-HD WEIGHT – A LONG-TERM PROBLEM FOR MANY

* Data report the pre- to post-dialysis weight (in Kg or L) expressed as mean ±SD over the total assessed dialysis.[8]

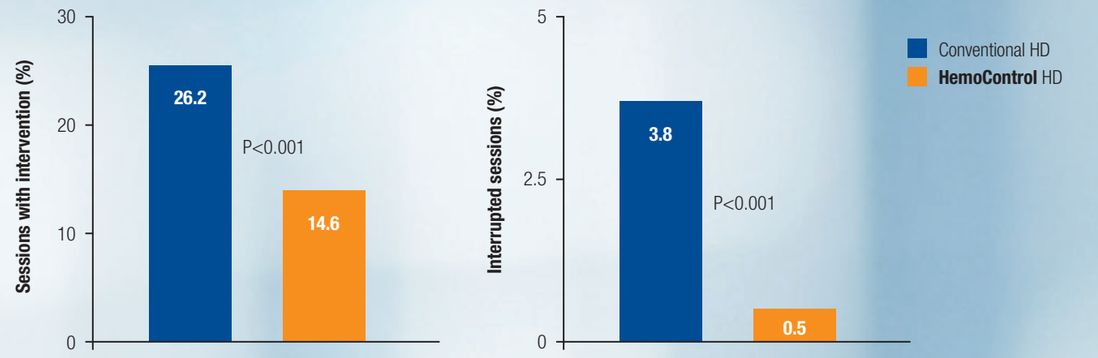
References:

8. Winkler RE, et al. Blood Volume Regulation. In: Technical Problems in Patients on Hemodialysis. Rijeka. Croatia. 2011: 235-250.

9. Ronco C, et al. Impact on biofeedback-induced stability on hemodialysis tolerance and efficiency. Kid Ont. 2000;58 800-808.

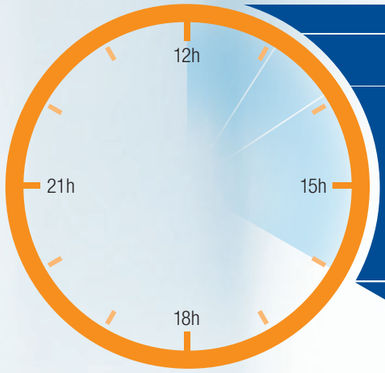
THE HEMOCONTROL MODALITY SIGNIFICANTLY REDUCES THE NEED FOR **NURSE INTERVENTION AND INTERRUPTED SESSIONS DURING HD**[10]

THE IMPACT OF THE HEMOCONTROL MODALITY IN HD[10*]



Adapted from Doria, 2014[10]

EXAMPLE OF MARY'S IN-CENTRE HD SESSION WITH THE HEMOCONTROL MODALITY



Mary starts HD treatment – the **HemoControl** biofeedback function is activated	**12:00**
The **HemoControl** function starts adjusting the UF rate and the Na+ concentration based on Mary's capacity to refill and within the predefined tolerances	**12:05**
SmartScan notification alerts the nurse that a manual adjustment may be needed as the tolerances are exceeded. As Mary's BP can tolerate UF, the nurse decides to increase UF volume by 0.2L	**13:15**
Nurse report: Mary has been refilling well and has tolerated an extra 0.2L fluid removal, without a BP drop. The signs of overloading are still visible and should be dealt with little by little at each session	**16:00**

HEMOCONTROL TREATMENT SUCCESSFULLY REDUCED IDH SYMPTOMS AND THE NEED FOR MULTIPLE FLUID BOLUSES, IMPROVING RECOVERY TIME AND REDUCING NURSE INTERVENTIONS

* Results from a 6-month crossover study in 10 IDH-prone patients, aged 76.7±8.3 years. The primary endpoint was number of HD sessions in which physicians/nurses intervened to manage IDH episodes; external staff (1 physician and 1 nurse) reviewed the interventions to decide whether they were in accordance with protocol. A secondary endpoint was number of HD sessions ended before reaching the prescribed treatment time.[10]

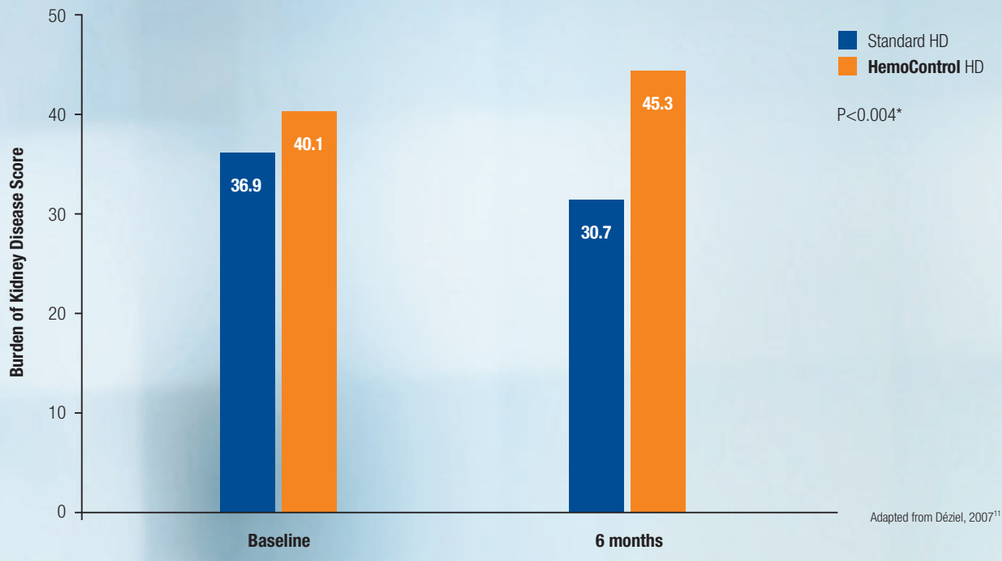
Reference:

10. Doria M, et al. The dialysis staff workload and the blood volume tracking system during the hemodialysis sessions of hypotension-prone patients. In J Artif Organs. 2014;37(4):292-298.

HEMOCONTROL TREATMENT MAY REDUCE **THE BURDEN OF KIDNEY DISEASE**[11]

A reduction in IDH episodes and nurse interventions contributes to improved quality of HD[11]

BURDEN OF KIDNEY DISEASE IN HD[11]



Adapted from Déziel, 2007[11]

HemoControl treatment has been shown to significantly reduce the burden of kidney disease (P=0.004)[11]

- This significant improvement was observed regardless of age, gender, ethnicity, hypotension and nursing interventions

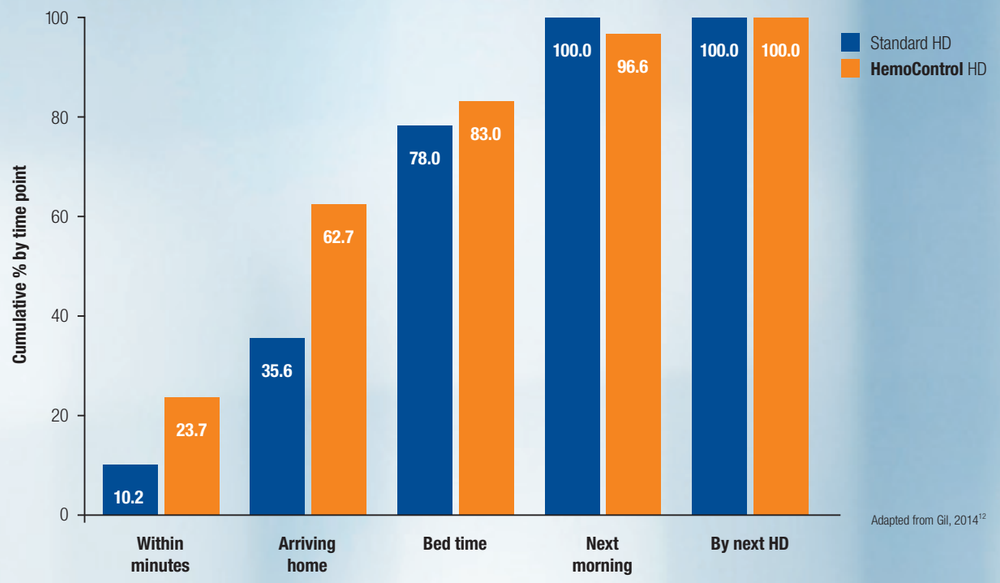
IMPROVE TREATMENT TOLERANCE FOR PATIENTS LIKE MARY THROUGH SMOOTH, EVENT-FREE, IN-CENTRE HD WITH THE HEMOCONTROL MODALITY

* P value for comparison in mean score variation between the HemoControl group and the standard HD group.

Reference:
11. Déziel C, et al. Impact of hemocontrol on hypertension, nursing interventions, and quality of life: A randomised, controlled trial. Clin J Am Soc Nephrol. 2007;2:661-668.

HEMOCONTROL TREATMENT IS READY **TO HELP PATIENTS LIKE MARY**

RECOVERY TIME, POST-HD[12*]



Adapted from Gil, 2014[12]

Recovery time from fatigue after HD is significantly shorter after an HD session using the **HemoControl** modality compared with standard HD (P=0.048)[12]

- without the **HemoControl** modality, Mary is often fatigued after in-centre HD and can barely enjoy her evening

SHORTER RECOVERY TIME LETS PATIENTS LIKE MARY FOCUS MORE ON THEIR LIFE AND LESS ON THEIR TREATMENT

* Results from an 18-week, multicentre, crossover clinical study in 60 patients, aged 57±11 years; all were chronic HD patients and were IDH-prone.[12]

Reference:
12. Gil HW, et al. Efficacy of hemocontrol biofeedback system in intradialytic hypotension-prone hemodialysis patients. J Korean Med Sci. 2014;29:805-810.

THE HEMOCONTROL MODALITY IS AN INTEGRATED FUNCTION OF **THE ARTIS PHYSIO DIALYSIS SYSTEM**

- With the **HemoControl** modality, 39% of IDH episodes may be avoided[6]
- The **HemoControl** modality proactively adjusts UF rates and sodium concentration as a response to the variation of blood volume monitored throughout the HD session
- The reduction of IDH episodes is favourable to treatment tolerance and may help to facilitate clinic operations

INDIVIDUALISED TREATMENT WITH THE ARTIS PHYSIO

- The **Artis Physio** dialysis system provides all necessary treatment modalities and tools to take full benefit of individualised quality-assured dialysis

THE HEMOCONTROL MODALITY MAY HELP PATIENTS LIKE MARY ACHIEVE UF TARGETS AND ALLEVIATE IDH-RELATED CV RISK

Reference:
6. Nesrallah GE, et al. Biofeedback dialysis for hypotension and hypervolemia: a systematic review and meta-analysis. Nephrol Dial Transplant. 2013;28:182-191

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EUMP/MG179/15-0001(2) Oct 2017