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Intradialytic Blood Pressure Dysregulation: Frequency and Risk Factors among Hemodialysis Patients at Mansoura University Hospital

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Abstract: Background: Intradialytic blood pressure dysregulation (IDBPD), comprising intradialytic hypotension (IDH) and intradialytic hypertension (IDHTN), is a well-recognized hemodialysis (HD) complication. However, their frequency, risk factors and clinical impact have only been scarcely examined. Aim of the study: is to determine the frequency of IDBPD and its associated risk factors among HD patients. Methods: Fifty-two ESRD patients on regular HD (mean age 43.10 ± 14.80 years, 61.5% males) were observed for occurrence of IDH or IDHTN for three months. Patients' demographic data and co-morbid conditions were recorded. Symptomatology during the attacks. and any mechanical, clinical or pharmacological interventions were also observed. Results: Of the total observed sessions, IDH occurred in 5.6% and clinical symptoms & intervention occurred were noted in 69% & 71%, of sessions with IDH, respectively, while IDHTN occurred in 12%; associated symptoms and intervention occurred in 62% & 71% of sessions with IDTHN, respectively. Female gender was a risk factor for both types of dysregulation. Background hypotension, was significantly associated with occurrence of IDH with relative risk of 9.27, while background hypertension was significantly associated IDHTN with a relative risk of 6.93. Conclusion: IDBPD was frequently encountered in the studied population and their frequency increased as sessions progressed. IDHTN was commoner than IDH; although the latter was attended with more symptoms. Females are more prone to IDBPD, and background hypotension was a risk factor for IDH, while background hypertension was a risk for IDHTN. Further research is needed to find out means for protection against such devastating problem.

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Key words: Intradialytic (hypotension & hypertension), frequency, and risks factors.

1. Introduction

Intradialytic blood pressure dysregulation, comprising IDH and IDHTN, is a well-recognized hemodialysis (HD) complication Intradialytic hypotension is considered one of the most frequent complications of HD treatment and is associated with increased cardio-vascular morbidity and mortality [1]. Many literatures report that up 50 % of HD sessions are complicated by IDH [2]. Hypertension is very prevalent among patients undergoing HD. Despite it is recognized as a high risk of cardiovascular mortality for these populations, the way of blood pressure regulation is poorly understood. The prevalence of intradialytic hypertension (IDHTN) is 28.4% [3].

To the best of our knowledge, the problem of IDBPD and its corelates were not thoroughly scrutinized in our locality. Furthermore, unlike what is known and published in many previous literatures, it was felt that IDHTN occurrence was not as uncommon than that previously reported; therefore,

the present study was planned to examine this problem in our local environment. So, the aim of the current research is to determine the frequency of IDBPD and its associated risk factors among HD patients in Mansoura Nephrology and Dialysis Unit (MNDU).

2. Patient and method

This observational prospective study was conducted on 52 HD patients comprising 61.5% male at MNDU in Mansoura University Hospital. Patients maintained on HD for six months or more, aging between 18 to 60 years and consented voluntarily to participate were included in the study. Exclusion criteria were organ decompensation as decompensated heart failure of NYHA grade III & IV, stigmata of liver diseases, hepatic encephalopathy, liver cell failure, CNS problems, respiratory problems and disabling psychosis. All patients were maintained on 12 hours dialysis per week distributed on 3 sessions that were performed with volumetric dialysis machines utilizing either high-flux or low-flux dialyzers. A standard commercially available bicarbonate-based buffer dialysis solution was used.

Data collection

All the HD sessions related to the studied patients were observed for seven months, during the period from the first of August, 2016 till the end of February, 2017, and concerning information for demographic characteristics of the patients, comorbidities, HD parameter, and laboratory data were recorded.

Pre-dialytic, after period of quiet rest, and intradialytic BP measurements were obtained from brachial artery using a mercury sphygmomanometer in setting position from non-fistula arm. IDH was defined according to K/DOQI (2005) as a decrease in SBP of ≥ 20 mm Hg with a modification of restricting the definition to those with nadir BP below the lower limit 100/60, whether or not associated with symptoms sudden-onset headache, dizziness. e.g. unconsciousness, thirst, dyspnea, angina, muscle cramps and vomiting. IDHTN was defined as increase in SBP \geq 20mmHg from predialysis SBP that exceeds the normal limit 140/90mmHg. All sessions were monitored, and occurrence of IDBPD and its associated clinical symptoms were recorded, during the period of observation.

A total of1963 sessions had been observed during the period of the study. Sessions with IDBPD were analyzed as target sessions and 46 sessions without IDBPD of the same patients were taken as a control sample.

Statistical analysis:

Data were analyzed using the statistical package of social science (SPSS, IBM) software version 24. Categorical data were expressed as numbers and percentages and were analyzed by Chi-square or Fisher-exact tests. Scale data were expressed as means \pm SD or medians (IQR) as appropriate. P value was considered significant when< 0.05.

3. Results

Demographic, HD and medical characteristics of the studied patients are illustrated in table 1. Causes of illness are presented in figure 1. The laboratory data of the patients are illustrated in table 2. Regarding hemoglobin level, 26 (50%) patients had hemoglobin level less than 11 g/dl, 11 (21.2%) had hemoglobin levels equal to or more than 11.5 g/dl, the remaining patients had hemoglobin levels within the target values (11-12 g/dl) (**K/DOQI, 2006**).

During the period of observation, patients who experienced one or more sessions of IDH or IDHTN

are counted in the groups of IDH or IDHTN patients, respectively. Intradialytic hypotension was observed in about 25% of the patients, while, IDHTN was observed in 40.4% of patients. Simultaneous IDH and IDHTN successively in the same patient were observed in 23.1% of the studied cases, on the other hand only 11.5% never developed any episodes of IDBPD (Figure 2).

Among the 1963 sessions, 82.4% were free from IDBPD, while 5.6% were inflicted by IDH, and 11.9% were troubled with IDHTN (Figure 3). It was noticed that the frequency of both types of IDBPD increased as the time of the session progressed (Figure 4).

The 'intra-personal' frequency of the IDBPD in afflicted patients is shown in Figure 5. More than 90% of patients with IDH experienced IDH episodes in less than 30% of their total observed sessions. Two patients had a relatively higher frequency of IDH episodes; both of whom were suffering from chronic background hypotension that was resistant to volume repletion and antihypotensive medications. The first is a 26-year-old renal transplant rejection male, who had been on dialysis for 3 years, and experienced IDH in 41% of his total observed sessions, while the second patient is a 60-year-old female, who had been on dialysis for 6 years, with a history of diabetes mellitus and experienced IDH in 38.5% of her total observed sessions. Similarly, the majority of the patients with IDHTN developed IDHTN episodes in less than 30% of their total observed sessions, while about 20% of the patients had relatively higher frequency. This group of patients had a mean age of 43.3 ± 12.9 years, duration of dialysis of 6.3 ± 3.5 years, and BMI of 23.2 ± 2.7 kg/m²; all of them were suffering from background hypertension that was resistant to antihypertensive medications (Figure 5).

Intradialytic hypotension and IDHTN were significantly more common in sessions of female patients than those with male patients. However, there was no significant difference in developing IDBPD between males and females (**Table 3**).

Intradialytic hypotensive episodes were significantly more common in patients with background hypotension, while it was less common in those with background hypertension. In contrast, IDHTN was significantly more common in patients with background hypertension; and less common in patients with either background hypotension or ischemic heart disease. The relative risk for developing IDH was 9.27 in sessions of patients with history of hypotension, while the relative risk for developing IDHTN was 6.93 in sessions of patients with background of hypertension. On the other hand, the relative risk for developing IDHTN was 0.51 in sessions of patients with ischemic heart disease (Table 4).

More than 69% of sessions with IDH episodes, and 42.1% of the sessions with IDHTN were associated with symptoms including headache, fatigue, palpitation, and nausea; a difference that is statistically significant (Figure 6 & Figure 7). Interventions during episodes of IDBPD were applied without interference from the researcher. Interventions including, machine manipulation, IV fluid administration, dry weight adjustment, and medications were applied in 71% of total observed sessions with IDH, while 62.6% of sessions with IDHTN episodes required interventions (**Table 4**).

Table (1): Demographic	HD and medical histor	y of the studied natie	nts (n=52)
I abic (I). Demographic	, IID and incultar instor	y of the studied parts	115 (II-54)

Gender: Male/Female	32/20 (61.5% / 38.5%)
Age (years):Mean ±SD; Median (IQR)	$43.10 \pm 14.80; 43.00 (28-56.8)$
Access type: Catheter/Fistula	2/50 (3.9% / 96.1%)
Duration of dialysis (years)Mean ±SD	4.03 ± 3
History of Co-Morbid Conditions:	
Diabetes Mellitus [n (%)]	12 (23.1%)
Hypotension, [n (%)]	5 (9.6%)
Hypertension, [n (%)]	38 (73.14%)
Ischemic Heart Disease, [n (%)]	8 (15.4%)

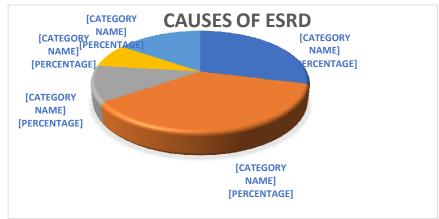


Figure (1): Distribution of causes of ESRD

Table (2): Laboratory data of the studied patients (total number = 5
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Variables	Mean ± SD	Median (IQR)
HB (g/dl)	10.59 ± 2.24	10.95 (9.2 - 11.8)
<i>PLT (l)</i>	$189 \times 10^9 \pm 66.57 \times 10^9$	$185 \times 10^{9} [(138 - 234) \times 10^{9}]$
MCV (fl)	88.18 ± 5.57	88.35 (85.13 - 91.98)
S. Iron (µg/dl)	75.15 ± 34.24	72.50 (53.00 - 89.25)
TIBC (µg/dl)	198.57 ± 57.30	206.00 (177.75 - 235.25)
S. Ferritin (µg/dl)	769.00 ± 454.60	766.10 (443.25 - 1016.00)
T. Sat (%) *	37.74% ± 18.43%	36.00% (25.25% - 47.50%)
S. Albumin (gm/dl)	3.68 ± 0.39	3.70 (8.13 - 8.98)
S. Bilirubin (mg/dl)	0.82 ± 0.43	0.80 (0.70 - 0.80)
SGOT (U/ml)	24.42 ± 5.10	22.00 (21.00 - 26.00)
SGPT (U/ml)	24.81 ± 8.10	22.00 (20.00 - 26.75)
S. Ca (mg/dl)	8.51 ± 0.65	8.60 (8.13 - 8.98)
S. PO4(mg/dl)	4.76 ± 1.48	4.30 (3.73 - 5.60)
S. PTH (pg/ml)	697.76 ± 632.57	435.40 (168.28 - 1135.50)
Ionized Ca (mmol/l)	1.16 ± 0.20	1.10 (1.06 - 1.19)
S. Mg (mg/dl)	2.40 ± 0.27	2.40 (2.20 - 2.59)

*Transferrin saturation

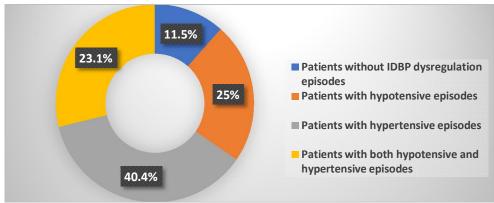
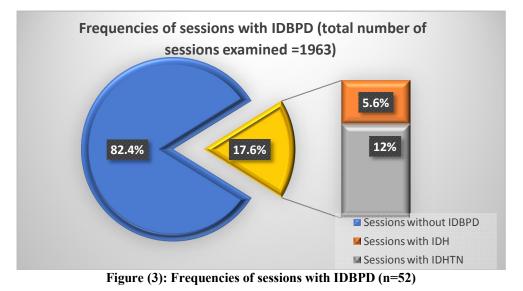


Figure (2): Frequencies of patients with IDBPD (n=52)



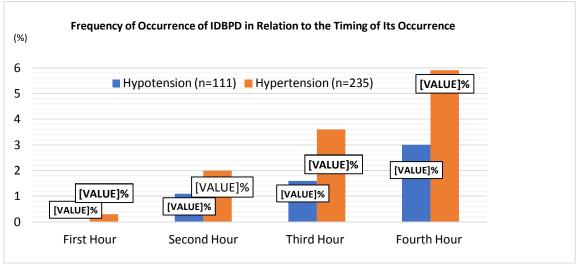


Figure (4): Frequency of occurrence of IDBPD in relation to timing of its occurrence

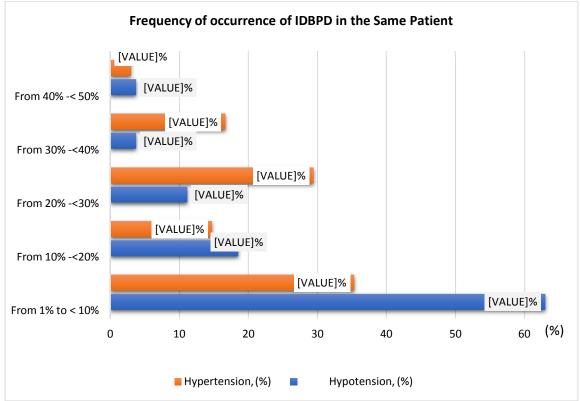


Figure (5): Frequency of distribution of IDBPD in the same patient.

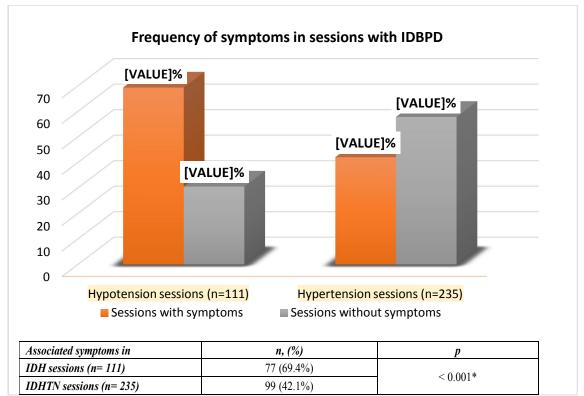
	otal number=1963)	with mit unity the blood pressu	¥ 9	
Gender	IDH	IDHTN		
Female / Male	61 (8.2%) / 50 (4.1%)	125 (16.9%) / 110 (9.0%)		
р	< 0.001*	< 0.001*		
At patient level (total number= 52)				
Gender	Group-1	Group-2	Group-3	
Female / Male	5 (38.5%) / 7 (30.4%)	8 (61.5%)/ 10 (43.5%)	7 (43.8%) / 9 (65.3%)	
р	0.720**	0.489**	0.121**	

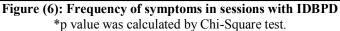
Table (3): Relation	of gender with intradialytic blo	ood pressure dysregulation

*p value was computed by Chi-Square test. **p value was computed by Fisher-Exact test.

Table (4). Relative fisk of co-morbid conditions						
Histom of	IDH		IDHTN			
History of	Relative Risk	95% confidence interval	p	Relative Risk	95% confidence interval	p
Hypotension	9.27	6.6018-13.0185		0.021	0.0013-0.3301	
Hypertension	0.14	0.0966-0.2160		6.93	3.9083-12.2755	
Diabetes Mellitus	0.88	0.5605-1.3698		0.88	0.6565-1.1882	
Ischemic Heart Disease	1.38	0.8965-2.1177		0.51	0.3398-0.7781	

Table (4): Relative risk of co-morbid conditions





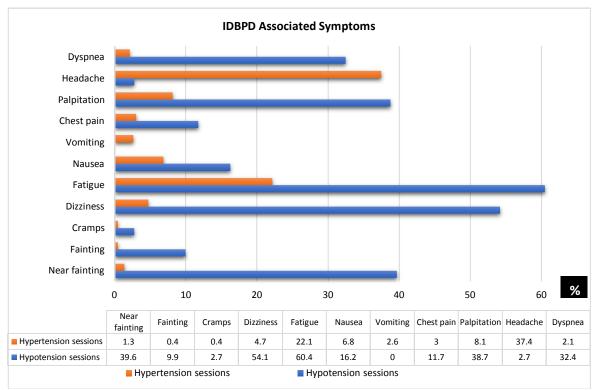


Figure (7) Frequencies of IDBPD sessions associated symptoms (total number = 346)

	n, Frequencies			
Variables	Sessions with IDH	Sessions with IDHTN		
	(n=111)	(n= 235)		
Machine manipulation*	65(59.6%)	9(3.8%)		
Dry weight manipulation	14(13.2%)	15(6.4%)		
IV fluids	56(51.4%)	n=10(4.3%)		
Types of fluids: [¶]				
Normal saline	54(48.6%)	3(1.3%)		
• Dextrose 25%	3(2.7%)	7(3.0%)		
• 0.45% Saline	1(0.9%)	-		
Fluid volumes (ml):				
50 -<100		2(0.9%)		
100 -<200	27(24.3%)	5(2.1%)		
200 -<300	19(17.1%)	2(0.9%)		
=300	7(6.3%)	1(0.4%)		
>300	5(4.5%)			
Medications	11(9.9%)	133(56.6)		
Details of Medications				
• Captopril (25mg)		113(48.1%)		
• Nifedipine (10mg)		15(6.4%)		
Nitroglycerin Infusion		3(1.3%)		
• Isosorbide Dinitrate (5mg)		1(0.4%)		
• Carvedilol (6.25mg)		1(0.4%)		
• Midodrine (5mg)	11(9.9%)	-		

Table (4) Interventions for	• management of sessions with	IDBPD enisodes	(total number = 346)
1 abic (+) micr (chubis 10)	management of sessions with	IDDI D cpisoues	

* e.g. cessation of UF, \downarrow blood flow rate (BFR).

**p value was computed using Chi-Square test.

[¶]More than one type of fluid were occasionally administered in same sessions.

4. Discussion

Intradialytic-hypotension is one of the most common complications that occurs during the dialysis procedure. Because IDH is likely to cause discomfort and dialysis inadequacy, leading to an increase in the risk of mortality, IDH could be considered one of the risk factors for the poor outcome in HD patients [4]. Intradialytic hypertension, is related to cardiovascular mortality. Patients with elevated systolic blood pressure during HD are 2.6 times to be hospitalized [5].

In this study the incidence of IDH was a little bit more than 5%, of the total observed sessions. In support of the present results, other previous studies reported a frequency of IDH ranging from 6.7% to 13.1% among HD session [6] [7] [8] [9] [10] [11] [12]. In an analogy to the present findings, [13] showed that 15.2% of HD sessions developed IDHTN followed by hypotension in 8.5% of sessions [13].

On the other hand, exaggerated frequency of IDH, was reported in other studies: for example, Flyth, et al. [9] revealed that 68% of the sessions were inflicted with IDH. Similarly, [14] reported that 30.7% of all their studied HD sessions were associated with

IDH. This variation might be ascribed to the observation that most of their patients aged between 60 and 80 years; and moreover 24% of them suffered from congestive heart failure which is can lead to or exaggerate IDH; a subject selection that is obviously dissimilar to that in the present study [14].

It is worthwhile stating that older publications reported higher frequency of IDH than more recent ones. An explanation for this divergence may reside in the fact that the practice of HD has been developing over the time evolving from acetate to bicarbonate and more utilization of sodium profiling, cool dialysate and volumetric control of UF. These recent improvements of HD care have undoubtedly contributed to the decline of IDH frequencies [15]. Another reason for the variation of the frequency of IDH between different studies may arise from changing definitions of the condition making comparisons between different publication difficult. As previously mentioned, a lot of controversies in the reported frequencies of IDH may have evoked from great variability in the definitions of this problem. The above-mentioned notion has been reported in the study of [9] who relatively recently investigated the lack of uniform IDH diagnostic criteria by examining the associations between commonly used definitions in relation to frequency of IDH and mortality. In their study, IDH defined as systolic BP fall >20 mmHg was observed in 68% of treatments during the period of the study, while hypotension, defined as systolic BP fall below 90 mmHg–which is similar to the present study definition– was present in $\Box 10\%$ of the observed sessions.

Regarding IDHTN, in other studies, the frequency of intradialytic hypertension was described in 5-21.3% of HD treatments [15] [16] [17] [18] [19]. A recent study showed that an increase of more than 10 mmHg of post-dialysis BP compared to that of predialysis was observed in 33.2% of the sessions [11]. The results of the relatively recent aforementioned studies disclosed a tendency for a higher frequency of IDHTN in comparison to relatively older publications. In a study published in 1995, a survey of dialysis patients noted that 8% of sessions were associated with an increase in MAP of 15 mmHg or more, during or immediately after dialysis [20]. On the other hand, other previous studies showed that the frequency of patients who experienced IDHTN ranged from 34.5% to 37.5% which is not dissimilar to the current study [21] [22] [23]. Nevertheless, Sebastian [3], reported a relatively lower frequency of patients with IDHTN (28.4%), while Lada [24] declared a frequency of 25% of the same condition. In contrary to the abovementioned discussion, a preceding analysis from the US Renal Data System Dialysis Morbidity and Mortality Wave II cohort, showed that 12.2% of patients experienced IDHTN, defined as increase in SBP >10 mm Hg from pre to post dialysis [12]. Furthermore, Mees [25] noted that 5-15% of hemodialysis patients had hypertension resistant to ultrafiltration.

The lower frequency of IDHTN reported in the relatively older publications could be viewed in the light of the fact that IDH was more prevalent at that time, which could have curtailed many of the potentially incurrent episodes of IDHTN. Having said that, IDHTN has not had a widely accepted or standard definition, neither has it received the focus of attention like that of IDH. Moreover, the pathophysiologic mechanisms of IDHTN and its clinical consequences have been poorly understood [5]. The lack of definition uniformity creates a difficultly in making comparison with previous publications. The reason that the current study has a frequency that is different from the above-mentioned literatures that it has adopted definition with systolic blood pressure (SBP) increasing rate more than 20 mmHg; dissimilar to the previous literatures. The current study adopted a stricter definition of IDHTN with SBP elevation more than 20 mmHg, and hence

the resulting frequency was lower than that in some of the above-mentioned literatures; as some episodes of IDHTN could have been overlooked utilizing this definition contrasting less strict definitions that considered IDHTN episodes with lower levels of BP readings. Having said that, one limitation in the current study and other previous publication is overlooking isolated increase in diastolic BP as part of the definition of IDHTN, which would have increased the frequency even more than in the current study.

It is interesting to elucidate the impacts of IDHTN on the morbidity and mortality of hemodialysis patients. In a systemic review and metaanalysis, Stevens [26], discussed the possible impacts of high systolic blood pressure; increased long term variability in systolic blood pressure was associated with risk of all-cause mortality, cardiovascular disease mortality, cardiovascular disease events, coronary heart disease, and stroke.

It is interesting to study the frequency of occurrence of IDBPD in the same patient. Regarding IDH, more than one third of the patents never suffered from IDH, while more than one third experienced IDH in more than 10% of their sessions. Rocha, et al. [14] observed 18 HD session and mentioned that the majority of the patients (76.7%) experienced IDH episodes in less than 40% of their total observed sessions, and few patients had more than 10 IDH events. The most frequent number of IDH episodes were 2(11%) and 3(16.6%) (14% each), 4 (22.2%) (11.6%), and 6(33.3%) (9.3%), and the mean and the median were 5.5 and 4 events, respectively. Another study revealed that 6 patients had repeated IDH episodes. More than half of all patients had at least one episode of IDH during the observation period (observational period), while a third had at least two or more IDH episodes [10].

On reviewing previous literature, it is obvious that there are various adverse clinical outcomes that follow the recurrence of IDH episodes. One of the crucial adverse impact is loss of residual kidney function because of frequent hypoperfusion injury to the kidney [27]. Moreover, in a study by Jansen et al [28], IDH was independently associated with approximately 1 ml/min/1.73m² lower mean urea and creatinine clearance of the native kidney function. Arterio-venous fistulaethrombosis is another expected complication of recurrence of IDH [29]. Other longterm clinical consequences of repeated IDH are multisystem ischemic insults that lead to end organ dysfunction, such as myocardium stunning, cerebral ischemia and gut hypoperfusion. Greater intradialytic decline in systolic BP has been associated with the development of regional wall motion abnormalities, and eventually a decline in left ventricular ejection fraction [30]. Intradialytic hypotension has been linked to episodic stunning of the myocardium [30] [31] and over time, repeated ischemia induces cardiac hypertrophy and fibrosis, further impairing response to decreased filling pressures and increasing risk for hemodynamic instability. On the other hand, hypoperfusion of the cerebral circulation is found to be an important consequence, with prior studies reporting a significant correlation between decline in mean arterial pressure and intradialytic cerebral ischemia [32]. Furthermore, Mizumasa et al. [33] reported significant inverse correlation between the Frontal Atrophy Index and the number of IDH episodes. Related intradialytic gut hypoperfusion may increase systemic endotoxin levels [34]. Finally, recurrent IDH episodes have repeatedly linked to mortality.

Regarding IDHTN, a 6-month observational study showed that IDHTN occurred in more than 31% of the sessions of approximately quarter of patients [18]. In another study, a total of 56.4% of the patients suffered from IDHTN in 32% or less of their total sessions; a result that denotes more aggregation of IDHTN in comparison to the present study. [34].

In the present study, it was noticed that the frequency of IDBPD increased as the time of the session progressed as the higher incidence of both types of blood pressure changes occurred in the third and fourth hour of the sessions. It is plausible to conceive that IDH is concentrated mostly in the late hours of dialysis when a maximum UF and shift of osmolar would have been achieved. Concerning IDH, in harmony with the current study, other studies reported that IDH mostly occurred in the late hours of the session [10]; [35]. On the other hand, Van-Buren et al, [36] showed that higher IDHTN measurements occurred in the late hours of the sessions.

This clustering of IDH in the last two hours of sessions could be explained by the fact that UF rate reaches its maximum level which induces intravascular volume depletion in the late. On the other hand; rapid reduction of urea that might predispose to osmolarity change during dialysis could also explain why IDH occurs with high frequency in the last two hours.

Similarly, the phenomenon of high incidence of IDHTN in the late hours of the session might be explained by sodium shift from dialysate to the patient in some sessions which could lead to gradual accumulation of sodium in the ECF. After a lag time this accumulation has the probability of increasing the ECF osmolarity and hence withdrawing fluid from the intracellular to the extracellular compartments with a resultant of increased ECF volume [37] [38] [39].

The current study reveals that \sim 70% of sessions with IDH episodes, and more than 40% of the sessions with IDHTN are associated with symptoms and

interventions were applied in more than 70% and 60% of total observed sessions with IDH and IDHTN, respectively. Several prior studies have addressed the problem of symptoms related to IDH. Symptomatic hypotensive episodes occurred in 9.4%, 6% & 2.9% of dialysis sessions, respectively [10]; [40] [42], while Nishimoto [42], reported that intervention was carried out in 40% of dialysis sessions. On the other hand, Kuipers et al, [7] reported that a total of 21.4% of IDH sessions were associated with symptoms, while interventions to address IDH were required in 8.5% of IDH sessions. In the present study, IDHTN episodes presented with less aggressive symptoms and thus can induce many adverse outcomes silently, so the dialysis team should measure blood pressure frequently. Furthermore, frequent measuring of blood pressure can detect subclinical cases of IDH early and could save the patients worsening of their symptoms and development of adverse clinical impacts.

There are many co-morbid conditions that may predispose the patient to IDH episodes, in line with the current study, Sands et al. [2] revealed that lower pre - dialysis systolic blood pressure was associated with occurrence of IDH. On the other hand, neither diabetes mellitus nor ischemic heart disease were shown to be associated with the occurrence of IDH as reported by Jinbo et al, [43], however, the current study revealed that diabetes mellitus has no significant association with IDH occurrence. In accordance with the current study, Amira et al, [13] and Nishimoto et al, [42] showed that patients with history of diabetes mellitus were not prone to IDH. on the other hand, Nishimoto et al, [42] showed that ischemic heart disease was not associated with occurrence of IDH. in addition, pre-dialysis systolic-diastolic HTN was also an associated factor for IDHTN [11]. Moreover, experienced hypertension patients who had significantly higher pre-dialysis systolic and diastolic blood pressure [13]. Paike et al. [22] showed that DM and in contrast to current study background hypertension were not significantly associated with IDHTN.

In conclusion, there are many risk factors that contribute to occurrence of IDBPD. This study revealed that sessions of female patient background hypotension are significantly associated with occurrence of IDH. Concerning IDHTN, sessions of female patients are significantly more liable to IDHTN than those with male patients. Intradialytic hypertension is significantly more common in sessions of patients with background hypertension, while it was significantly less common in sessions of patients with background hypotension and IHD.

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