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Randomised Controlled Trial

Bioelectrical impedance analysis versus physician adjustment in acute kidney injury patients to reduce intradialytic hypotension: A randomized controlled trial

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ABSTRACT

Introduction: Volume overload and intradialytic hypotension (IDH) are significant complications that can increase the mortality rate in hemodialysis patients.Bioelectrical impedance analysis (BIA) has been used to estimate the optimum weight in chronic hemodialysis patients to prevent intradialytic hypotension. However, data regarding BIA for evaluating hydration in acute kidney injury patients is scarce. We reported the case series of 9 patients who used BIA in comparison with physician adjustment to prevent intradialytic hypotension in patients with acute kidney injury who received renal replacement therapy.

Methods: We randomized 9 patients with acute kidney injury (AKI) and volume overload who underwent 45 sessions of acute hemodialysis at Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand between October 2017 and February 2018 to BIA and physician –adjusted group. Volume overload was defined as a BIA value of more than>0.4. In the physician-adjusted group (control), the estimates for physical examination and fluid balance were recorded. The primary outcome was an intradialytic hypotensive episode. The secondary outcome was hemodialysis-related adverse events and other clinical outcomes. This work is fully compliant with CONSORT criteria (detailed in the supplemental file)

Result: Among 9 patients (55.6% male, median age 65.56 years),the main underlying diseases were hypertension and diabetes mellitus. The main cause of AKI was sepsis. After randomization of overall of 45 sessions in 9 patients with AKI, the intradialytic hypotension event rate in the BIA group was significantly lower than that in the control group (5 events vs 12 events; $P = 0.042$). There were no differences in the rates of hemodialysis-related adverse events and other clinical outcomes between the two groups.

Conclusion: The use of bioelectrical impedance analysis-guided ultrafiltration in patients with acute kidney injury requiring renal replacement therapy can help reduce intradialytic hypotension.

1. Introduction

Intradialytic hypotension (IDH) is a common complication during hemodialysis. It had been reported to occur from 15 to 50% of dialysis treatments, depending on the definition used. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI defined IDH as a decrease in systolic blood pressure by $\geq$ 20 mmHg or a decrease in mean arterial pressure (MAP) by 10 mmHg associated with symptoms [1]. Associated risk factors include old age, female sex, diabetes, autonomic dysfunction, low predialysis blood pressure, low albumin, and severe anemia [2,3]. The main mechanisms are acute hypovolemia induced by rapid removal of blood volume, along with an inadequate response of the cardiovascular in refilling the blood volume from the interstitial space to the intravascular space [4,5]. IDH has thus been associated with cardiovascular mortality as well as patient-reported symptoms, inadequate dialysis, end-organ ischemia, vascular access thrombosis and all-cause mortality [6–10].

Recently, devices called bioelectrical impedance analysis (BIA) has been introduced to guide the management of fluid and nutritional status in the patient with AKI receiving renal replacement therapy (RRT) [11]. BIA measures body compositions with the advantages of non-invasiveness, convenience, low cost, real-time measurements, and

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good reproducibility [12,13]. Recently, BIA was demonstrated to be valuable for evaluating hydration in critically ill patients in the ICU [14]. The accurate assessment of the intravascular volume status is essential for clinicians in daily practice since both hypovolemia and volume overload are associated with increased morbidity and mortality in critical care patients [15]. We report a pilot randomized trial of nine patients using BIA to guide fluid management compared with that using the physician adjustment method.

2. Material and methods

A prospective study was conducted between October 2017 and February 2018 in intensive care unit at Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand. Since this is the first clinical trial that evaluate BIA in AKI patients,we therefore performed pilot study in AKI patients who needed hemodialysis for 16 sessions.The objective was to compare the efficacy of BIA and physician-adjustment method in order to lower the incidence of intra hemodialytic hypotension and complication rates during hemodialysis. The criteria for success was the number of hypotensive episodes and all the complications during hemodialysis. We included nine patients for this pilot study. All the participants provided informed consent, and the study was approved by the local ethics committee. This study was performed following the principles of the Declaration of Helsinki and Good Clinical Practice. Also, it is registered at ClinicalTrials.Gov Identifier: 03916861. This work is fully compliant with CONSORT criteria.

According to the preliminary test to calculate the sample size,the patients were randomized by block randomization from the nurse coordinator into 2 groups: BIA-guide protocol and physician adjustment (control).We found that in BIA-guide protocol group had IDH 1 in total 8 sessions.In contrary, the physician adjustment (control) group, there were 4 IDH from total of 8 sessions.The difference was considered statistically significant.Then the sample size was calculated by mean of superiority trial as followed

$$N = \frac{(Z\alpha + Z\beta)2\,(\pi 1\,(1-\pi 1) + \pi 2\,(1-\pi 2))}{(\pi 1 - \pi 2 - s)2}$$

N = Sample size
α = *type − I error* = 0.05
β = *type − II error* = 0.2 *then* Z_β = 0.842
Z = *Standard value under normal distribution curve* : $Z_{\alpha/2}$ = 1.96 (*two sided test*) *Correlation coefficient* = 0.5 0

$$N = \frac{(1.96 + 0.842)2\,(0.5\,(1-0.5) + 0.125\,(1-0.125))}{(0.5 - 0.125 - 0.2)2}$$

$= 73$ HD sessions/group

N = 146 HD sessions

Then we enrolled patients admitted in ICU who had acute kidney injury (KDIGO stage3) [16] with volume overload and unresponsive to medication therapy and who required renal replacement therapy (RRT) were included. The patients were given intravenous furosemide in the dose range 120–250 mg as a stress test (furosemide stress test) [17]. Patients who were pregnant, those with advanced malignancy, those with previous kidney transplantation, those with AKI from toxins, those who were currently on a pacemaker and had underlying chronic kidney disease (serum creatinine more than 1.2 mg/dL for more than 3 months), and patients with severe cardiovascular disease from chronic cardiac failure or valvular regurgitation, were excluded.

2.1. Study design

After obtaining informed consent, the patients with a diagnosis of AKI and volume overload who required RRT were included.

The following basic data were collected: complete blood count (CBC), urinalysis, serum creatinine, serum albumin, blood sugar, and Acute Physiology and Chronic Health Evaluation II (APACHE II) [18] and The Sequential Organ Failure Assessment (SOFA) scores [19]. The patients were randomized into 2 groups by random sampling. The first group was monitored by Inbody S20 analysis to measure fluid status. The bioimpedance was measured each time prior to the hemodialysis session.The other group, the fluid monitoring was managed by physician adjustment by physical examination and fluid balance recording. The fluid balance (FB) is the total fluid administered minus the total fluid eliminated over a period of time.

2.2. Bioimpedance measurement

A multi-frequency BIA analyzer (Inbody S20, Biospace Co. Ltd, Seoul, Korea) was used to measure resistance or impedance at 6 frequencies ranging between 1 kHz and 1 MHz [20,21].]Eight tactile electrodes were in contact with surfaces of both thumb, palm, front sole, and rear sole. This analyzer is modeling body to 5 cylinders (right arm, left arm, trunk, right leg and left leg). Segmental analysis by Inbody S20 of body composition is based on the 4-compartment model. This 4-Compartment Model assumes that body is composed of four different elements: total body water, protein, minerals, and body fat. Total body water is separated into intracellular (ICW) and extracellular water (ECW) by cellular membranes. In the case of a healthy body, the proportion of ICW and ECW should be maintained at about 3:2 [22]. BIA can not estimate ICF and ECF separately. After it measures a resistance or impedance at frequencies ranging between 1 kHz and 1 MHz from each side, values of resistance or impedance were calculated at all frequencies Then, these data was exchanged to body fluid amounts by means of BIA software. All patients were maintained in the supine position [23]. The BIA measurement of more than 0.4 was considered as edema. This ratio is the result of extracellular water (ECW) divided by the total body water (TBW). ECW/TBW.The normal range of ECW/TBW is higher than 0.36 and less than 0.39. When it is higher than 0.39 and less than 0.40, it is likely to cause mild edema (edema index). When it is higher than 0.40, it is highly possible to cause edema [24,25]. This value was validated by manufacture guideline.

2.3. Technique of BIA measurement

To observe changes of the human body through body composition analysis, it is crucial to perform the analysis each time under the same conditions, temperature, posture.

(1) Make sure not to use this equipment with those that have medical electrical devices, such as a pacemaker.
(2) Do not eat before measurement.
(3) Do not exercise or perform any physical activities before testing.
(4) Do not take a bath or shower prior to measurement.
(5) Perform the measurement after urination or excretion, if possible. Residues inside the human body are interpreted as fat mass. Waste in the body means the analysis will be less accurate.
(6) Measurement should ideally be done before mid-day.
(7) Perform the measurement under normal temperature conditions 20–25 °C (68–77 °F).
(8) It's important to maintain examinee's posture for 10–15 min so that impedance can be measured accurately.
(9) Measuring on a wet bed may affect the results.
(10) Please make sure the examinee's body has no contact with a conductor when testing his or her body.

It is recommended that the examinee lying posture for about 10–15 min before the test, so that body water may be dispersed evenly inside the body. Spread arms naturally to a 15° angle away from trunk.

Make sure thighs do not touch each other, and spread legs to shoulder width. Connect the electrodes at right and left arm, right and left feet. The machine will display the analysis impedance, reactance and phase angles.

The dialysis modalities were intermittent hemodialysis (IHD), 4 h in each session with Rexeed dialyzer (Asahi, Japan) surface area 1.5 m^2. Dialysate flow was 500 ml/min and blood flow was 300 ml/min.

The intervention consisted of.

- Volume control by adjusting the ultrafiltration rate during intermittent HD by using the vale from BIA
- In the control arm (physician-adjusted method), we used the data calculated from the record chart on the amount of fluid intake and output per day together with physical examination by physician to guide the fluid removal by HD

Outcome measurements, such as intradialytic hypotension episodes and intradialytic complications such as chest pain and palpitation, will be recorded. The study was approved by the local ethics committee and was performed in accordance with the principles of the Declaration of Helsinki.

2.4. Statistical analysis

Continuous variables with normal distributions are reported as the mean +SD, skewed data as median (interquartile range), and categorical data as a count (percentage). Normality was tested with the Shapiro-Wilkinson test. Comparisons of variables with a normal distribution were performed with the *t*-test, and comparisons of variables with a skewed distribution were performed with the Mann-Whitney *U* test. The statistical analyses were performed using SPSS version 22.0. Two-tailed P values < 0.05 were considered statistically significant.

3. Results

The study included nine acute kidney injury patients and volume overload who underwent acute intermittent hemodialysis for a total of 45 sessions at the Faculty of Medicine, Vajira Hospital,Navamindradhiraj University in Bangkok, Thailand, between October 2017 and February 2018. Volume overload was defined by a BIA value of more than 0.4. The baseline characteristics are shown in Table 1.

The patients were randomized into 2 groups based on the hemodialysis sessions (HD).Each patient can have both of these two modalities of fluid monitoring. The first group underwent the BIA-guided protocol (B). The second group underwent the protocol in which clinical information was obtained by the physician and was guided by the fluid balance record (control group, C). The clinical information included hemodynamic stability, symptoms and signs of hypervolemia (edema, dyspnea, crackles) and signs of hypovolemia (poor skin turgor, dizziness, hypotension, tachycardia). There were no differences in the baseline characteristics between the two groups in terms of age, sex, blood pressure level, SOFA and APACHE II scores. Eight of nine patients were diabetic. Table 2 shows the baseline characteristics of the patients by randomization group. The ultrafiltration volume, urine output, and fluid excess were greater in the control group than in the other group. The mean age of the patients was 65.6 years. There were 5 males (55.6%). The most prevalent underlying diseases were diabetes mellitus (n = 8; 88.9%) and hypertension (n = 7, 77.8%). The most common cause of AKI was sepsis.

Table 1
Baseline Characteristics of All randomly Assigned Patients.

Characteristics	N = 9	%
Sex		
Male	5	(55.6)
Age (yr)	65.56 ± 15.40	
Underlying diseases		
DM	8	(88.9)
HT	7	(77.8)
DLP	6	(66.7)
CAD	1	(11.1)
AF	1	(11.1)
Cirrhosis	2	(22.2)
Vascular access: internal jugular	6	(66.67)

Abbreviations: AF, Atrial fibrillation; CAD, Coronary artery disease; DM, Diabetes mellitus; DLP, Dyslipidemia; HT, Hypertension.

3.1. Basic laboratory parameters

The baseline laboratory parameters, such as complete blood count (CBC), electrolyte, calcium, phosphorus, magnesium and serum albumin were not significantly different between the two groups (Table 3).

3.2. Hydration status and ultrafiltration volume

The average fluid balance per day, cumulative fluid balance (CFB), fluid overload in hemodialysis day and urine output were higher in the control group than in the BIA group, but this difference was not statistically significant (1.4 L vs 1.2 L, 4.4 L vs 3.32 L, 3.83 L vs 3.58 L and 55.47 + 336.80 mL vs 526.74 + 361.95 mL, respectively). However, the ultrafiltration volume in the BIA group was not significantly higher than that in the control group.

Table 2
Baseline characteristics of patients by randomization group.

Characteristics	BIA group (22 sessions)		Control group (23 sessions)		p-value*
Sex					
Male	15	(68.2)	14	(60.9)	0.608
Age (yr)	56	(48–78)	59	(50–80)	0.963
Underlying diseases					
DM	19	(86.4)	20	(87.0)	1.000
HT	17	(77.3)	19	(82.6)	0.772
DLP	15	(68.2)	17	(73.9)	0.672
CAD	2	(9.1)	1	(4.3)	0.608
AF	3	(13.6)	3	(13.0)	1.000
Cirrhosis	8	(36.4)	8	(34.8)	0.912
CKD (n)	10	(45.5)	11	(47.8)	0.873
Weight (kg)	71	(55–74)	71	(55–74)	0.663
BMI (kg/m2)	24.44	(23.67–24.57)	24.44	(23.19–24.57)	0.714
SBP (mmHg)	119.95 ± 19.69		122.43 ± 18.36		0.664
DBP (mmHg)	62.05 ± 15.26		61.48 ± 12.22		0.891
MAP (mmHg)	81.35 ± 15.78		81.8 ± 11.94		0.915
SOFA	7.5	(5–9)	7	(5–9)	0.720
APACHE	20.5	(19–22)	20	(19–22)	0.982
Vasopressor: Levodopa	8	(36.4)	8	(34.8)	0.912
FB/day	1.2	(0.7–2.1)	1.4	(1.0–1.7)	0.973
CFB (L)	3.3	(2.5–5.0)	4.4	(3.3–5.6)	0.296
Urine/day (L)	526.14 ± 361.95		554.70 ± 336.88		0.785
fluid overload (L)	3.58 ± 1.21		3.83 ± 1.5		0.551
Ultrafiltration (L)	3.13 ± 1.09		2.99 ± 1.2		0.675
Diuretic use	21	(95.5)	21	(91.3)	1.000
Vascular access: IJV	13	(59.1)	13	(56.5)	0.862
Dialyzer: Rexeed	22	(100.0)	23	(100.0)	NA
Dialysate Temperature	36.5	(36–36.5)	36	(36–36.5)	0.314
Dialysate potassium	3	(2.0–3.0)	3	(2.0–3.0)	0.975
Dialysate calcium	3.5	(2.5–3.5)	3.5	(2.5–3.5)	0.306
Dialysate sodium	140	(138–140)	140	(138–140)	0.782

Abbreviations: AF, Atrial fibrillation; CAD, Coronary artery disease; CFB, Cumulative fluid balance; CKD, Chronic kidney disease; DM, Diabetes mellitus; DLP, Dyslipidemia; DBP; Diastolic blood pressure; FB, Fluid balance; HT, Hypertension; MAP, Mean arterial blood pressure; SBP, Systolic blood pressure.

Table 3
Baseline laboratory characteristics of patients by randomization group.

Characteristics	BIA group (22 sessions)		Control group (23 sessions)		p-value*
Hct (%)	26.2	(23.6–29.3)	25.5	(24.3–28.3)	0.919
WBC (cells/mm3)	9925	(6650–15800)	12,100	(8175–15,120)	0.991
Platelet (mm3)	54,000	(36000–118000)	67,000	(43,000–101,500)	0.658
FBS (mg/dL)	163.64 ± 47.48		172.87 ± 55.44		0.552
Pre-BUN (mg/dL)	82.18 ± 25.20		88.87 ± 30.19		0.425
Post-BUN(mg/dL)	59.32 ± 22.54		61.04 ± 21.78		0.795
Cr-admit (mg/dl)	1.37	(0.98–1.55)	1.37	(1.10–1.69)	0.566
Cr (mg/dL)	4.42 ± 1.80		4.57 ± 1.69		0.768
Na (mmol/L)	132.91 ± 6.23		132.57 ± 5.50		0.845
K (mmol/L)	3.77 ± 0.44		3.84 ± 0.50		0.616
Cl (mmol/L)	97.36 ± 5.89		97.52 ± 5.11		0.924
CO2 (mmol/L)	21.27 ± 2.83		20.09 ± 3.01		0.181
Ca (mg/dL)	8.5	(8.0–8.9)	8.3	(8.0–8.9)	1.000
Phosphate (mg/dL)	4.95 ± 1.77		5.3 ± 1.77		0.500
Mg (mg/dL)	2	(1.7–2.2)	2	(1.9–2.5)	0.657
Albumin (g/L)	2.07 ± 0.44		2.04 ± 0.50		0.788

Abbreviations: AF, Atrial fibrillation; CAD, Coronary artery disease; BUN, Blood urea nitrogen; CFB, Cumulative fluid balance; CKD, Chronic kidney disease; DM, Diabetes mellitus; DLP, Dyslipidemia; DBP, Diastolic blood pressure; FB, Fluid balance; Hct, Hematocrit; HT, Hypertension; MAP, Mean arterial blood pressure; Mg, Magnesium; SBP, Systolic blood pressure.

3.3. Blood pressure and the prevalence of hypotension

Mean arterial blood pressure at baseline was not different between the 2 groups (81.35 + 15.78 mmHg in the BIA group vs 81.8 + 11.94 mmHg in the control group, P value = 0.915) As many as 52.2% of dialysis sessions in the control group were complicated by a decrease in systolic blood pressure (SBP) of >20 mmHg, compared with 22.7% of hypotensive episodes shown in the BIA group (22.7% p = 0.042). The lowest blood pressure that recorded was 85/43 mm Hg (Fig. 1).

4. Prevalence of other clinical outcomes

During all of the HD sessions, there were no differences in any of the other secondary outcomes between the two groups (Table 4) i.e., ventilator day, hospital length of stay, mortality, cardiac arrhythmia, and residual fluid overload. The renal recovery was also not different between the two treatment groups (Fig. 2).

5. Discussion

Fluid balance in critically ill patients has an impact on mortality, and proper fluid management is essential in the treatment of AKI and related conditions, such as septic shock and heart failure [26]. Moreover, some recent studies have emphasized the effect of fluid balance on mortality

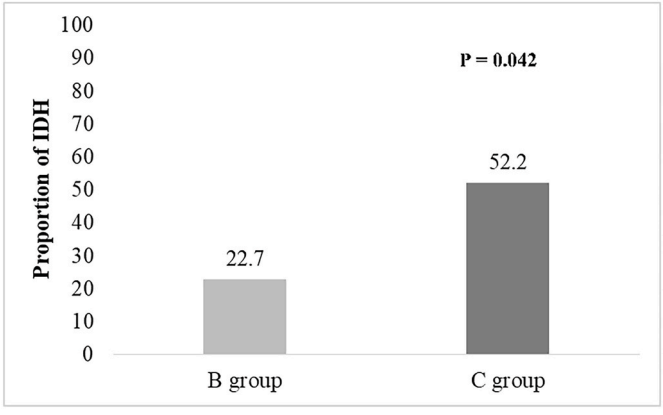

Fig. 1. Proportions of intradialytic hypotension in the two groups
BTO DC: BIA-Guided group
C: Control, Physician-adjusted group
IDH, Intradialytic hypotension.

Table 4
Intradialytic hypotension and clinical outcomes.

Outcome	BIA group (22 session)		Control group (23 session)		p-value*
IDH	5	(22.7)	12	(52.2)	0.042
Ventilator day (day)	17	(77.3)	16	(69.6)	0.559
RRT use (n)	22	(100.0)	21	(91.3)	0.489
Renal recovery (n)	2	(9.1)	3	(13.0)	1.000
Fluid overload (L)	13	(59.1)	15	(65.2)	0.672
Bleeding (episode)	2	(9.1)	2	(8.7)	1.000

Abbreviations: CAD, Coronary artery disease; IDH, Intradialytic hypotension; RRT, Renal replacement therapy.

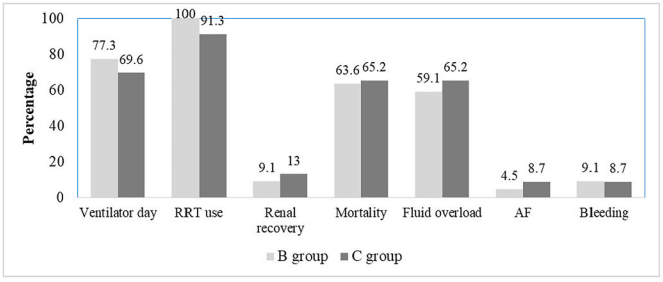

Fig. 2. Proportions of intradialytic hypotension in the two groups
B: BIA-Guided group
C: Control, Physician-adjusted group
RRT: Renal replacement therapy
AF: Atrial fibrillation.

[27,28]. Traditionally, hydration status was evaluated by the means of fluid balance recording or body weight measurement. These methods are easy to perform but subjective and often unreliable [15]. In addition, precise body weight measurements may be difficult to measure in ICU patients. In contrast, the recording of fluid balance and the differences in input and output of fluid is subject to error since it does not include insensible loss [28]. Bioelectrical impedance analysis (BIA), which has been validated in healthy individuals as well as in maintenance HD and peritoneal dialysis patients, may be a more promising tool to help guide fluid volume control in AKI patients.

Hur et al. investigated bioimpedance spectroscopy to assess fluid overload in HD patients. They found that bioimpedance spectroscopy provides a better management of fluid status, leading to regression of the left ventricular mass index, a decrease in blood pressure, and an

improvement of arterial stiffness [29].

Hyperhydration, as assessed by BIA, has been shown to be correlated with long-term mortality in critically ill patients with or without AKI, while cumulative fluid balance recording failed to show any significant association between fluid balance and ICU mortality [30]. Hence, BIA may have feasibility to guide fluid balance management in critically ill patients.

Taking this into account, the use of BIA will be compared to standard fluid balance recording and the physician-adjusted method in terms of intradialytic hypotension and other secondary outcomes in AKI patients. To date, there is no study that has compared these two methods in this regard.We therefore performed the pilot study to test the hypothesis and feasibility in order to obtain sufficient data for the main study. problems.

We found that the BIA-guided protocol can reduce significantly the incidence of IDH ($P = 0.042$). However, the secondary outcomes, such as ventilator day, duration of RRT, renal recovery, hospital length of stay, mortality and cardiac complications such as atrial fibrillation, were not significantly different between the BIA group and control group (Table 4). Previous studies have shown the correlation effect of BIA with volume status on the mortality in critically ill patients (VENUS trials) [31]. We report a series of nine cases whose majority were diabetic group that involved BIA-guided fluid management in CRRT-treated AKI patients. This study will be the first case series to compare the BIA-guided protocol with the physician adjustment protocol in terms of reducing the incidence of intradialytic hypotension. Hypotension from hypovolemia is the strongest causative factor in morbidity during dialysis and can contribute to increased kidney damage [32]. Therefore, accurate fluid removal during HD therapy is of utmost importance.

BIA is commonly used in healthy subjects [33] and in chronic kidney disease patients undergoing HD and peritoneal dialysis (PD). However, its role in critically ill patients is still controversial [34]. Recently, Rosa Hise et al. also found an association between hydration status and death using BIA as a method to measure fluid status in critically ill patients with AKI [35].

In our series, the BIA-guided protocol helped reduce intradialytic hypotension episodes, even though the fluid accumulation per day in the physician-adjusted group was greater than that in the BIA group. The use of BIA can contribute to a reduction in hypotensive episodes. As mentioned above, the greater reductions in mean arterial blood pressure (MAP) from dialysis was independently associated with an increased risk of death and a lower probability of renal recovery. The ultrafiltration volume was less in the physician-adjusted group than in the BIA group, which may be due to the inclusion of more septic shock patients in the physician-adjusted group. The other secondary outcomes were not significantly different between the two groups, which could be due to the low number of patients in this study and the inclusion of only a single center. This may not represent the general population as a whole. A limitation of this study is that the measurement of outcome was performed in each HD session, which could have confounding effects from the ultrafiltration form previous HD session. This can be overcome by performing crossover trials on this topic in the future.

6. Conclusion

The evidence from this study demonstrates the superiority of BIA over the conventional physician-adjusted method and fluid balance recording in terms of intradialytic hypotension. This finding implies that it has positive consequences on IDH, such as renal recovery and mortality, even though this was not significant. BIA could be a useful instrument to assess hydration status in critically ill patients and provide better management of fluid status.

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Author contributions

NK created the research idea and study design,data analysis/interpretation: TT; statistical analysis: supervision or mentorship: write the manuscript.

NK,TT takes responsibility that this study has been reported honestly, accurately and transparently, and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved .

Data availability statement

All data generated and/or analyzed in this study are included in this published article.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Annals of medicine and surgery

The following information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned. If you have nothing to declare in any of these categories then this should be stated.

Conflicts of interest

The authors have no conflict of interest to declare.x.

Sources of funding

This research received a grant from Navamindradhiraj University.

Ethical approval

The study was approved by the local ethics committee and was performed in accordance with the principles of the Declaration of Helsinki.

Consent

Studies on patients or volunteers require ethics committee approval and fully informed written consent which should be documented in the paper.

Authors must obtain written and signed consent to publish a case report from the patient (or, where applicable, the patient's guardian or next of kin) prior to submission. We ask Authors to confirm as part of the submission process that such consent has been obtained, and the manuscript must include a statement to this effect in a consent section at the end of the manuscript, as follows: "Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request".

Patients have a right to privacy. Patients' and volunteers' names, initials, or hospital numbers should not be used. Images of patients or volunteers should not be used unless the information is essential for scientific purposes and explicit permission has been given as part of the consent. If such consent is made subject to any conditions, **the Editor in Chief** must be made aware of all such conditions.

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

Registration of research studies

1. Name of the registry: Clinicaltarials.Gov
2. Unique Identifying number or registration ID: NCT03916861
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sid=S0008T3Z&selectactio

Guarantor

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M.D.

Declaration of competing interest

The authors have no conflict of interest to declare.

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