

Intradialytic Hypertension Increases Non-access Related Hospitalization and Mortality in Maintenance Hemodialysis Patients

Abstract

Background and Aims: Intradialytic hypertension, in patients on maintenance hemodialysis, is associated with increased morbidity and mortality. As there is no data available from India, this study was aimed to determine the prevalence and outcome of intradialytic hypertension (IDH) in a tertiary care dialysis centre in India. **Methods:** This was a prospective analytical study of 120 patients on hemodialysis. At screening phase, all patients were subjected to fluid optimization and adjustment in the antihypertensive medicines for appropriate control of blood pressure (BP). BP measurements during hemodialysis were recorded. The prevalence of IDH was noted. IDH was defined as increase in systolic BP of >10 mmHg from pre to post hemodialysis or after 2nd hour of dialysis when significant ultrafiltration had occurred, on 3 consecutive sessions. Factors associated with IDH were evaluated and compared with cohort without IDH. The outcome of these patients in terms of morbidity and mortality over a follow-up period of 12 months were recorded. **Results:** The prevalence of IDH was 21.9%. The baseline demographic parameters of patients in both the groups (with and without IDH) including age, sex, dialysis access, duration of dialysis, and comorbidities were similar. Laboratory parameters were similar except serum potassium and serum phosphorus, which were lower in patients with IDH. Out of all the variables studied, only low serum phosphorus was associated independently with IDH. During follow-up, at 6 months, 19/71 (26%) non-IDH and 12/20 (60%) IDH patients ($P = 0.006$) and at 12 month, 30/71 (42%) non-IDH patients and 12/20 (60%) IDH patients required admission ($P = 0.05$). Mortality at 6 months was similar, 5/71 (7%) in non-IDH and 4/20 (20%) in IDH ($P = 0.10$) patients, but was higher at 12 months, 11/71 (15.5%) in non-IDH and 8/20 (40%) in IDH ($P = 0.028$). **Conclusion:** Incidence of intradialytic hypertension is high (21.9%) with increased morbidity in terms of hospitalization and increased mortality over a period of one year.

Keywords: Intradialytic complications, intradialytic hypertension, hemodialysis

Introduction

Hypertension is highly prevalent in end stage renal disease (ESRD) patients. While hemodialysis lowers blood pressure (BP) in most ESRD patients, some patients exhibit a paradoxical increase in BP during hemodialysis. This increase in BP during hemodialysis, termed intradialytic hypertension is estimated to be 5-15% of the HD population.^[1] The pathophysiology of IDH is poorly understood and the clinical consequences are only recently been investigated. The mechanisms proposed to explain intradialytic hypertension include: (1) volume overload, (2) renin-angiotensin-aldosterone and sympathetic system activation, (3) removal of antihypertensive medications with dialysis, (4) endothelial cell dysfunction,

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and (5) electrolyte imbalances involving dialysate sodium, calcium, or magnesium.^[1]

Intradialytic hypertension (IDH), defined as systolic BP increase of >10 mmHg from pre- to post-HD, is associated with increased risk of short-term (6 months) and long-term (2 years) morbidity and mortality.^[1] Therefore, the recognition of intradialytic hypertension can provide nephrologists an opportunity to identify patients at high risk of adverse outcomes using readily available data from the hemodialysis unit. It will help in better management and prognostication of such patients. In India, there is limited data available in the literature on IDH in patients on hemodialysis.

The purpose of this study was to determine: (1) prevalence of intradialytic hypertension in our hemodialysis population, (2) the

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factors associated with intradialytic hypertension, and (3) to study impact of intradialytic hypertension on morbidity and mortality over a period of 12 months.

Methods

This randomized prospective study was carried out with patients attending hemodialysis unit of a tertiary care hemodialysis centre during the period of 1st July 2015 to 31st May 2017. Patients with age more than 18 years and on regular 3 times a week hemodialysis for at least 3 months period, who were free of vascular, infectious or bleeding complications within 1 month of recruitment were included in the study. Patients who missed 2 or more hemodialysis treatments over 1 month, drug abusers, having arrhythmias, or body mass index ≥ 40 kg/m², planning kidney transplant within 6 months, and those who had poor adherence to drug treatment especially to antihypertensive drug therapy were excluded from the study. Prior approval of institutional ethics committee was taken and written informed consent was obtained from all participants.

At screening phase, optimal blood pressure control was attempted in all patients. All hemodialysis (HD) patients were subjected to fluid optimization and adjustment in the antihypertensive medicines over a period of 2 weeks. Bio-electric impedance analysis (BIA) was done for all participants and dry weight was adjusted accordingly, where indicated. All participants were then subjected to 44 hours ambulatory blood pressure monitoring after mid-week hemodialysis for assessment of their blood pressure (BP) control.

Blood pressure monitoring

Ambulatory blood pressure monitoring: After a mid-week HD treatment, subjects wore ABP monitor on the non-access arm. Arm size was measured to determine appropriate cuff size. The ABP monitor was turned on and the subject was instructed to wear the cuff and monitor for entire 44 hour inter-dialytic period, except for bathing. BP was measured every 30 minutes from 6 a.m. until 10 p.m., and then hourly from 10 p.m. to 6 a.m. Subjects continued their typical diet and antihypertensive regimen. In cases where the cuff had turned off or had taken insufficient recordings, the procedure was repeated. Those subjects who were <60 years of age and had average ABP of <140/90 mmHg, and those who were >60 years of age and had average ABP <150/90 mmHg were enrolled for the study [JNC VIII].^[2]

Intradialytic BP measurement: Blood pressure was measured by an automated device. Measurements were obtained before HD, every 30 minutes during HD and after HD from the non-access arm. Pre-HD BP was measured in the non-access arm after 5 min rest in the supine position before insertion of needle. Similarly, post-HD BP were obtained after 5 minutes of termination of procedure. HD BP was recorded for consecutive 3 HD sessions.

Intradialytic hypertension was defined as any or both of the following: (1) an increase in systolic BP ≥ 10 mmHg from pre to post-dialysis for 3 consecutive HD sessions, or (2) increase in SBP ≥ 10 mmHg after two hours of HD after significant ultrafiltration has taken place in 3 consecutive HD sessions.^[1] Prevalence of intra dialytic hypertension was calculated.

All patients were divided into two groups. Patients without IDH (group 1) served as controls to compare with patients having IDH (group 2) for baseline characteristics and other outcomes. All these patients were followed over a period of 12 months to study the outcomes including morbidity in terms of non-access related and non-transplant hospitalizations and overall mortality.

Statistics: Sample size calculation was based on the results (effect sizes) from the previously published studies. The data on categorical variables was shown as n (% of cases) and the data on continuous variables was presented as Mean and Standard deviation (SD) across two study groups. The inter-group comparison of categorical variables was done using Chi-square test or Fisher's exact probability test for 2×2 contingency table. The statistical significance of inter-group difference of mean of continuous variables was tested using independent sample *t* test or unpaired *t* test. The underlying normality assumption was tested before subjecting the study variables to the 't' test. The entire data was entered and cleaned in MS Excel before its statistical analysis. All the results were shown in tabular as well as graphical format to visualize the statistically significant difference more clearly. In the entire study, the *P* value less than 0.05 were considered to be statistically significant. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data was statistically analysed using Statistical Package for Social Sciences (SPSS ver 16.0, IBM Corporation, USA) for MS Windows.

Results

Out of 200 patients on maintenance hemodialysis at our centre, 120 patients were enrolled for the study as per inclusion and exclusion criteria and willingness to participate with a written informed consent. We did optimization of blood pressure medicines, optimization of fluid status assisted by BIA, counselling for fluid intake and compliance over the first 2 weeks. Subsequently, 44 hours ABPM was done for all these patients. Overall, 29 patients were excluded [Figure 1]. 20 patients were excluded as their mean BP was higher than the criteria. 7 patients were further excluded as they could not perform ABPM on 2 successive attempts or were denied after the first attempt in view of sore limb. Further, 2 patients were excluded as they were non-compliant in dialysis. Finally, 91 patients were studied till 12 months or the end point (mortality).

Out of 91 patients included in our study, 21.9% (20 patients, Group 2) patients had Intradialytic hypertension and the

remainder of the 71 patients (78.03%, Group 1) served as controls.

Their demographic characteristics including age, sex, comorbidities like diabetes, hypertension, and ischemic heart disease were similar. Their dialysis access and duration on dialysis was also similar in both the groups [Table 1]. Laboratory parameters were similar except serum potassium and serum phosphorus, which were lower in patients with IDH [Table 2]. Drugs, being a possible pathogenic factor, when compared between the two groups, were similar including antihypertensives and erythropoietin. Fluid overload, another factor for IDH was monitored with ‘dry weight’ and interdialytic weight gain or average ‘ultrafiltration’. Dry weight was estimated by both clinical and BIA methods. The 1 week average pre-HD weight was 62.1 ± 10.8 Kgs in group 1 and 58.4 ± 10.2 Kgs in group 2. Similarly, the 1-week average post-HD weight was 59.9 ± 10.5 Kgs in group 1 and 56.5 ± 9.9 Kgs in group 2. No statistically significant difference was observed between these two variables when compared across the group (pre-HD $P = 0.174$; post-HD $P = 0.196$), but the difference in mean pre-HD weight against mean post-HD weight within the group was statistically significant. This difference can be explained by ultrafiltration done during the HD (Group 1 $P = 0.001$;

Group 2 $P = 0.001$). The mean ultrafiltration volume was 2.68 ± 0.80 litres for Group 1 and 2.49 ± 0.81 litres for Group 2 and was non-significant ($P = 0.36$). The detailed BIA results and comparison between the two groups was also similar (not shown).

Ambulatory blood pressure measurement was done for all patients. The 44 hours mean SBP, SBP during the day time and during night was 135.5 ± 17.6, 136.2 ± 17 and 131.6 ± 21.1 respectively for group 1 subjects and was 140.2 ± 20.4, 141.8 ± 21.0 and 137.2 ± 21.9, respectively, for group 2 subjects. Apparently, the mean SBP was higher in group 2 as compared to group 1, but was statistically insignificant. Similarly, the mean DBP over 44 hours, DBP during the day time and night time was higher in group 2 cases compared to group 1, but insignificant.

The 1-week averaged pre-HD SBP and DBP were 148.6 ± 16.7 and 75.1 ± 9.9 mmHg for group 1 and 142.1 ± 15.2 and 73.4 ± 9.2 mmHg for group 2 ($P = 0.08$ for SBP, 0.499 for DBP). The 1-week averaged post-HD systolic and diastolic BP were 149.3 ± 20.9 and 77.1 ± 9.2 mmHg for group 1 and 158.8 ± 18.5 and 80.4 ± 9.2 mmHg for group 2 ($P = 0.105$ for

Table 1: Baseline characteristics of study population

Parameters	Group 1 (n=71) [without IDH]	Group 2 (n=20) [with IDH]	P
Age (in years)	55 (± 13.3)	55.5 (± 10.8)	0.751
Males (%)	48 (67.6)	15 (75)	0.517
Diabetes mellitus (%)	34 (47.9)	9 (45)	0.819
Hypertension (%)	63 (88.7)	19 (95)	0.678
Ischemic heart disease (%)	10 (14.1)	4 (20)	0.499
Duration on HD (in months)	48.1 (± 40.7)	43 (± 33.6)	0.619
Access			
AV fistula (%)	65 (91.6%)	15 (75%)	0.132
Temporary HD cath (%)	1 (1.4%)	1 (5%)	
Permanent HD cath (%)	5 (7%)	4 (20%)	

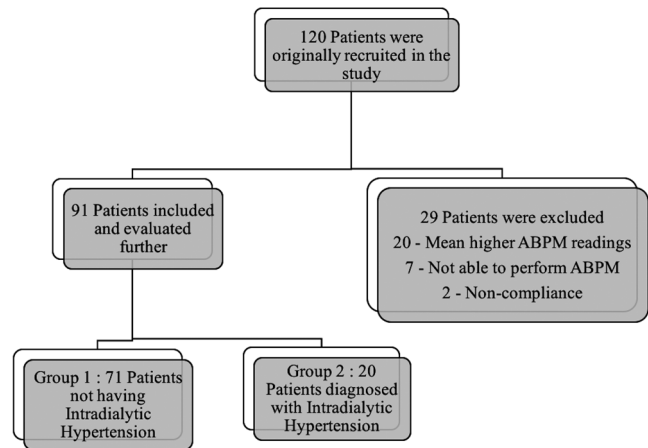


Figure 1: Flow of patients studied for Intra-dialytic Hypertension

Table 2: The laboratory parameters across the two study groups

Laboratory parameters	Group 1 (n=71) [Without IDH]		Group 2 (n=20) [With IDH]		P
	Mean	SD	Mean	SD	
Hemoglobin (gm/dL)	10.53	1.47	10.53	1.12	0.989
Blood urea nitrogen (mg/dL)	41.73	10.40	38.85	9.21	0.265
Sr. Creatinine (mg/dL)	8.24	2.08	7.59	1.93	0.211
Sr. Sodium (mEq/L)	135.98	4.63	145.61	46.91	0.088
Sr. Potassium (mEq/L)	5.02	0.71	4.66	0.47	0.037*
Sr. Calcium (mg/dL)	8.64	0.59	8.38	0.51	0.081
Sr. Phosphorous (mg/dL)	4.66	1.11	3.67	0.80	0.001***
Blood glucose (mg/dL)	145.97	69.17	169.15	111.99	0.260
Sr. Albumin (gm/dL)	3.63	0.41	3.65	0.26	0.807
Sr. Bicarbonate (mmol/L)	19.58	3.03	19.66	3.06	0.913
ALT (IU)	23.80	11.88	21.45	6.44	0.400
Uric Acid (mg/dL)	5.51	1.26	6.06	1.03	0.076

Table 3: The distribution of Pre and Post HD mean blood pressure levels across study groups

Blood pressure (mmHg)	Group 1 (n=71) [Without IDH]		Group 2 (n=20) [With IDH]		P
	Mean	SD	Mean	SD	
Pre-HD					
Systolic BP	148.6	16.7	142.1	15.2	0.089
Diastolic BP	75.1	9.9	73.4	9.2	0.499
Post-HD					
Systolic BP	149.3	20.9	158.8	18.5	0.105
Diastolic BP	77.1	9.2	80.4	9.2	0.142
During HD					
Highest Systolic BP after 2 h of HD	154.2	17.5	162.8	15.5	0.114
Delta					
Systolic BP (Highest BP after 2 h of HD - Pre HD)	5.4	13.7	20.8	8.3	0.001***

SBP, 0.142 for DBP). The mean highest delta SBP (highest SBP – Pre HD SBP) after two hours of HD was 5.4 ± 13.7 mmHg for group 1 and 20.8 ± 8.3 mmHg for group 2 cases ($P = 0.001$) [Table 3].

Out of all the variables studied, demographic and laboratory parameters, only low serum phosphorus was associated independently with IDH [Table 4].

The outcome in terms of morbidity as a result of hospitalization and mortality was compared between those having IDH and those did not. Non-access related hospitalization was higher in patients with IDH at 6 and 12 months [19/71 (26%) non-IDH and 12/20 (60%) IDH patients ($P = 0.006$) at 6 months and at 12 month follow-up, 30/71 (42%) non-IDH patients and 12/20 (60%) IDH patients required admission ($P = 0.05$)]. The reasons for hospitalization included sepsis, pneumonia, stroke, ischemic heart disease, and angina. Mortality was higher at 12 months in those having IDH [11/71 (15.5%) in non-IDH and 8/20 (40%) in IDH, $P = 0.028$], but similar in both the groups at 6 months [5/71 (7%) in non-IDH and 4/20 (20%) in IDH, $P = 0.103$]. The reasons for mortality included sepsis, sudden cardiac death, pneumonia, stroke, and ischemic heart disease.

Discussions

Intradialytic hypertension is a well-recognized complication of maintenance hemodialysis. Patients with IDH have increased risk of morbidity and mortality compared to patients whose BP decreases during HD.^[3] Though IDH has been recognized for many years, there is limited data available in the literature from India. One report regarding prevalence of IDH from India comes from an abstract but had different definition for IDH and was not specifically designed to study the Intradialytic hypertension nor its outcome.^[4] Hence, we planned to study IDH with the aim to evaluate the prevalence of IDH, to study factors responsible for IDH, and to observe impact of IDH on morbidity and mortality over 12 months in patients attending regular HD sessions at a single dialysis unit.

In our study, the prevalence of IDH was found to be 21.9%. This was higher than that reported from literature.

Table 4: Multivariate analysis to obtain the independent determinants of intradialytic hypertension [Logistic Regression Analysis]

Variables in the model	Odds ratio (OR)	95% CI of OR	P
Age group			
<50 years	1.00	-	-
>50 years	1.12	0.77-1.95	0.674 ^{NS}
Sex			
Female	1.00	-	-
Male	1.77	0.71-2.39	0.391 ^{NS}
Systemic illness			
None	1.00	-	-
Present	1.74	0.83-1.91	0.312 ^{NS}
Hemoglobin (gm%)			
>10.0	1.00	-	-
<10.0	1.23	0.89-1.35	0.582 ^{NS}
Sr. Creatinine (mg/dl)			
<7.0	1.00	-	-
>7.0	1.55	0.85-2.12	0.101 ^{NS}
Sr. Sodium (meq/l)			
<135	1.00	-	-
>135	1.61	0.82-2.07	0.226 ^{NS}
Sr. Potassium (meq/l)			
>4.5	1.00	-	-
<4.5	1.68	0.93-2.43	0.087 ^{NS}
Sr. Phosphorous (mg/dl)			
>4.5	1.00	-	-
<4.5	2.96	1.13-4.06	0.022*
Sr Albumin (grams/dl)			
>3.5	1.00	-	-
<3.5	1.25	0.72-2.16	0.142 ^{NS}

In a retrospective analysis of the Crit Line Intradialytic Monitoring Benefit (CLIMB) study, 13.2% of prevalent HD patients had average SBP increases of at least 10 mmHg from pre-HD to post-HD when assessed over 4 HD treatments.^[5] In the study conducted by Dorhout Mees, IDH was seen in 5-15% of patients.^[6] USRDS reported 12.2% prevalence of IDH.^[7] The Indian study which is only published as an abstract also had prevalence of 22% but they had labelled IDH with rise in BP of >20 mmHg.^[4]

When we looked into the outcome measures, morbidity in terms of hospitalization was significantly higher in the group with intradialytic hypertension. This is similar to the observation depicted in the CLIMB study, where they found higher combined end points of hospitalization and death.^[8] We also found higher incidence of mortality at 12 months in patients with IDH. Interim analysis at 6 months did not show any difference in mortality. Inrig *et al.* showed negligible effect of IDH (HR 1.12) on all-cause mortality. However, in the secondary analysis of 438 participants in CLIMB, participants whose SBP rose with HD or whose SBP failed to lower from pre-HD to post-HD, had a 2-fold adjusted increased odds of combined end point of hospitalization or death at 6-months compared to participants whose SBP fell with HD.^[8] Even USRDS data showed 12% excess risk of all-cause mortality over 2 years with every 10 mmHg rise in SBP from pre to post hemodialysis.^[7] Yang *et al.* also showed 3.9 times higher risk of mortality with >5 mmHg rise of BP from pre to post HD.^[9]

Several demographic factors have been studied to be associated with IDH. However, the results are variable among the patients studied. Some study found IDH to be more common in older patients and males.^[10] In CLIMB study, IDH was more prevalent in older age, higher anti-hypertensive medicines, lower dry weight, and lower interdialytic weight gain patients. USRDS showed higher prevalence in older adults, with lower dry weight, lower creatinine, lower albumin, and more numbers of BP medicines.^[7] However, in our study, patients with IDH were not older as compared to controls – the mean age of patients having IDH was 55.5 ± 10.8 years, and those without IDH was 55.0 ± 13.3 years. This result was similar to another study done by Van Buren *et al.*, who found mean age of patients with IDH to be 55.5 ± 10.6 years and that of those without IDH to be 54.1 ± 12.5 years with no statistically significant difference between both the groups ($P = 0.6$).^[3] Chou *et al.* also found similar results in their study (for patients with IDH mean age was 53.2 ± 3.9 and for patients without IDH it was 54.3 ± 4.2 ; $P =$ not significant).^[11]

There was no sex predilection in cases with IDH ($P = 0.517$). Majority of our study population were males – 75% in IDH and 67.6% in non-IDH group. This result was in contrast to study done by Van Buren *et al.*, where majority of their subjects were females, though no difference was observed between the groups (62% in IDH group and 60% in non-IDH group; $P = 0.8$).^[3] Chou *et al.* also found results similar to our study.^[11]

IDH appears to occur more commonly in patients with lower body weight.^[10] In a study done by Inrig *et al.*, among 1,748 incident HD patients, patients with >10 mmHg intradialytic increase in SBP had lower dry weight and lower interdialytic weight gain.^[7] In our study also, the mean estimated dry weight by Body Composition

Monitor (BIA) was lower in IDH group as compared to controls (62.4 ± 11.1 Kgs in non-IDH and it was 56.3 ± 10.8 Kgs in IDH, $P = 0.046$). However, clinical dry weight was similar in both the groups (59.8 ± 10.6 Kgs in non-IDH and 56.2 ± 9.8 kgs in IDH). Contradictory to the above finding, Van Buren *et al.* did not find any difference between estimated dry weights of cases and controls.

When comorbidities like diabetes, hypertension and presence of ischemic heart disease were looked in as an association, again there was no difference between the two groups. Hypertension, however, was found to be the most prevalent single disease amongst both the groups (88.7% in group 1 and 95% in group 2). This observation was similar to the study done by Van Buren *et al.* in which they found HTN as the most prevalent disease across both the study groups with no statistically significant difference for diabetes, hypertension and ischemic heart disease.^[1] Similarly study done by Inrig *et al.* also showed HTN as the most prevalent disease amongst their study population and confirmed our findings.^[8]

Duration of dialysis also had no impact on IDH. The mean duration of HD treatment in non-IDH and IDH cases was 48.1 ± 40.7 months and 43.0 ± 33.6 months respectively with no statistically significant difference observed between the groups ($P = 0.619$). This result was similar to the study done by Chou *et al.* in which the mean duration of HD treatment in non-IDH and IDH was 53.1 ± 9.1 and 49.9 ± 7.4 months respectively with no statistically significant difference observed between them.^[11]

Dialysis access type also was similar in both the groups. AV Fistula was the predominant access type between both groups (91.6% in non-IDH and 75% in IDH; $P = 0.132$). In the study done by Inrig JK *et al.* AV Graft was the predominant access.^[8] This only represents the practice pattern and no relation has been described in literature.

Amongst the various laboratory parameters studied, serum potassium and serum phosphorus levels showed statistically significant difference between the two groups. Both potassium and phosphorus were lower in IDH group. Low serum potassium can have a direct vasoconstrictor effect contributing to IDH. However, the role of dialysate potassium in IDH is uncertain from the literature.^[10] In contrast, patients with IDH in Van Buren *et al.* and Inrig JK *et al.* studies did not show any such difference.^[1,11] Low Potassium as an association or risk factor needs to be relooked in a larger study. We did not find any difference in serum creatinine or albumin as was shown by USRDS study,^[7] but not in CLIMB study.^[8] When subjected to multivariate analysis, low serum phosphorus was found to be the only independent variable associated with IDH. None of the other studies have noted this difference. The relationship and its significance of this finding needs to be further confirmed and evaluated. Low serum magnesium level is associated with intra-dialytic hypotension but

higher levels have not been shown to be associated with IDH in any study. We did not monitor serum magnesium levels in our study.

Drugs also have been implicated as a possible factor in IDH. Washing away of dialyzable drugs and use of erythropoietin are of consideration. Also, patients who exhibit IDH appear to be prescribed more antihypertensive medications, but the role of specific agents remains to be determined.^[10] In our study, we did not find any difference either in number of anti-hypertensives or the types of blood pressure medicines prescribed to either group. Amongst the five different classes of antihypertensive medications (i.e., Calcium channel blocker, β blocker, α blocker, α_2 adrenergic agonist and ACEI/ARB), there was no statistically significant difference observed between the two groups over the use of these medications. The use of erythropoietin also was similar in the two groups. Similarly, amongst other medications (i.e., Antiplatelets, Erythropoietin, Iron supplementation, Diuretic, Vitamin D analog, Phosphate binders, Multivitamins), there was an insignificant difference observed between the groups.

Although we tried a well-designed prospective study to evaluate the prevalence and nature of intradialytic hypertension, which is first for our country to the best of our knowledge, there are strengths and weaknesses of this analysis. Its strengths include pre-enrolment fluid and blood pressure optimization, use of BIA for estimation of dry weight, and use of ABPM for assessment of mean blood pressure, thereby negating some of the confounding factors. Its limitations include being a single centre study with relatively small numbers. As the definition of IDH is not uniform, its prevalence may vary depending on the definition used. A large and preferably multicentre study will confirm the prevalence and factors associated with IDH in India.

Conclusion

To summarize, our study showed a relatively high prevalence of intradialytic hypertension in our patient population (21.9%). Patients with intradialytic hypertension have increased risk of non-access related admissions leading to higher morbidity and increase in mortality in a short span of 1 year. Demographic factors have no association with IDH. Low serum phosphorus was independently associated with IDH.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have

given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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