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Ultrafiltration (UF) Effectiveness on intradialytic hypertension (IDH) in chronic hemodialysed patients in a nephrology unit in Dakar: UF-IDH clinical trial

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ABSTRACT

Introduction
Progressive ultrafiltration (UF) could improve IDH. The aim of this work was to evaluate the effectiveness of progressive UF in the management of IDH.

Methods
This randomized clinical trial in two groups: interventional group A (UF, n = 12) and control group B (n = 12), was conducted in chronic hemodialysis patients with IDH. A first phase of cross-sectional collection of BP before and after dialysis, during 2 weeks, made it possible to obtain this cohort of 24 patients. A progressive decrease in basal weight of 0.25 kg per session as a function of hemodynamic tolerance was achieved in group A. The primary endpoint, the proportion of patients with disappearance of IDH, was assessed at baseline end of the 4th and 8th week.

Results
At the 4th week, the IDH disappeared in 83.3% and 41.7% of the patients of the group A and B respectively with a hazard ratio (HR) at 0.29; IC 95 = [0.14-0.59]; p = 0.035. At the 8th week, the IDH was missing in 72.7% and 66.7% of the patients of the group A and B respectively with a HR at 0.76; IC 95 = [0.58-1.00]; p = 0.75. In addition, the decrease in basal weight was associated with the occurrence of side effects (p = 0.0001) with a HR of 5 [1.45-7.27]. UF discontinuation was required in 4 patients in group A (36.4%).

Conclusion
Progressive UF was associated with a significant reduction in the prevalence of IDH in our patients at week 4.

Keywords: intradialytic hypertension - ultrafiltration - hemodialysis – Dakar.

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Introduction

The definition of intradialytic hypertension (IDH) remains unclear and depends on the authors. It is defined to be an increased blood pressure (BP) by more than 10 mmHg in postdialysis compared to the pre-dialysis period [1]. Its diagnosis is based on three main criteria: 1 the increase of the BP levels during the session higher than those recorded at the beginning of the session; the persistence of this phenomenon at the end and just after the session with a referencial postdialysis number> 130/80 mmHg [2]; the recurrence of this phenomenon during several dialysis sessions.

Its prevalence varies according to the definition used. It was estimated at 15% in a study in the USA [3]. In Morocco and South Africa, it was estimated respectively at 29.17% [4] and 28.4% [5]. Faye et al in Senegal reported a prevalence of 22.6% [6].

This prevalence of IDH in Senegal is warning because IDH is currently considered a cardiovascular mortality risk factor [7]. A high risk of hospitalization and death at 6months was noted by Inrig et al. [8] in patients who had an increased BP of 10 mmHg during the dialysis session, compared to patients whose BP decreased during the dialysis session.

Several physiopathological mechanisms have been proposed to explain the genesis of IDH. Volume expansion remains the main mechanism. This hypothesis is supported by a post hoc analysis of the dry weight reduction in hypertensive hemodialysis patients trial (DRIP). Besides a decrease of outpatients BP, this analysis outlines a change of the slope of intradialytic BP [9]. More recently, a cross-sectional study used impedancemetry to compare body composition in hemodialysed patients with different intradialytic BP profiles [10]. The results showed that patients with increased BP on dialysis had a higher ratio of extracellular water and total body water. These studies support the practice suggesting that the initial management approach of patients with IDH should include an assessment of the dry weight. But in some patients, it increases and remains high during and after the dialysis session despite the UF, hence the term paradoxical high blood pressure [1]. To our knowledge, no interventional study on IDH has been performed in Senegal. It is in the vires of this that we conducted this work to evaluate the effectiveness and tolerance of ultrafiltration (UF) on IDH.

Patients and methods

(Supporting information= study protocol, study flowchart)

Trial process

An interventional, randomized (1:1), open to 2-arm and monocentre study was conducted over 10 weeks in the 2 hemodialysis units at Aristide Le Dantec Hospital (September,10- November, 17, 2018). All chronic hemodialysed patients (for more than 3 months) in the various aforementioned units, undergoing IDH, aged at least 18 years and consenting to the study were included. Patients with the following criteria were not included: missing 3 sessions out of the last 6 before randomization; a clinical volume overload; clinical dehydration; intolerance to UF; severe cardiovascular comorbidities (stroke, ischemic heart disease, severe lower limbs obliterating arteriopathy (LLOA) or left ventricular ejection fraction (LVEF) less than 50%); deciding to not participate in the study; chronic hypotension.

Data were collected through: a pre and postdialysis systolic blood pressure (SBP) and diastolic blood pressure (DBP) record chart; an epidemiological, anthropometric, clinical, paraclinical and therapeutic data collection chart; a record of the average BP and weight and a record of the different causes of UF arrest.

The study was conducted in two phases:

First phase:

The BP before and after the last 6 hemodialysis sessions from 10 to 22 September 2018 were gathered. The IDH [1] was retained according to the following criteria: the increase of the SBP just after the hemodialysis session> 10 mmHg compared to those recorded at the beginning of the session with a threshold value of 130/80 mmHg; recurrence of this phenomenon during at least 4

consecutive hemodialysis sessions. This collection allowed to set a cohort of hemodialysed patients with IDH. The design of the study is illustrated in Figure 1.

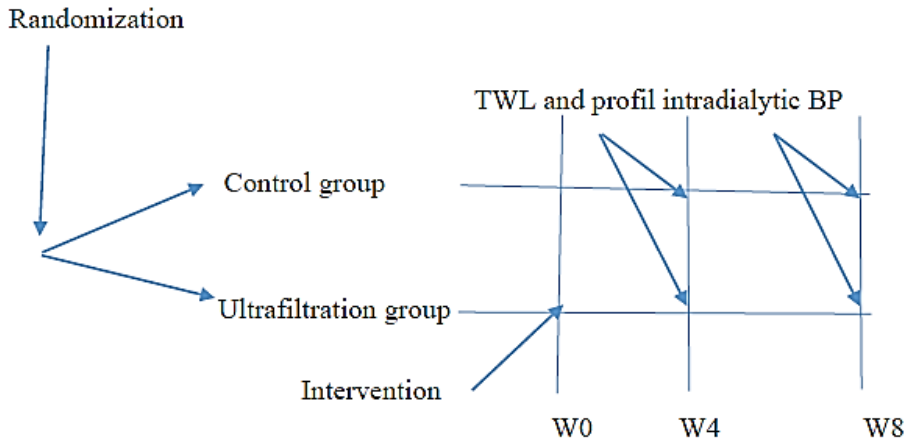


Figure 1 : Diagram of UF-IDH clinical trial, Dakar/Sénégal, 2018

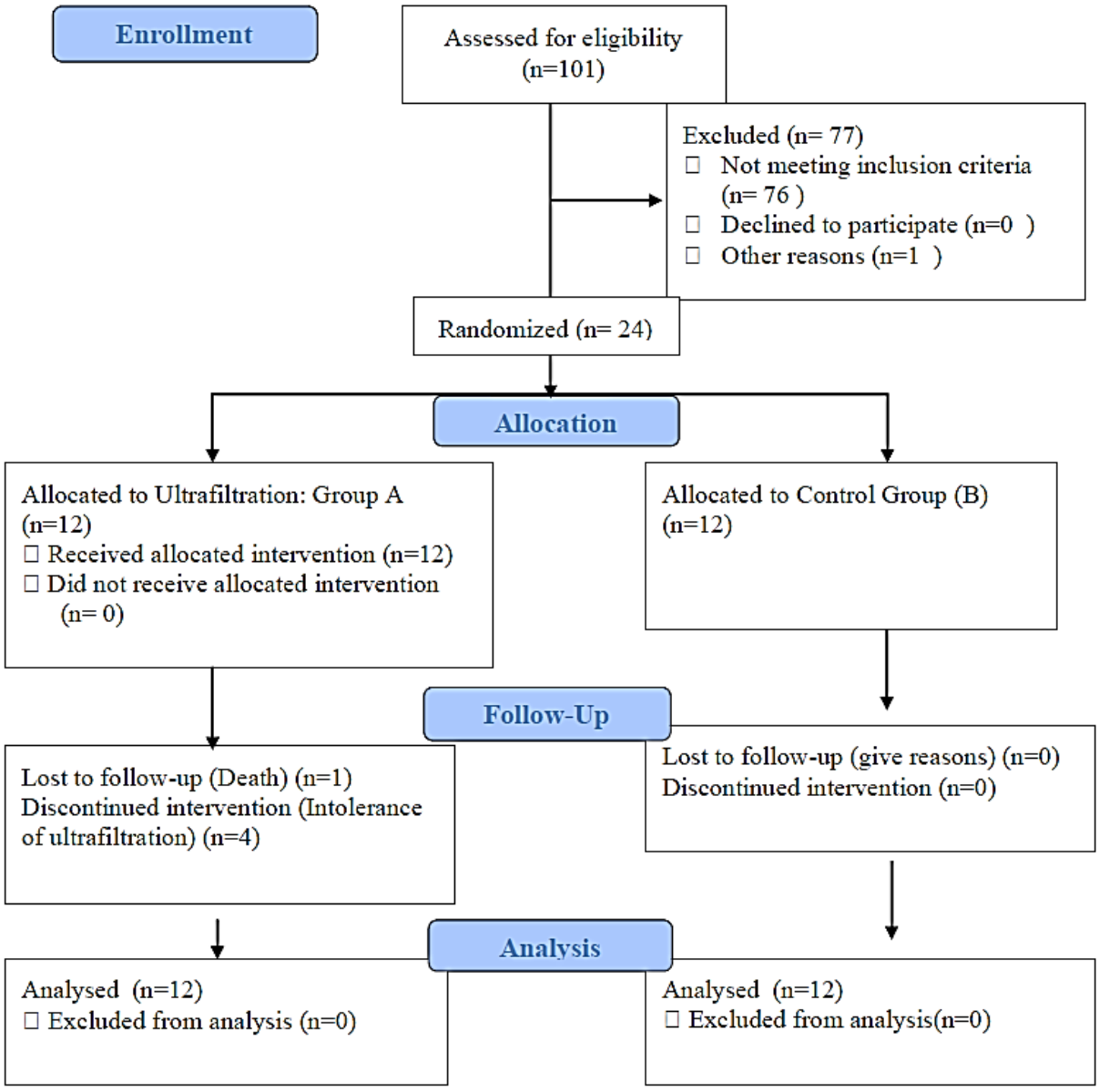


Figure 2 : Flowchart of UF-IDH clinical trial, Dakar/Sénégal, 2018

Second phase: It was about the intervention phase that lasted eight (8) weeks from September 24 to November 17, 2018. Patients with IDH were randomized into two (2) groups: group A for intervention (ultrafiltration group) and group B (control group). Patients in the ultrafiltration group underwent a very gradual decrease in baseline weight of 0.25 kg per session with a decreasing UF profile depending on hemodynamic tolerance. This hemodynamic tolerance was appreciated by the clinical assessment in particular the occurrence of cramps, hypotension or other signs of hypovolemia and the doctor decided to stop the UF or not. All signs of intolerance and all modifications of the initial procedure were recorded on the collection chart by the doctor. The mean total weight loss (TWL) was calculated at the end of week 4 (W4) and week 8 (W8). The intradialytic blood pressure profile was evaluated during weeks 3 and 4 (W3 and W4) and during weeks 7 and 8 (W7 and W8) of intervention (Figure2). Antihypertensive treatment could be reduced in both groups during the intervention phase according to BP levels and the physician's assessment. The other elements for intradialytic BP control including temperature and sodium content of the dialysate were appreciated by the physician. These two groups were compared according to the judgment criteria at week 4 and 8 of intervention. Patients with intolerance to UF (UF arrest due to side effects for 3 successive sessions despite adequate management of antihypertensive treatment) were analyzed.

Judgment criteria

The main judgment criterion was the proportion of patients with IDH disappearance. The secondary judgment criteria consisted of: the change in SBP average at week 4 and week 8; the assessment of UF tolerance in the interventional group; the assessment of interdialytic weight gain (IDWG) at week 8 and the assessment of the need for antihypertensive drugs at week 8.

Statistical analysis

A double entry by Excel (16.0 Redmon / USA) and Epi-info (7.1.5 Comté De DeKalb / Georgy / USA) and a double analysis by Sphinx version V5 (74650 Chavanod / France) and STATA 15 were performed. Per protocol analysis was carried. The results are presented by averages and standard deviations for the quantitative parameters and by proportion for the qualitative parameters. The relative risk or hazard ratio followed by the confidence interval were used as association estimators. The Wilcoxson test for proportions and the Kolmogorov-Smirnov test for average comparison were used as statistical tests. The threshold of significance was retained for a p-value <0.05.

Ethical considerations

The protocol was submitted to the ethics committee of the Faculty of Medicine, Pharmacy and Odontology of Cheikh Anta Diop University in Dakar. All patients had freely signed an informed and formal consent form. This clinical trial was registered on the 0398/2019 / CER / code of the UCAD Research Ethics Board.

Registre and registration number

This clinical trial was not registered before recruitment began because the authors were unaware that there was a clinical trial registry. But The authors confirm that all ongoing and related trials for this intervention are registered

Results

In the first phase, out of 101 chronic hemodialysed patients, 25 had IDH, a prevalence of 25%. After excluding 1 patient who was transferred to peritoneal dialysis, 24 were retained. The mean age of the patients was 50.42 ± 12.55 years with a sex ratio of 1.18. The most common causative nephropathy was benign nephroangiosclerosis (NAS) in 11 patients (45.83%). The mean duration of dialysis was 93.62 ± 55 months. Twenty-three (23) patients (95.8%) received 3 sessions of 4 hours per week with an average dry weight of 59.87±11.08 Kg. The average number of antihypertensive drugs was 2.15 ± 1.06. Among the parameters studied, except erythropoesis stimulating agent (ESA) (P = 0.03), there was no statistically significant difference between groups A and B (Table I).

Table I: Characteristics of the 24 chronic hemodialysis patients included in the UF-IDH clinical trial, Dakar / Senegal 2018.

Parameters	Mean/percent/effective(n)			P
	Total	A	B	
Age (ans)	50,42 ± 12,55	50,33 ± 12,40	50,50 ± 13,30	0,94
Dialysis duration (month)	93,62 ± 55	80,20 ± 51,60	106,40 ± 60,20	0,26
Dry weight (kg)	59,87±11,08	59,90 ± 10,90	56,90 ± 13,40	0,54
IDWG (kg)	1,83 ± 0,73	1,88 ± 0,60	1,74 ± 0,80	0,60
Dialysate sodium (mEq/l)	138± 0,00	138,00 ± 0,00	138,00 ± 0,00	0,36
Dialysate température (°C)	36,50± 0,00	36,50 ± 0,00	36,50 ± 0,00	0,18
Dialysate Calcium (mmol/l)	1,50± 0,09	1,54 ± 0,09	1,50 ± 0,00	0,18
Œdéma (n)	1	1	0	0,37
STJV (n)	0	0	0	0,00
Dehydratation (n)	0	0	0	0,00
Residual diuresis (n)	9	4	5	0,45
Hemoglobin (g/dl)	8,32 ± 1,76	8,40 ± 1,60	8,30 ± 2,00	0,92
Hematocrit (%)	25,11 ± 5,43	25,30 ± 4,40	42,90 ± 55,10	0,26
Albumin (g/l)	36,85 ± 36,00	39,40 ± 0,60	35,60 ± 7,30	0,52
Pre-dialysis SBP (mmHg)	150,33 ±11,63	151,48 ± 11,00	149,18 ± 10,60	0,83
Post-dialysis SBP (mmHg)	166,38 ± 15,62	169,38 ± 14,43	163,38 ± 15,90	0,70
Pre-dialysis DBP (mmHg)	79,60 ± 8,45	79,06 ± 8,00	80,14 ± 8,50	0,86
Post-dialysis DBP (mmHg)	84,79 ± 8,51	85,20 ± 8,60	83,78 ± 7,89	0,82
Pre-dialysis CF (ppm)	72,96 ± 8,20	73,00 ± 8,00	72,92 ± 8,10	0,90
Post-dialysis CF (ppm)	74,43 ± 10,60	75,00 ± 9,10	73,86 ± 10,00	0,82
ESA (%)	20,83	4,16	16,66	0,03

STJV=spontaneous turbulence of jugular vein, IDWG=interdialytic weight gain, SBP= systolic blood pressure, DBP= diastolic blood prssure, CF= cardiac frequency, ESA= erythropoesis stimulating agent.

Table II: Proportion of intradialytic hypertension at week 4 (W4) by group in the UF-IDH clinical trial, Dakar / Senegal, 2018.

	Intradialytic Hypertension			
Group	Presence		Absence	
	Effective	Proportion (%)	Effective	Proportions(%)
A	2	16,66	10	83,33
B	7	58,33	5	41,66
Total	9	37,50	15	62,50
p=0,03 ; HR = 0,29 ; IC 95= [0,14-0,59]				

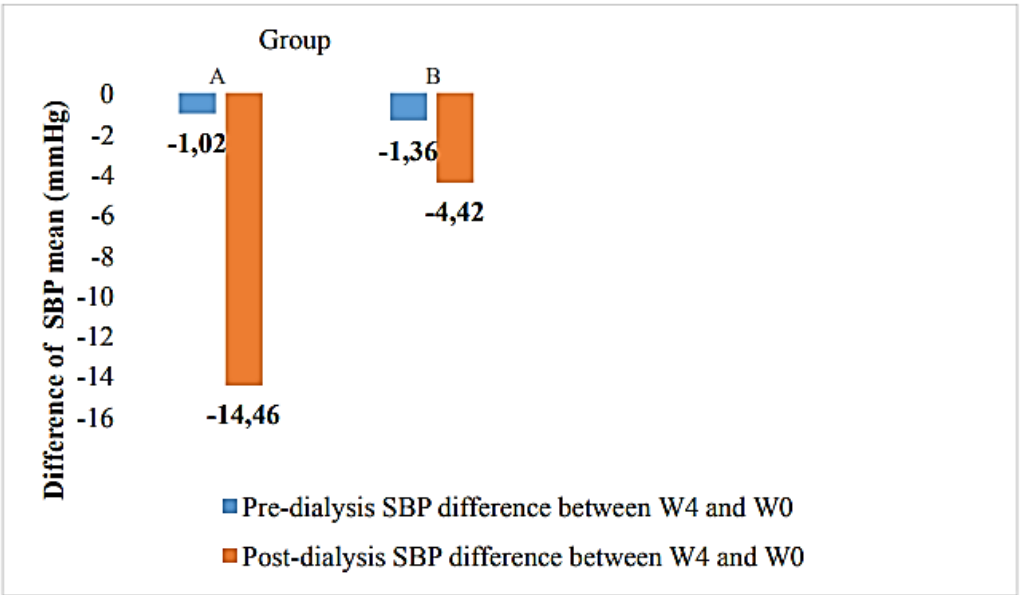
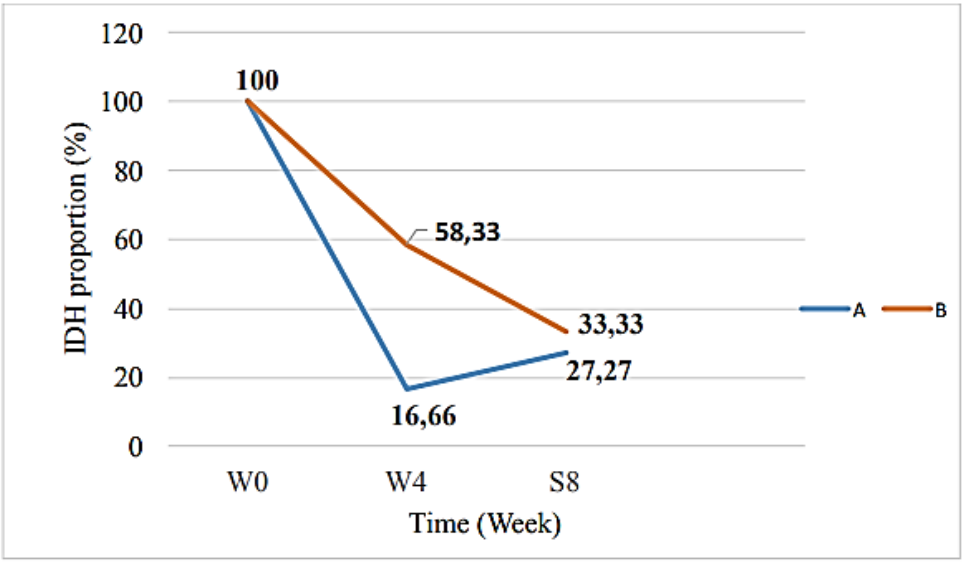


Figure 3: Differences in pre and post-dialysis mean SBP between week 4 and week 0 (SBP W4 - SBP W0) by groups.



W0 (first phase), W4 (week 4), W8 (week 8)

Figure 4: Evolution of the proportion of intradialytic hypertension between randomization, week 4 and week 8 in the UF-IDH clinical trial, Dakar / Senegal, 2018.

Table III: Results of ultrafiltration on secondary endpoints at week 4 in the UF-IDH clinical trial, Dakar / Senegal, 2018.

Groups	A	B	P
Pre-dialysis SBP mean (mmHg)	150,46 ± 14,44	147,82 ± 11,81	0,63
Post-dialysis SBP mean (mmHg)	154,92 ± 21,28	158,96 ± 14,05	0,59
Pre-dialysis DBP mean (mmHg)	76,25 ± 12,61	80,08 ± 8,74	0,40
Post-dialysis DBP mean (mmHg)	78,75 ± 14,19	86,21 ± 11,86	0,18
Pre-dialysis CF mean (ppm)	70,46 ± 8,35	75,46 ± 7,60	0,14
Post-dialysis CF mean (ppm)	67,92 ± 7,71	71,57 ± 10,97	0,36
Antihypertensive drug number	2,25 ± 0,75	2,08 ± 0,51	0,53
Mean difference of pre and post-dialysis SBP (mmHg)	3,63 ± 15,53	11,14 ± 11,77	0,20
TWL (kg)	1,08 ± 0,73	0,00 ± 0,00	0,00
IDWG (kg)	2,08 ± 1,03	1,77 ± 0,73	0,41

IDWG= interdialytic weight gain, SBP= Systolyc Blood Pressure, DBP= Diastolic Blood Pressure, CF= Cardiac Frequency, ppm=pulsation per minute, TWL= Total Weight Loss

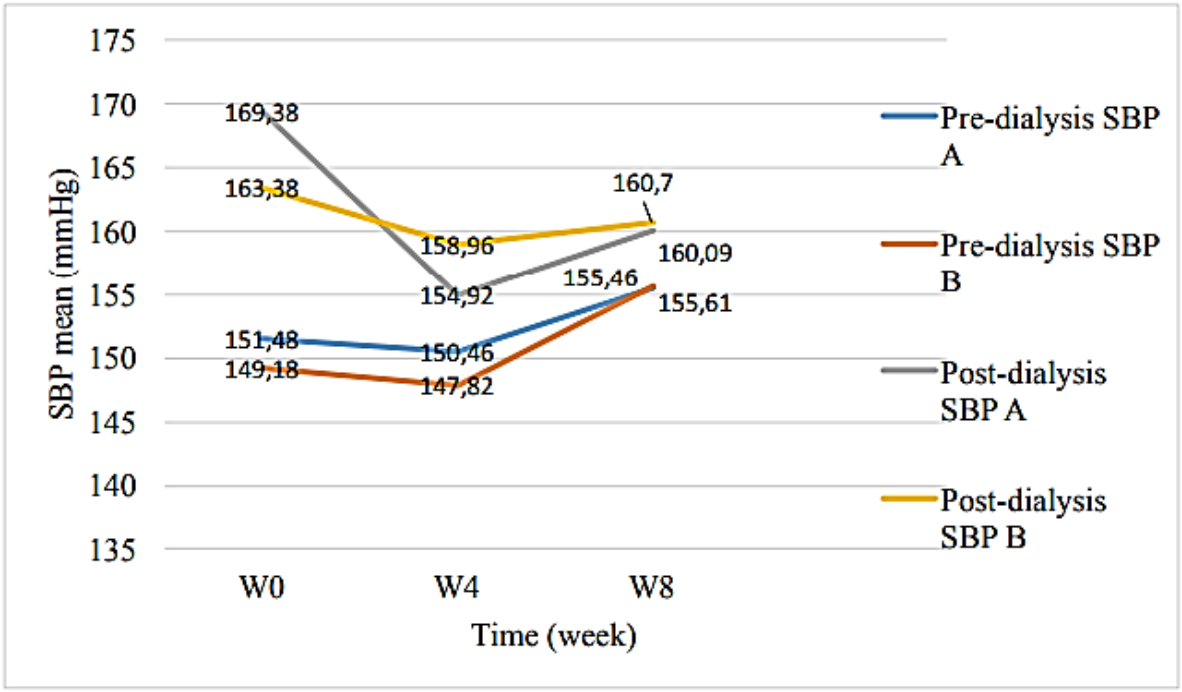


Figure 5: Mean SBP changes between randomization, week 4 and week 8 in the UF-IDH clinical trial, Dakar / Senegal, 2018. Pre-dialysis SBP A (Pre-dialysis SBP in group A) ; Post-dialysis SBP A (Post-dialysis SBP in groupe A) ; Pre-dialysis SBP B(Pre-dialysis SBP in group B) ; Post-dialysis SBP B (Postdialysis SBP in group B)

Table IV: Results of ultrafiltration on secondary endpoints at week 8 in the UF-IDH clinical trial, Dakar / Senegal, 2018.

Groupes	A	B	P
Pre-dialysis SBP mean (mmHg)	155,18 ±18,50	155,61 ± 14,90	0,95
Post-dialysis SBP mean (mmHg)	160,09 ± 21,35	160,70 ±20,37	0,94
Pre-dialysis DBP mean (mmHg)	81,94 ± 8,08	84,85 ± 10,88	0,48
Post-dialysis DBP mean (mmHg)	82,06 ± 10,77	89,29 ± 11,86	0,14
Pre-dialysis cardiac frequency mean (ppm)	71,14 ± 7,94	77,33 ± 5,31	0,04
Post-dialysis cardiac frequency mean (ppm)	71,11 ± 13,92	76,72 ± 9,76	0,27
Antihypertensive drug number	2,00 ± 0,89	2,08 ± 0,51	0,78
Mean difference of pre and post-dialysis SBP (mmHg)	4,91 ± 12,38	5,07 ± 9,94	0,97
TWL (kg)	0,45 ± 0,65	0,00 ± 0,00	0,02
IDWG (kg)	1,84 ± 0,67	1,72 ± 0,66	0,66

IDWG= interdialytic weight gain, SBP= Systolyc Blood Pressure, DBP= Diastolic Blood Pressure, CF= Cardiac Frequency, ppm=pulsation per minute, TWL= Total Weight Loss

At W4 a reduction of IDH proportion was observed in 10 patients of group A (83.33%) and 5 patients of group B (41.66%) (p = 0.035; HR = 0.29, IC 95 [0.14-0.59] (Table III). Pre-dialysis SBP mean was rated at 150.46 ± 14.44 mmHg, post-dialysis SBP one was at 154.92 ± 21.28 mmHg in group A (Table III) with differences (pre-dialysis SBP W4 – pre-dialysis SBP W0, post-dialysis SBP W4 – post-dialysis SBP W0) of -1.02 mmHg and -14.46 mmHg respectively. In group B, these differences were -1.36 mmHg and -4.42 mmHg (Figure 3). With a total weight loss of 1.08 kg, we did not observe a statistically significant difference in either IDWG or number of antihypertensive drugs between the 2 groups (Table IV). UF was associated with the occurrence of adverse effects (p = 0.0001), mainly consisted of cramps (81.80%). UF was stopped in 4 patients (36.40%). A death by meningoencephalitis has been reported in one patient.

At W8, a reduction in IDH was observed in 8 patients of group A (72.72%), and in 8 patients of group B (66.66%) (p = 0.75, HR = 0.76 ; 95% CI :0.58-1.00). Figure 4 illustrates the evolution of the IDH from W0 to W8. Pre-dialysis SBP was at 155.18 ± 18.50 mmHg, and the post-dialysis SBP was at 160.09 ± 21.35 mmHg in group A (Table IV) with an average difference of 4.91 mmHg, in group B this difference was 5.07 mmHg. Figure 5 illustrates SBP evolution from W0 to W8. IDWG remained stable in both groups despite an additional weight loss of 0.45 kg in group A. The average number of antihypertensive drugs was 2.00 ± 0.89 in group A and 2, 08 ± 0.51 in group B (Table IV). Five patients underwent adverse effects featured by cramps representing 45.45% and no UF intolerance was recorded.

Discussion

IDH is generally perceived as a rare phenomenon in hemodialysis [11, 12]. In several studies using the same criteria, its prevalence was less than 15% [3]. In our study, we report a prevalence of 25% IDH. This prevalence was similar to that

reported by Faye et al. [6] in Senegal and Attilio et al. [7] in Italy which was 22.60% and 23.10% respectively. It was lower to the prevalence outlined by Sinomono [4] in Morocco, Sebastian [5] in South Africa and Mackanga [13] in Gabon, who respectively reported 29.17%, 28.40% and 28.99%. It was higher than CLIMB [14] and the WAVE 2 studies [15], which reported a respective prevalence of 13.20% and 12%. Known as a cardiovascular risk factor [7], its management is necessary and will go through the proper management of the blood volume with the estimation of an ideal weight and the individualization of the parameters of hemodialysis. Indeed the 2nd phase consisted in the gradual reduction of the dry weight of the patients.

Thus, at W4, the average weight loss was 1.08 ± 0.73 kg. This result was similar to Agarwal et al. [16] ones who reported a decrease of 0.9 kg. It was lower than the number outlined by Cirit et al. [1] with 6.7 kg in 2 weeks of intervention but higher than that of Loutradis et al. [17] who reported a decrease of 0.7 kg in the active group. This weight loss was less important (0.45kg) at W8. This can be explained by the UF stop-overs at week 4 which represented 36.4% but also by the non-supervision of patients who voluntarily lowered the UF flow under a fear per or post dialysis events. The dry weight decrease is often limited by adverse effects including muscle cramps and hypotensive episodes. It will therefore require a progressive decrease in dry weight and sometimes an increase during the hemodialysis session and / or an increase in the frequency of hemodialysis sessions. It will also be necessary to associate with this decrease in dry weight, a drop in antihypertensive therapy. Indeed, in the work of Faye et al., the higher number of antihypertensive drugs, the more IDH was common [6]. Sometimes, a sodium profile associated with a UF profile and especially UF double-check modules can help manage the volume of these patients with IDH [18]. Lastly, therapeutic education, particularly sodium restriction, keeps an important place in this management [19].

The significant reduction in the proportion of patients with IDH by intensive and progressive UF at W4 highlights the involvement of hypervolemia in its genesis. In the DRIP [9] trial, 53% of the patients in the UF group and 31% of the patients in the control group had a SBP reduction of 10 mmHg or more in week 4 with a statistically significant difference (ORMH = 2.24 ; 95% CI : 1.32-3.81 ; p = 0.003) [4]. The effect of extracellular volume expansion was also explored by Hongqi Ren et al. [20] in China in a study that included 131 chronic hemodialysed patients.

In this study the extracellular water to total water ratio was higher in the IDH group in pre- and post-dialysis with p = 0.01 and 0.02 respectively. In our context, these results should lead the nephrologists to reconsider the estimation of the dry weight which must no longer be limited to clinical criteria. In fact, the equipment of our hemodialysis centers for ultrasound and bioimpedancemetry (BIA) equipment would improve this estimation as well as the management of dry weight.

However, this reduction in the proportion of IDH was lower at W8. This could be explained by the lower weight loss at those moments, insufficient to correct the overestimation of the dry weight involved in IDH genesis. A study of greater power is needed to better appreciate UF effectiveness in our patients.

In this study, besides the reduction of IDH proportion, the efficacy of intensive UF at W4 was demonstrated by decreasing BP averages. In fact, UF was associated with a greater reduction of the post-dialysis SBP without the difference being statistically significant (-14.46 mmHg vs -4.42 mmHg, p = 0.59). This reduction was lower on the pre-dialysis SBP (-1.02 vs -1.36, p = 0.63). We observed the same evolutionary pattern on DBP (p = 0.40 vs 0.18). In a Turkish study of 7 patients, Cirit et al. reported a reduction in pre-dialysis systolic and diastolic blood pressure (SBP and DBP) of 46/22 mmHg after a decrease in dry weight of 6.7 kg [1]. In another study of 19 hemodialysed patients who received a sodium restriction in addition to UF, Ozkahya et al. [21]

reported a reduction in pre-dialysis BP from 127/78 to 118/73 mmHg in 12 months. Agarwal [16] reported a reduction of 7.4 / 3.6 mmHg in ambulatory BP (44 h) to week 4 after a dry weight reduction of 0.9 Kg.

However at W8 an increase of SBP and DBP in pre and post-dialysis was noted, compared with. This result was different from that of Loutardis et al. [17] who noted a reduction in pre and post-dialysis BP in the active group at W8 but with no statistically significant difference. In contrast, intradialytic BP (136.94 ± 14.93 / 83.77 ± 9.13 vs. 129.26 ± 15.48/ 80.13 ± 11.25 mmHg, p = 0.007 and p = 0.014 for SBP / DBP), as well as 44 hours after (136.11 ± 15.21 / 80.31 ± 10.19 vs 129.61 ± 14.57 / 76.44 ± 9.25, p <0.001 and p = 0.001 for SBP / DBP) and 48-hour ambulatory BP were significantly reduced at the end of the study in the active group. Agarwal et al. [16] reported a significant reduction in ambulatory BP at W8 attributable to UF (-6.6 / -3.3, p = 0.021 / 0.037 for SBP / DBP). It should be noted that these studies did not assess pre and post-dialysis BP but rather ambulatory and intradialytic BP. This lack of efficacy of UF

in our study can be explained by a lower weight loss to W8. Moreover, the efficiency of UF is sometimes delayed, occurring weeks or months after the intervention: it is the "lag phenomenon". Hence the need for long-term monitoring for a better assessment.

Although IDWG and the number of antihypertensive drugs remained stable during the study, UF was statistically associated with the occurrence of adverse effects. In fact 36.40% ran into intradialytic hypotension episodes. This significant proportion of hypotensive episodes in our study can be explained by the association of other comorbidities, in particular anemia, but also by the dietary habits of the patients during hemodialysis session. The use of hemodialysis machines with a double-check systems could improve UF tolerance in our patients.

Our study has limitations: the small sample size reducing the power of the study (randomization can not ensure comparability of groups); the short follow-up length to assess the effectiveness of the UF which can be delayed occurring months after the intervention; the lack of appreciation of the interdialytic BP.

From these results we recommend to nephrologists:

• The reduction in dry weight must be considered as part of IDH management;

• This reduction must be associated with the individualization of the sodium content of the dialysate to limit IDWG and improve UF tolerance, a very strong therapeutic education, the use of sodium profile and UF but also the UF double-check modules;

• The use of new tools including BIA and pulmonary ultrasound will allow better management of dry weight;

• Conduct a large scale study using dry weight estimation techniques to better appreciate the effectiveness of the UF in our context.

Conclusion

Intensive and progressive UF was associated with a reduction of IDH proportion at week 4. However, it was not always well tolerated. A large scale study is needed to be undertaken for a better understanding of this efficacy in our patients.

Conflicts of interest: there is no conflicts of interest

Supporting information: Protocol study, CONSORT checklist, Tables and figures

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