ORIGINAL RESEARCH PAPER

Nephrology

KEY WORDS: End Stage Renal Disease, Hemodialysis, Dry weight, Bioelectrical Impedence Analysis

TO ASSESS AND COMPARE THE COMPLICATIONS DURING HEMODIALYSIS USING TWO METHODS TO SET THE DRY BODY WEIGHT- BIOELECTRICAL IMPEDENCE ANALYSIS (BIA) TECHNIQUE AND CONVENTIONAL METHOD – ORIGINAL ARTICLE

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ABSTRACT

Introduction: Establishment of accurate dry weight is pivotal in maintaining quality of life of patients receiving hemodialysis treatment. Achieving "normohydration" or appropriate dry weight is associated with longer survival of dialysis patients. Conventional Method is based on patient's clinical signs whereas Bioelectrical impedence analysis (BIA) is a noninvasive and simple technique to determine dry weight.

Objectives: To assess and compare the complications during hemodialysis using two methods to set the dry weight- Bioelectrical Impedence Analysis (BIA) technique and Conventional Method.

Methods: Randomized controlled study conducted over one year on patients with ESRD on Maintenance Hemodialysis. Patients were allocated in two groups. Dry weight of patients in Group I was set by BIA technique and in Group II by conventional method. Patients were observed during hemodialysis session for complications pertaining to both hypovolumia and hypervolumia and complications in the two groups were compared.

Results: 60 patients (Male:Female ratio of 2:1), mean age of 57±11.54yrs, were randomly divided in two groups. Baseline characteristics of the two groups were similar as far as age, sex, height, duration on hemodialysis, associated history of DM-2 and HTN was concerned. Hypovolumic complications were seen in fewer patients in BIA group (40%) as compared to conventional group (56.7%). Number of event free dialysis was more in BIA group (28 patients (93.4%) in BIA group had more than 4 event free dialysis as compared to 20 (66.7%) patients in conventional group). Overall, the difference in complication rate between the two groups was not statistically significant. There was statistically significant drop in systolic and diastolic blood pressure in BIA group post-HD ($p<0.001$) but the same was not seen in conventional group.

Conclusion: In BIA group, the overall complication rate was less and patients had higher number of event free dialysis sessions in comparison to conventional group, although the difference was not statistically significant. The reduction in blood pressure (both systolic and diastolic) post-HD was significant in BIA group but not in conventional group. Thus, BIA is comparable to conventional method and is a reliable method of setting the dry weight in patients on hemodialysis.

INTRODUCTION

Patients with terminal or end stage renal disease (ESRD) require lifetime renal replacement therapy. Depending on the medical condition of the patient, local clinical guidelines and the availability of different therapeutic options, patients can be treated with hemodialysis or peritoneal dialysis modalities.Hemodynamic instability is a challenge that complicates the management of ESRD, and it can present as volume-related hypotension during the dialysis sessions or as hypertension or fluid overload due to insufficient fluid clearance through dialysis (1). Chronic fluid overload was shown to be present even in early stages of renal insufficiency and may contribute significantly to hypertension, accelerated arteriosclerosis and the high prevalence of left ventricular hypertrophy observed in ESRD patients (2). Removal of excess fluid is therefore considered crucial for blood pressure control and for cardiovascular protection in dialysis therapies. Blood Pressure to hypotensive levels during ultrafiltration and unassociated with other obvious causes (3). Gunal proposed that normotension without the use of antihypertensive medications in conjunction with a cardio-thoracic index below 48% is the most important criterion showing that the dry weight is achieved (4).The main problem is how to determine the dry weight. In most situations, dry weight is determined clinically. However, the dry weight recorded in the patient file is not a constant value and may vary between hemodialysis sessions, requiring a revisal in each session because of increased catabolism may lead to hypervolemia if the same weight is maintained (4). Traditional dry weight estimation is done by clinical examination, especially blood pressure monitoring and is based on a trial and error method until euvolemia is achieved. Clinical assessment is a feasible method for determining and achieving dry weight (5). Alternatively, objective methods have been developed to provide reliable and accurate estimates of the dry weight and fluid clearance needs; these include blood volume monitoring, natriuretic peptide measurements, extravascular lung water indices and bioimpedance methods (1). Bioimpedance devices are a technology based on passing a bioelectrical current through the body, and it estimates the body fluid volume by the amount of resistance this current endures in the body tissues. The bioelectrical current used in these devices can have segmental, spectral, or multi-bioelectrical frequencies (6).

Bioelectrical impedance analysis (BIA) is a noninvasive method to determine body composition and dry weight in hemodialysis patients with interobserver and intraobserver error of < 2%, making it a reliable tool for fluid management in hemodialysis patients (7). While BIA has been validated in Caucasian adults, it is not known whether the prediction equations on which it functions are applicable to all hemodialysis patients worldwide (8). The body composition of Asians is quite different from that of Caucasians in terms of fat content and lean mass (9) (10). There is paucity of studies from Asian population, validating the use of BIA in hemodialysis patients. This study aims to compare complications during hemodialysis using two different methods to set the dry weight.

AIMS AND OBJECTIVES

To assess and compare the complications during hemodialysis using two methods to set the dry body weight – Bioelectrical Impedence analysis technique and Conventional method.

MATERIAL AND METHODS

STUDY DESIGN

This was a randomized controlled study conducted in the department of Nephrology at Christian Medical College and Hospital, Ludhiana and included patients with ESRD on maintenance biweekly hemodialysis. The study period was one year, from 15th July 2016 to 14th July 2017. Sample size was 60 patients.

Inclusion Criteria

- Patients with End stage renal disease on maintenance hemodialysis.
- Patients on regular biweekly hemodialysis.
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Exclusion Criteria

- Pregnancy.
- Patients with pacemakers or any implantable electronic device.
- Patients with major amputations of extremities.
- Patients on once a week or thrice a week hemodialysis.
- Patients unwilling or unable to give informed written consent.

METHODOLOGY

All the patients of ESRD on maintenance biweekly hemodialysis in Nephrology department at Christian Medical College and Hospital, Ludhiana were invited to be part of the study. Patients were verified for fulfilling inclusion criteria and ruled out for presence of exclusion criteria. A written informed consent was taken.

Randomization - Patients were allocated using block randomization method in blocks of two, four with allocation ratio 1:1 into two groups, group I and group II.

Methodology - History and clinical examination of all the patients was done and recorded as per proforma. Dry weight of patients in Group I was set using

Bioelectrical impedence analysis technique and dry weight of patients in Group II was set by conventional method.

BIA Technique - Bodystat QuadScan 4000 was used to measure the calf BIA. Prediction Marker was assessed after every half an hour. Point beyond which no change in Prediction Marker occured despite ongoing ultrafiltration, dry weight was said to be achieved. Conventional Method - In conventional method, patient was assessed pre and post-HD in each dialysis session. If patient had symptoms of hypovolemia during last session of dialysis or Pre-HD, dry weight was increased by 0.5 kg. If the symptoms of hypervolumia were present post-HD, then dry weight was decreased by 0.5 kg.

Dialysis was planned according to dry weight obtained in each group. Patients in both the groups were observed during hemodialysis session for complications pertaining to both hypovolumia and hypervolumia. Hypovolumic complications were said to be present if patient had either of the two: postural hypotension or muscle cramps and nausea/vomiting. as SBP/DBP ≥ 140/90 mmHg. At each subsequent dialysis session, dry body weight of patients was reassessed (using Bioelectrical Impedence analysis technique in Group I and Conventional Method in Group II) and patients were observed during dialysis session for complications. Each patient was followed up for eight hemodialysis sessions. The primary outcome was to measure the total number of event free dialysis i.e. the dialysis sessions free from any hypovolumic or hypervolumic complications. Patients were discontinued from the study at the end of eight hemodialysis sessions or at any stage if it was found that patient continuation in the study was not in the interest of the patient or if the patient withdrew the consent.

STATISTICAL ANALYSIS

In the descriptive analysis, continuous variables were expressed as Mean±S.D or Median (IQR) and categorical variables were expressed as count (percentage). Chi-square test was used to compare the categorical variables between the two groups and Fisher Exact test was used when expected cell count was <5. For comparison of continuous variables between the two groups Independent t-test was used for normally distributed data and Mann-Whitney U test was used for non-normally distributed data. Paired t-test or Wilcoxon signed test was used to obtain the improvement in blood pressure and weight within the groups from Pre-HD to Post-HD sessions. The significance level was set at p<0.05. All statistical analysis was performed using SPSS, version 21.0. Armonk, NY: IBM corp.

RESULTS

AGE DISTRIBUTION

TABLE 1: DEMOGRAPHIC PROFILE OF PATIENTS				
Characteristics	Total (n=60)	Group I (n=30)	Group II (n=30)	p-value
Age (years) Mean±S.D	57±11.54	56±9.79	58±13.12	0.445
Age groups (years)	**n (%)**	**n (%)**	**n (%)**	

Total number of patients in this study were 60 (40 (66.7%) males and 20 (33.3%) females), with a mean age of 57±11.54 yrs (Minimum age – 32 yrs and maximum – 100 yrs). Mean age of patients was 56±9.79 yrs in Group

FLOW RATE

	TABLE 2: FLOW RATE			
Flow rate (ml/min)	**Total (n=60)**	**Group I (n=30)**	**Group II (n=30)**	**p-value**
Mean±S.D	313.33±35.50	310.00±33.22	316.67±37.91	0.472
Minimum	200	200	200	
Maximum	350	350	350	

Mean Flow Rate was 313.33±35.50 ml/min. (Minimum Flow Rate – 200 ml/min and maximum – 350 ml/min). Mean Flow Rate of patients in Group I was 310.00±33.22 ml/min and in Group II was 316.67±37.91 ml/min (p=0.472).

VASCULAR ACCESS FOR HD

TABLE 3: VASCULAR ACCESS FOR HD				
Access	**Total (n=60)**	**Group I (n=30)**	**Group II (n=30)**	
	n (%)	**n (%)**	**n (%)**	**p-value**
Left RC AV fistula	26 (43.3)	14 (46.7)	12 (40.0)	0.829
Left BC AV fistula	28 (46.7)	14 (46.7)	14 (46.7)	
Right RC AV fistula	3 (5.0)	1(3.3)	2 (6.7)	
Right BC AV fistula	2 (3.3)	1 (3.3)	1 (3.3)	
Femoral Perm Cath	1 (1.7)	0 (0)	1 (3.3)	

Out of 60 patients, 26 (43.3%) had left RC AV fistula, 28 (46.7%) had left BC AV fistula, 3 (5%) had right RC AV fistula, 2 (3.3%) had right BC AV fistula and 1 (1.7%) had femoral perm cath.

WEIGHT

	TABLE 4: WEIGHT			
Weight (kg)	**Total (n=60)**	**Group I (n=30)**	**Group II (n=30)**	
	Mean±S.D	**Mean±S.D**	**Mean±S.D**	**p-value**
Pre-HD weight	62±14.30	63±16.44	61±12.02	**<0.001**
Post-HD weight	60±14.28	60±16.40	59±12.02	**0.001**
Dry weight	60±14.28	60±16.41	59±12.06	**<0.001**

Mean Pre-HD weight was 62±14.30 kg. (Minimum Pre-HD weight was 37.41 kg and maximum was 114.66 kg). Mean Pre-HD weight of patients in Group I was 63±16.44 kg and in Group II was 61±12.02 kg.

TABLE 5: PRE-HD AND POST-HD WEIGHT IN GROUP I			
	Mean±S.D	**t-score**	**p-value**
Pre-HD weight	63±16.44	13.632	**<0.001**
Post-HD weight	60±16.40		

TABLE 6: PRE-HD AND POST-HD WEIGHT IN GROUP II			
	Mean±S.D	**t-score**	**p-value**
Pre-HD weight	61±12.02	12.918	**<0.001**
Post-HD weight	59±12.02		

COMPLICATIONS DURING HD

TABLE 7: NAUSEA				
Nausea	**Total (n=60)**	**Group I (n=30)**	**Group II (n=30)**	
	n (%)	**n (%)**	**n (%)**	**p-value**
Yes	26 (43.3)	10 (33.3)	16 (53.3)	0.118
No	34 (56.7)	20 (66.7)	14 (46.7)	

Out of 60 patients, 34 patients (56.7%) did not have nausea in any of the 8 sessions of HD that they were observed for. 11 patients (18.3%) had nausea during 1 session of HD, 8 (13.3%) during 2 sessions of HD, 5 (8.3%) during 3 sessions of HD, 1 (1.7%) during 4 sessions of HD and 1 (1.7%) during 5 sessions of HD. In Group I, 20 patients (66.7%) and in Group II, 14 patients (46.7%) did not have nausea in any session of HD (p=0.118)

TABLE 8: NAUSEA DURING HD SESSIONS

HD sessions during which patient had Nausea	Total (n=60)	Group I (n=30)	Group II (n=30)	
	n (%)	n (%)	n (%)	p-value
1	11 (18.3)	6 (20.0)	5 (16.7)	0.363
2	8 (13.3)	3 (10.0)	5 (16.7)	
3	5 (8.3)	1 (3.3)	4 (13.3)	
4	1 (1.7)	0 (0)	1 (3.3)	
5	1 (1.7)	0 (0)	1 (3.3)	

VOMITING

TABLE 9: VOMITING

Vomiting	Total (n=60)	Group I (n=30)	Group II (n=30)	
	n (%)	n (%)	n (%)	p-value
Yes	14 (23.3)	6 (20.0)	8 (26.7)	0.542
No	46 (76.7)	24 (80.0)	22 (73.3)	

Out of 60 patients, 46 (76.7%) had no vomiting during the 8 sessions of HD that they were observed for. 8 patients (13.3%) had vomiting during 1 session of HD, 5 (8.3%) during 2 sessions of HD and 1 (1.7%) during 4 sessions of HD. In Group I, 24 patients (80%) and in Group II, 22 patients (73.3%) did not have vomiting in any session of HD (p=0.542). In Group II, 4 patients (13.3%) had vomiting during 1 session of HD, 3 (10%) during 2 sessions of HD and 1 (3.3%) during 4 sessions of HD. The difference between the two groups was insignificant (p=0.732).

POSTURAL HYPOTENSION

TABLE 10: POSTURAL HYPOTENSION

Postural hypotension	Total (n=60)	Group I (n=30)	Group II (n=30)	
	n (%)	n (%)	n (%)	p-value
Yes	29 (48.3)	12 (40.0)	17 (56.7)	0.196
No	31 (51.7)	18 (60.0)	13 (43.3)	

Out of 60 patients, 31 (51.7%) had no Postural Hypotension during the 8 sessions of HD that they were observed for. 10 patients (16.7%) had Postural Hypotension during 1 session of HD, 11 (18.3%) during 2 sessions of HD, 6 (10%) during 3 sessions of HD, 1 (1.7%) during 4 sessions of HD and 1 (1.7%) during 7 Sessions of HD.

HYPOVOLUMIC COMPLICATION

TABLE 11: HYPOVOLUMIC COMPLICATIONS

Hypovolemic complications	Total (n=60)	Group I (n=30)	Group II (n=30)	
	n (%)	n (%)	n (%)	p-value
Yes	29 (48.3)	12 (40.0)	17 (56.7)	0.196
No	31 (51.7)	18 (60.0)	13 (43.3)	

Out of 60 patients, 31 (51.7%) had no Hypovolumic Complication during the 8 sessions of HD that they were observed for. 11 patients (18.3%) had Hypovolumic Complications during 1 session of HD, 9 (15%) during 2 sessions of HD, 7 (11.7%) during 3 sessions of HD, 1 (1.7%) during 4 sessions of HD and 1 (1.7%) during 7 Sessions of HD.

HYPERTENSION

TABLE 12: HYPERTENSION

Hypertension	Total (n=60)	Group I (n=30)	Group II (n=30)	
	n (%)	n (%)	n (%)	p-value
Yes	28 (46.7)	14 (46.7)	14 (46.7)	1.000
No	32 (53.3)	16 (53.3)	16 (53.3)	

Out of 60 patients, 32 (53.3%) had no Hypertension during the 8 sessions of HD that they were observed for. 7 patients (11.7%) had Hypertension during 1 session of HD, 11 (18.3%) during 2 sessions of HD, 6 (10%) during 3 sessions of HD, 2 (3.3%) during 5 sessions of HD, 1 (1.7%) during 6 Sessions of HD and 1 (1.7%) during 7 sessions of HD. The difference between the two groups was insignificant (p=0.821).

EVENT FREE HD SESSIONS

TABLE 13: EVENT FREE HD SESSIONS

Number of Event-free HD sessions	Total (n=60)	Group I (n=30)	Group II (n=30)	
	n (%)	n (%)	n (%)	p-value
1	2 (3.3)	0 (0)	2 (6.7)	0.162
2	2 (3.3)	1 (3.3)	1 (3.3)	
3	3 (5.0)	1 (3.3)	2 (6.7)	
4	5 (8.3)	0 (0)	5 (16.7)	
5	9 (15.0)	7 (23.3)	2 (6.7)	
6	16 (26.7)	8 (26.7)	8 (26.7)	
7	14 (23.3)	8 (26.7)	6 (20.0)	
8	9 (15.0)	5 (16.7)	4 (13.3)	

Out of 60 patients observed over 8 sessions of HD, 2 patients (3.3%) had 1 event free HD session, 2 (3.3%) had 2, 3 (5%) had 3, 5 (8.3%) had 4, 9 (15%) had 5, 16 (26.7%) had 6, 14 (23.3%) had 7 and 9 (15%) had 8 event free dialysis sessions. The difference between the two groups was not statistically significant (p=0.162).

DISCUSSION

It is very important to make an accurate estimation of dry weight in hemodialysis patients because of the essential role of dry weight in proper prescription of ultrafiltration volume. The more precise ultrafiltration volume is estimated, the less dialysis-related morbidities occur (11). Bioimpedance method analyzes three main compartments including body cell mass, body fat mass, and extracellular mass. Any change or difference in these compartments may lead to different BIA dry weight (12). There has been dearth of studies in the world studying and comparing the intradialytic complications when dry weight was set using different methods. Present study was conducted in the department of Nephrology at Christian Medical College and Hospital, Ludhiana. It aimed to compare the complications- both hypovolumic and hypervolumic, during dialysis using two different methods to set the dry weight – BIA and Conventional method . Several possible sources of bias have been identified in the literature when using BIA which include body position, food intake, environmental conditions, temperature of the skin, and bladder content (13).

As seen in our study, BIA is a reliable method of setting the dry weight in patients on hemodialysis. The complications seen during dialysis were comparable in both the groups, whether dry weight was set using BIA or by conventional method. One reason for fewer complications in the conventional group could be that each patient was seen in dialysis session by a trained nephrologist and the dry weight was adjusted in each visit depending upon the clinical condition of the patient. Based on this, we recommend using BIA for setting dry weight at peripheral dialysis centres where availability of nephrologist is a problem. Doing the same would result in lesser incidence of intradialytic complications and better blood pressure control.

In our study, there was a statistically significant drop in BP, both systolic and diastolic, when dry weight was set using BIA. This correlates with the findings obtained by other authors as described above (by Covic et al, Onofriescu et al and Oei et al). Limitations of our study were that it was a single-centre study of short duration with a small patient population. The underlying aetiology of CKD and coronary status was not taken into consideration. Also the symptoms observed could have multifactorial etiologies. However, it is a first study of its kind, where complications during dialysis were compared in two groups with different methods used to set the dry weight. Whatever new technologies we apply, careful attention to clinical examination and history would continue to play an important role in optimizing fluid management. Therefore,

combination of BIA technique with the clinical method for the correct dry weight estimation should be used and tested. As with all new technologies, there are issues that still need to be resolved. This will be achieved only with larger prospective interventional studies to explore its specific roles in dialysis cohorts. Present study is only amongst the initial steps toward the process of comparing conventional and BIA method in setting dry weight and comparing complications during dialysis, and hopefully, it will result in further investigation in this field in our population.

CONCLUSION

Establishment of accurate dry weight is important in maintaining quality of life of patients receiving hemodialysis. Rate of hypovolemic complications was less when dry weight was set using BIA method as compared to conventional method. In BIA group, the overall complication rate was less and patients had higher number of event free dialysis sessions in comparison to conventional group, although the difference was not statistically significant. Thus, BIA is comparable to conventional method and is a reliable method of setting the dry weight in patients on hemodialysis. The reduction in blood pressure (both systolic and diastolic) post-HD was significant in BIA group but not in conventional group. Further studies with long term follow up will be needed to confirm the same.

REFERENCES

1. Henrich WL. Hemodynamic instability during hemodialysis. Kidney Int.1986;30:605-12.
2. Bellizzi V, Scalfi L, Terracciano V, De Nicola L, Minutolo R, Marra M, et al. Early changes in bioelectrical estimates of body composition in chronic kidney disease. J Am Soc Nephrol. 2006;17:1481-7.
3. Thomson GE, Waterhouse K, McDonald HP, Jr, Friedman EA. Hemodialysis for chronic renal failure. Clinical observations. Arch Intern Med. 1960;120:153–67.
4. Gunal AI. How to determine 'dry weight'? Kidney Int Suppl. 2013;3:377-9.
5. Charra B, Laurent G, Chazot C, Calemard E, Terrat JC, Vanel T, et al. Clinical assessment of dry weight. Nephrol Dial Transplant.1996;11:16–9.
6. Kyle UG, Bosaeus I, De Lorenzo AD, Deurenberg P, Elia M, Gomez JM, et al. Bioelectrical impedance analysis--part I: review of principles and methods. Clin Nutr. 2004;23:1226-43
7. Davies SJ, Garcia Lopez E, Woodrow G, Donovan K, Plum J, Williams P, et al. Longitudinal relationships between fluid status, inflammation, urine volume and plasma metabolites of icodextrin in patients randomized to glucose or icodextrin for the long exchange. Nephrol Dial Transplant. 2008;23:2982–8.
8. Basile C, Vernaglione L, Di Iorio B, Bellizzi V, Chimienti D, Lomonte C, et al. Development and validation of bioimpedance analysis prediction equations for dry weight in hemodialysis patients. Clin J Am Soc Nephrol. 2007;2:675-80
9. Rush EC, Freitas I, Plank LD. Body size, body composition and fat distribution: Comparative analysis of European, Maori, Pacific Island and Asian Indian adults. Br J Nutr. 2009;102:632-41.
10. Norgan NG. Population differences in body composition in relation to the body mass index. Eur J Clin Nutr. 1994;48:S10-25.
11. Chanchairujira T, Mehta RL. Assessing fluid change in hemodialysis: Whole body versus sum of segmental bioimpedance spectroscopy. Kidney Int. 2001;60:2337–42
12. Guida B, De Nicola L, Pecoraro P, Trio R, Di Paola F, Iodice C, et al. Abnormalities of bioimpedance measures in overweight and obese hemodialysed patients. Int J Obes Relat Metab Disord. 2001;25:265–72.
13. Kyle UG, Bosaeus I, De Lorenzo AD, Deurenberg P, Elia M, Manuel Gómez J, et al. Bioelectrical impedance analysis—part II: utilization in clinical practice. Clinical nutrition. 2004;23:1430-53.