HFR Aequilibrium Improves Intradialytic Hypotension in Hemodialysis Patients

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Background
Intradialytic hypotension is the major clinical problem during hemodialysis treatment. HFR-Aequilibrium, a profiled hemodiafiltration supported by the Natrium sensor for the sodium measure, can reduce intradialytic hypotension. We present a clinical case with an observational period of 6 months, exactly 3 months with standard treatment followed by 3 months of HFR-Aequilibrium using Flexya dialysis machine.

Methods
A 52-year-old female patient with lupus nephritis started hemodialysis treatment in our Renal Unit at the age of 21. She also had epilepsy due to lupus encephalopathy. At the age of 29, after 8 years of dialysis treatment, she received a donor kidney transplant from a deceased patient. Ten years later, at the age of 39, she was submitted to ureterocystoneostomy for vesico-ureteral reflux. At the age of 40, her renal function declined because of antibody mediated rejection. At the age of 48, she started hemodialysis treatment in another Renal Unit for end-stage renal disease and after one year she joined two waiting lists for renal transplant. At the age of 50, she had intermittent claudication. Peripheral arterial disease of the lower extremities was diagnosed, and she was submitted to percutaneous transluminal angioplasty and stent placement in external iliac artery. About one year ago she decided to continue hemodialysis treatments in our Renal Unit. At first, we continued standard treatment, but then she switched from standard treatment to HFR-Aequilibrium because of intradialytic hypotension.

Results
She showed improvement of intradialytic cardiovascular stability because we registered a rate of 15% of sessions with nurse intervention for hypotension (6 of 39) during standard treatment vs. 3% of sessions with HFR-Aequilibrium (1 of 39). In the last year we switched 12 patients from standard treatment to HFR-Aequilibrium improving the quality of dialysis sessions with an interesting reduction of hypotensive episodes from 11% with standard treatment to 3% with HFR-Aequilibrium. Hypotensive prone patients with more than one episode per month had a reduction of nurse intervention for hypotension from 21% to 4% of sessions using HFR-Aequilibrium. (figure 1)

Conclusions
HFR-Aequilibrium, using Flexya dialysis machine, improves intradialytic cardiovascular stability in our patients, as shown in this clinical case and in our observational analysis of 12 patients.
All patients | Hypotensive prone
---|---
Standard HD | 11 | 21
HFR Aequilibrium | 3 | 4

Figure 1.

References
Isonatric Dialysis Biofeedback in Hemodiafiltration with Online Regeneration of Ultrafiltrate (HFR) in Hypertensive Hemodialysis Patients: A Randomized Controlled Study.

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Background
Dialysis biofeedback in hemodiafiltration with online regeneration of ultrafiltrate (HFR) could help to improve arterial hypertension. We evaluated the impact of isonatric HFR (HFR-iso) on hypertension control compared to conventional HFR.

Methods
The Isodial study is a prospective multicenter, open-label, controlled, and randomized study (15). Patients from ten French and Belgian dialysis centers were included. After a run-in period of one week, patients having an arterial blood pressure >140/90 mmHg were randomized either to conventional HFR (control treatment) or to Isonatric HFR (intervention treatment) with a 1:2 allocation ratio. Patients had 24 dialysis sessions during eight weeks in their treatment group. The randomization was centrally carried out according to a randomization list. This study received approval from the local ethics committee (CPP Ile de France VI) and all the patients gave written informed consent to participate. End points: The primary end point was the variation between the first and the last dialysis session of the predialytic mean systolic blood pressure (SBP) measured three times at each session before any connection to the hemodialysis circuit.

Inclusion and exclusion criteria: Patients were included in the study if they met the following criteria: older than 18 years old, dialyzed for more than three months, treated three times a week for 3.5 to 5 hours, having a systolic arterial blood pressure greater than 140 mm Hg or a diastolic blood pressure greater than 90 mm Hg evaluated at dialysis start for at least two of the three dialysis sessions in the week of the run-in period, absence of acute adverse medical events during the three last months and having signed the informed consent. Pregnant women, patients with a life-threatening disease, those with an acute illness during the last three months, patients included in another study protocol and patients with a psychiatric disease were not included. Hemodialysis treatment: Hemodialysis treatment was performed according to the following guidelines: 3.5 to 5 hours, prescribed blood flow rate, dialysate temperature <37°C and ultrafiltration rate to reach the dry weight in the two groups of treatment. Dialysate conductivity was set during the run-in period for the conventional HFR arm (control group) and was not modified during the study protocol. In HFR-iso (treatment group), the dialysate conductivity was automated and driven by the monitor to reach a patient conductivity equal to the value measured at 15 minutes of dialysis and using ultrafiltration and sodium profiles.
Sample size calculation: For an arterial blood pressure standard deviation of 15 mm Hg, the possibility to demonstrate a difference of 10 mmHg of the predialytic SBP between the two therapies with a power of 80% was reached with 28 patients per group. Considering a dropout rate of 10%, we planned to include 70 patients, 23 in the control group and 47 in the isonatric group. Statistics data was expressed as mean (± standard deviation) for quantitative variables and frequency (%) for qualitative variables. For normally distributed quantitative variables, the t-test was used, while for the non-normally distributed variables (variation of the defined daily dose of antihypertensive drugs, number of sessions with at least one hypotension and/or intolerance criteria), the Wilcoxon signed-rank test was performed to compare the variation in parameters between the first and the last dialysis session. Fisher’s exact-test was used to assess differences in frequency of qualitative variables. The course of the systolic arterial blood pressure during follow-up was analyzed using linear mixed models with time as both a fixed and random effect (degree of freedom estimated using Satterthwaite approximation) and the treatment effect characterized by a group* time interaction. To identify factors that influence the blood pressure, a covariance analysis was conducted with systolic arterial blood pressure as dependent variable and gender, age, dry weight, presence of diabetes or co-morbidities and total defined daily dose of antihypertensive treatment at baseline as independent variables. Influence of these variables on the evolution was tested via interactions between the given factor and the time variable.

Fig. Course of the predialytic systolic blood pressure according to the treatment group (for a mean age of 69 years)

In the isonatric HFR group, the intercept was 157.5 ± 3.8 mmHg and the slope was -0.12 ± 0.08 mmHg per day (p = 0.021). In the conventional HFR group, the intercept was 147.7 ± 2.6 mmHg and the slope was 13 ± 0.05 mmHg per day (p = 0.121). The conventional HFR group being the reference, the estimates were 9.9 ± 4.7 (p = 0.041) for the group, 0.3 ± 0.2 (p = 0.207) for the day, 0.1 ± 0.1 (p = 0.476) for the age, -0.3 ± 0.1 (p = 0.012) for the interaction time*group and -0.01 ± 0.00 (p = 0.053) for the interaction time*age.
Results
47 hemodialysis patients were included and randomized (ratio2/1) HFR-iso versus HFR during 24 dialysis sessions. In the isonatric HFR group (32 patients, 768 dialysis sessions), the predialytic SBP decreased from S1 to S4 of 9 ± 20 mmHg and increased of 5 ± 24 mmHg in the HFR group (15 patients, 360 dialysis sessions), variation that differed between the two groups (ΔS1-S24, p = 0.035; interaction group*time, p=0.012, figure). The DBP (HFR-iso -3 ± 14 mmHg vs HFR 5 ± 13 mmHg; p=0.088), the DDD of antihypertensive treatment and the dry weight did not vary significantly during the study. The number of sessions complicated by symptomatic hypotension was similar in the 2 groups.

Conclusions
Isonatric HFR improved blood pressure control without increasing dialysis hypotension episodes.

References