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RESEARCH ARTICLE

Home-based body water monitoring and management system for heart failure patients using bioelectrical impedance analysis

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Abstract

Introduction This study evaluated the feasibility, acceptability, and clinical effectiveness of a home-based body water monitoring and pre-emptive management system using bioelectrical impedance analysis (BIA) in patients with heart failure (HF).

Methods In this multicentre, open-label, randomized controlled trial, 40 HF patients receiving loop diuretics were assigned to standard care or a home BIA group using a home-based BIA device with a linked application providing weekly feedback and guidance on diuretic management. Feasibility outcomes included study completion, adherence, usability and acceptability scores, and adverse events over 12 weeks. Effectiveness outcomes included changes in NT-proBNP, oedema index, New York Heart Association (NYHA) functional class, HF hospitalization, and all-cause mortality.

Results Thirty-nine patients were included in the final analysis after exclusion of one patient lost to follow-up in the control group. Patients in the control group were older than those in the home BIA group (70.4 ± 8.3 vs 57.2 ± 13.5; $P = .003$), and baseline NT-proBNP levels were higher (2737.1 ± 3817.1 vs 1357.7 ± 2196.8 pg/ml; $P = .013$), while other baseline characteristics were comparable. In the home BIA group, the completion rate was 100.0% and adherence to BIA measurements was 82.5%. Acute kidney injury occurred in one patient (5.0%), with no discontinuations due to adverse events. Usability and acceptability were high (4.21 ± 0.59; 3.90 ± 0.53, respectively) on a 5-point Likert scale. There were no significant differences in changes in NT-proBNP or oedema index during follow-up between groups. Worsening NYHA class occurred less frequently in the home BIA group (10.0% vs 31.6%; $P = .095$). Changes in the oedema index correlated with changes in NT-proBNP ($r = 0.544$; $P = .002$), whereas changes in body weight did not ($r = 0.237$; $P = .147$). No HF hospitalizations or deaths occurred.

Conclusion Home-based BIA monitoring with pre-emptive management is feasible, acceptable, and safe for patients with HF.

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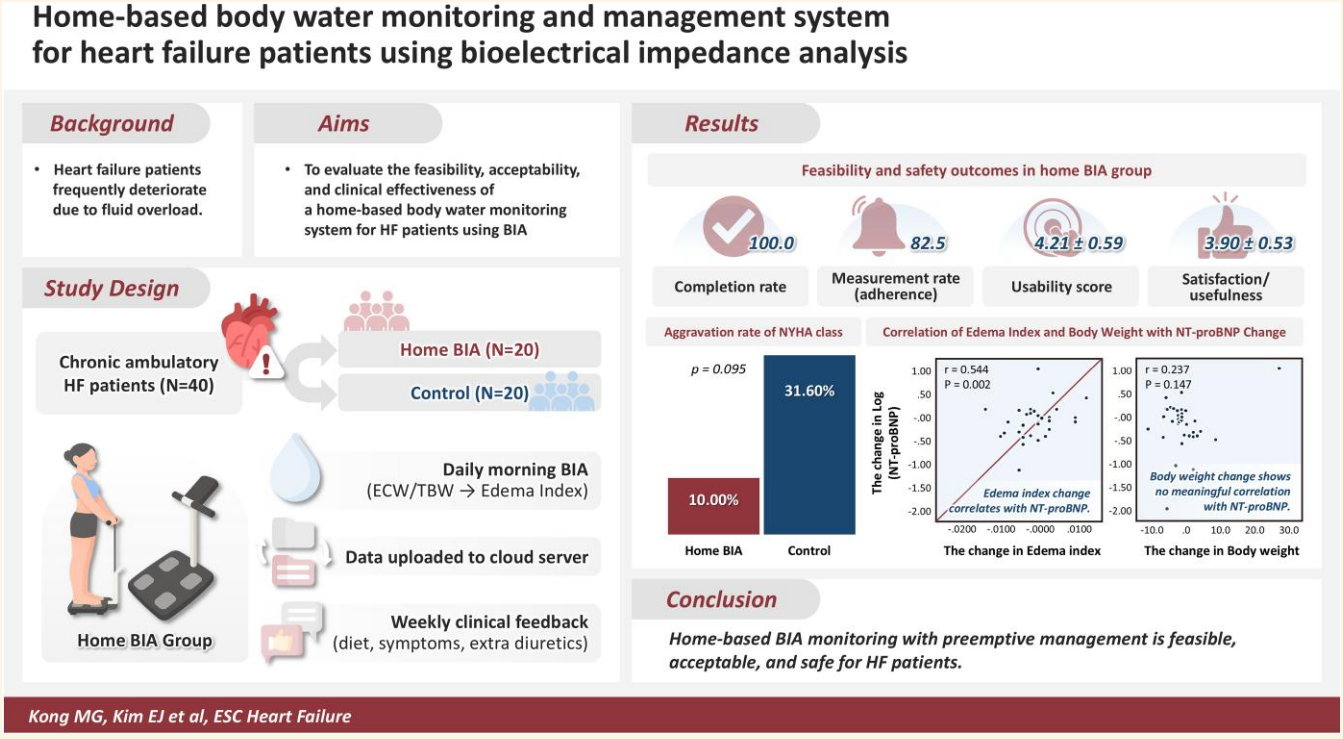
Graphical Abstract



Keywords Bioelectrical impedance analysis • Heart failure • Body water monitoring • Oedema index

Introduction

Heart failure (HF) prevalence has risen sharply owing to an ageing population and advances in medical technology, resulting in longer life expectancy.[1] As HF progresses, the frequency of acute decompensated episodes increases, leading to higher re-admission rates and a greater mortality risk.[2,3] Traditionally, HF management has focused on acute care, along with pharmacological, device-based, and surgical interventions. However, guidance for managing daily life post-discharge—such as recognizing symptom changes, dietary management, and adherence to physical activity and medication—is often lacking or insufficient. Monitoring body fluid status is essential to prevent urgent emergency room visits and re-hospitalizations due to dyspnoea and oedema in HF patients following discharge.[4]

Although European HF management guidelines recommend training patients to adjust their diuretic doses based on daily weight measurements and symptom progression, relying solely on daily weight monitoring has limitations.[5] Signs and symptoms of HF aggravation are typically recognized an average of 7 and 3 days before emergency events and hospitalizations, respectively.[6]

Recently, non-invasive bioelectrical impedance analysis (BIA) was explored as an alternative to invasive methods, such as wireless implantable haemodynamic monitoring systems for pulmonary artery pressure, in HF patients.[7,8] Studies suggest that BIA monitoring can predict worsening HF in these patients.[9,10] Furthermore, research indicates that monitoring the extracellular fluid-to-total body water ratio using non-invasive multi-frequency BIA can improve clinical outcomes.[11,12] However, most previous studies have been small-scale and retrospective in nature, and even those incorporating body water-based interventions employed algorithms using monthly measurements obtained during hospital visits rather than continuous monitoring. In this study, home BIA offers the potential advantage of continuous assessment of body water status for the management of oedema in patients with heart failure. Building upon these prior findings, this study sought to address these limitations by implementing a system based on daily body water measurements and a linked application, enabling continuous monitoring and weekly, pre-emptive clinical interventions to evaluate their feasibility, acceptability, and potential clinical efficacy in heart failure management.

Methods

Patients

This study involved chronic ambulatory patients diagnosed with HF who were using loop diuretics to manage HF symptoms, regardless of their left ventricular ejection fraction (LVEF), as measured on echocardiography. Patients who were unable to undergo BIA or those with oedema resulting from other conditions affecting body composition measurements were excluded. Detailed inclusion and exclusion criteria have been previously published.[13]

Study design and flow

This multicentre, prospective, open-label, randomized clinical trial was conducted at two tertiary hospitals in Korea: Korea University Guro Hospital and Soonchunhyang University Bucheon Hospital. The trial was registered

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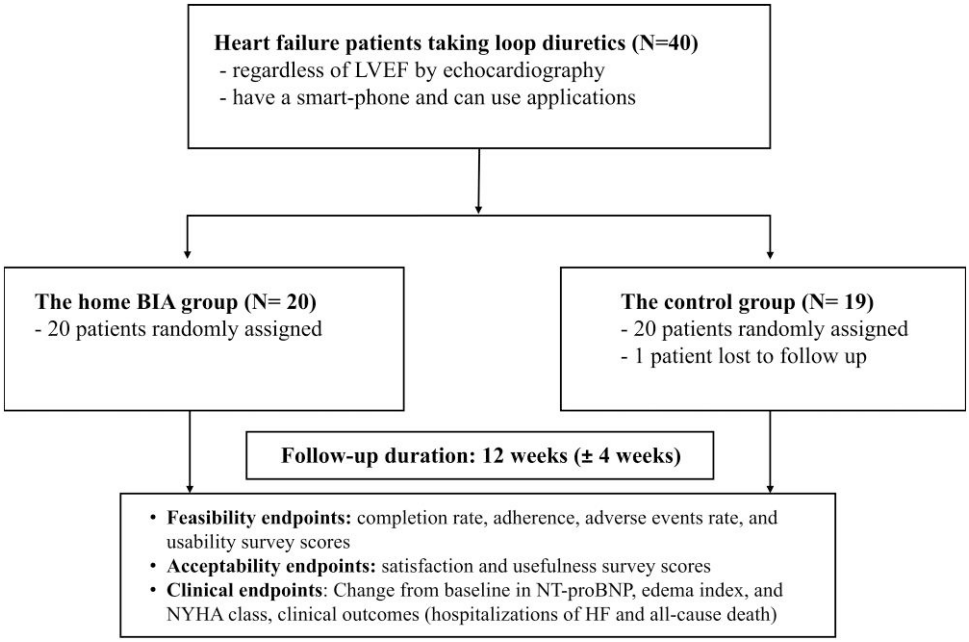

Figure 1 Study flow

at ClinicalTrials.gov (NCT 05177081). The study flowchart is shown in *Figure 1*. A total of 40 patients were randomized in a 1:1 ratio to either the home BIA monitoring group or the control group using a sealed opaque envelope method. The random sequence was generated in advance, and consecutively numbered envelopes were prepared by an independent research coordinator not involved in patient recruitment or assessment to ensure allocation concealment. Participants randomized to the home BIA group had their body fluid composition measured daily using a home BIA device at the same time each morning for 12 weeks. These patients received weekly text messages with updates about their fluid status and changes compared with the previous week. Body fluid changes were calculated based on the average measurements obtained on Fridays, Saturdays, and Sundays during the current and previous weeks. Additionally, patients received weekly guidance on behaviours, such as reducing salt intake, monitoring symptoms, attending medical appointments, and, if necessary, using extra diuretics (20–80 mg/day furosemide) based on fluid status analysis (Supplementary Figure S1). If a patient missed BIA measurements for three consecutive days, the system automatically sent a push notification. The control group received standard HF management without BIA-based intervention.

Body fluid measurement using BIA

BIA measurements included total body water (TBW), extracellular water (ECW), intracellular water (ICW), and the oedema index—ratio of ECW to TBW. These measurements were taken for different body segments, including the entire body, trunk, arms, and legs. All participants had their body fluid composition measured with a standard BIA device (InBody S10; InBody®, Seoul, Republic of Korea) at enrolment and at the end of the study (12 weeks). Participants in the home BIA group used a portable BIA device (BWA-ON; InBody®, Seoul, Republic of Korea) daily every morning. Both devices provide non-invasive, multifrequency bioimpedance measurements. The data from daily measurements were transmitted to a cloud server and analysed weekly at the control centre (Supplementary Figure S2).[13]

Endpoints

Feasibility was assessed through completion rates, adherence [(days of BIA usage/days of follow-up duration) × 100], adverse event rates, and usability survey scores based on a 5-point Likert scale at the 12-week follow-up. Acceptability was evaluated using satisfaction and usefulness scores from a similar survey. The preliminary clinical effectiveness endpoints included changes in NT-proBNP levels, oedema index, dyspnoea severity based on the New York Heart Association (NYHA) functional class, and clinical outcomes such as hospitalization for HF and all-cause mortality over a 12-week period.

Statistical analysis

Data were analysed using the per-protocol population. Categorical variables are reported as numbers and percentages, while continuous variables are presented as means and standard deviations. Changes in NT-proBNP levels were log-transformed and analysed. Comparisons between the two groups were made using the $\chi 2$ test or Mann–Whitney test. Pearson's correlation analysis was used to evaluate the relationship between changes in NT-proBNP levels and body water composition. All analyses were conducted using SPSS (version 20.0; IBM Corp., Armonk, NY, USA). All *P*-values were two-sided, with *P*-values $< .05$ indicating statistical significance.

Results

Baseline characteristics

Between August 2021 and April 2022, 40 patients were randomly assigned to either the home BIA group ($n = 20$) or the control group ($n = 20$). Data from 39 patients were analysed, excluding one patient in the control group who was lost to follow-up. *Table 1* shows that patients in the control group were older than those in the home BIA group (57.2 ± 13.5 vs 70.4 ± 8.3; $P = .003$). No significant differences were observed in other baseline characteristics, including male sex, BMI, proportion of HF with reduced ejection fraction, comorbidities, NYHA II or III classification, blood pressure, serum creatinine, and medication history between the two groups. There were also no differences in body fluid composition as measured using BIA, including ICW, ECW, TBW, and oedema index. The level of NT-proBNP was

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Table 1 Baseline characteristics

	Home BIA ($n = 20$)	Control ($n = 19$)	*P*-value
Age (years)	57.2 ± 13.5	70.4 ± 8.3	.003
Male	13 (65.0%)	9 (47.4%)	.267
Body weight (kg)	63.5 ± 9.1	62.5 ± 9.6	.901
BMI (kg/m^2)	23.4 ± 2.8	24.4 ± 2.8	.496
HF category			.113
HFrEF	12 (60.0%)	12 (63.2%)	
HFmrEF	3 (15.0%)	0 (.0%)	
HFpEF	2 (10.0%)	6 (31.6%)	
HFimpEF	3 (15.0%)	1 (5.3%)	
Diabetes	9 (45.0%)	7 (36.8%)	.605
Hypertension	13 (65.0%)	16 (84.2%)	.170
Coronary artery disease	4 (20.0%)	7 (36.8%)	.243
Chronic kidney disease	2 (10.0%)	3 (15.8%)	.589
Atrial fibrillation	7 (35.0%)	10 (52.6%)	.267
NYHA classification			.810
Class I	11 (55.0%)	10 (52.6%)	
Class II	8 (40.0%)	7 (36.8%)	
Class III	1 (5.0%)	2 (10.5%)	
Class IV	0 (0.0%)	0 (0.0%)	
Systolic blood pressure (mmHg)	118.5 ± 15.9	117.5 ± 16.3	.771
Diastolic blood pressure (mmHg)	69.7 ± 12.6	68.1 ± 8.7	.923
Heart rate (beats/min)	81.6 ± 11.8	76.1 ± 12.5	.089
LVEF (%)	37.7 ± 14.6	39.8 ± 16.9	.879
ICW (L)	20.7 ± 3.5	19.1 ± 4.1	.239
ECW (L)	13.5 ± 2.2	12.6 ± 2.9	.239
TBW (L)	34.2 ± 5.6	31.8 ± 6.9	.224
Oedema index	0.395 ± 0.014	0.398 ± 0.011	.210
NT-proBNP (pg/ml)	1357.7 ± 2196.8	2737.1 ± 3817.1	.013
BUN (mg/dl)	21.5 ± 8.3	20.1 ± 4.7	.708
Creatinine (mg/dl)	1.09 ± 0.37	1.07 ± 0.21	.989
Sodium (mmol/L)	139.5 ± 1.7	140.2 ± 2.0	.224
Potassium (mmol/L)	4.4 ± 0.4	4.4 ± 0.7	.428
Medication			
ACEi	1 (5.0%)	1 (5.3%)	.970
ARB	6 (30.0%)	10 (52.6%)	.151
ARNI	11 (55.0%)	6 (31.6%)	.140
Beta-blocker	19 (95.0%)	17 (89.5%)	.517
MRA	17 (85.0%)	13 (68.4%)	.219
SGLT2 inhibitor	8 (40.0%)	4 (21.1%)	.200
Furosemide	19 (95.0%)	15 (78.9%)	.134
Furosemide dose (mg/day)	34.7 ± 26.5	39.3 ± 25.8	.615
Torsemide	0 (0.0%)	2 (10.5%)	.136
Torsemide dose (mg/day)	0.0 ± 0.0	5.0 ± 0.0	
Azosemide	1 (5.0%)	2 (10.5%)	.517
Azosemide dose (mg/day)	30.0 ± 0.0	30.0 ± 0.0	
Thiazide	0 (0.0%)	0 (0.0%)	
CCB	2 (10.0%)	4 (21.1%)	.407
Statin	11 (55.0%)	14 (73.7%)	.320
NSAIDs	0 (0.0%)	0 (0.0%)	

BMI, body mass index; HF, heart failure; HFrEF, HF with reduced ejection fraction; HFmrEF, HF with mildly reduced ejection fraction; HFpEF, HF with preserved ejection fraction; HFimpEF, HF with improved ejection fraction; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; ICW, intracellular water; ECW, extracellular water; TBW, total body water; NT-proBNP, N-terminal pro-brain natriuretic peptide; ACEi, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; MRA, mineralocorticoid receptor antagonist; CCB, calcium channel blocker; NSAIDs, non-steroidal anti-inflammatory drug

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significantly higher in the control group (1357.7 ± 2196.8 vs 2737.1 ± 3817.1 pg/ml; $P = .013$) than in the home BIA group. Regarding prescription rates, there were no significant differences in optimal HF medical therapies, such as RAAS blockade, beta-blockers, MRAs, and SGLT2 inhibitors. Most patients in both groups were prescribed furosemide as a loop diuretic (95.0% and 78.9%, respectively), and there was no significant difference in the mean dose of furosemide between the two groups (34.7 ± 26.5 vs 39.3 ± 25.8; $P = .615$).

Feasibility, safety, and acceptability outcomes in the home BIA group

The study completion rate was 100.0% in the home BIA group. The adherence rate to home BIA during the study period was 82.5%. Acute kidney injury, defined as an increase in serum creatinine by more than 0.3 mg/dl from baseline, occurred in only one patient (5.0%), and the discontinuation rate due to adverse events was 0.0%. Survey results indicated that the home BIA monitoring system was feasible and acceptable. On a five-point Likert scale, the average usability score was 4.21 ± 0.59. The home BIA group strongly agreed that the device and application were easy to use and that they understood the weekly instructions. The average scores for satisfaction and usefulness, which assessed acceptability, were also high in the home BIA group (3.90 ± 0.53) (*Table 2*).

Table 2 Feasibility and safety outcomes in home BIA group

Outcomes	Home BIA
Completion rate of study (%)	100.0
Measurement rate of home BIA (%)	82.5
Usability scores of surveys (5-Likert scale), mean (SD)	4.21 (0.59)
Satisfaction and usefulness scores of surveys (5-Likert scale), Mean (SD)	3.90 (0.53)
Discontinuation of study due to adverse events, *N* (%)	0 (0.0%)
Acute kidney injury, *N* (%)	1 (5.0%)

BIA, bioelectrical impedance analysis

Change in dyspnoea according to NYHA class

There were no significant differences in the proportion of NYHA classes between the groups at baseline (*Table 1*). NYHA class improvement from baseline was not significantly different between the two groups. The aggravation in the NYHA class from baseline was numerically lower in the home BIA group than in the control group without statistical significance (10.0% vs 31.6%; $P = .095$) (*Figure 2*).

Correlation analysis between the change in NT-proBNP and other parameters

Simple correlations between changes in NT-proBNP levels and various parameters, including changes in oedema index, body weight, creatinine level, age, and LVEF, are shown in *Table 3*. The change in NT-proBNP levels significantly correlated with the change in the whole-body oedema index ($r = 0.544$; $P = .002$). However, the change in body weight ($r = 0.237$; $P = .147$) did not significantly correlate with the change in NT-proBNP levels (*Figure 3*).

Changes in NT-proBNP according to four subgroups by change in body weight and oedema index

Changes in NT-proBNP levels were analysed across four subgroups based on changes in body weight and oedema index as measured using BIA. Group 1 had no increase in body weight or oedema index, while Group 4 had an increase in both body weight and oedema index. *Figure 4* shows that the largest reduction in NT-proBNP occurred in

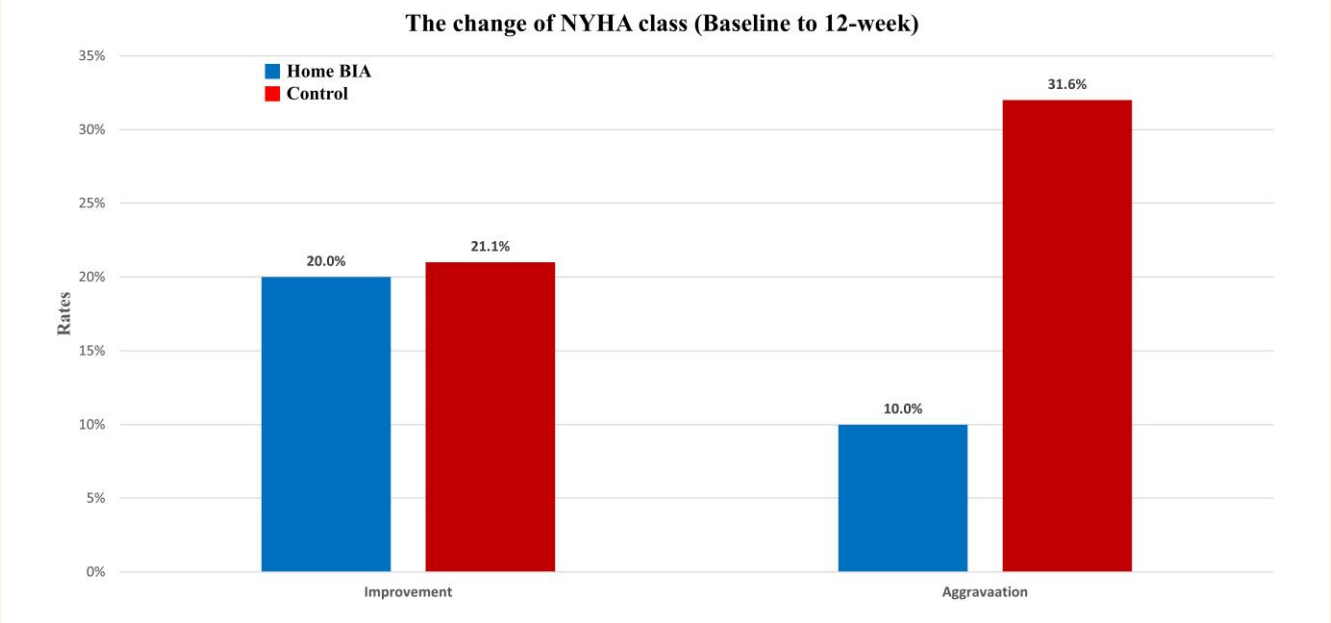

Figure 2 The change from baseline in NYHA class

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Group 1. NT-proBNP increased in Group 3, which was defined by an increase in the oedema index without a gain in body weight.

Continuous trend of difference between leg oedema index and whole-body oedema index

Figure 5 demonstrates the continuous trend of differences between the leg oedema index and whole-body oedema index throughout the entire measurement period in the home BIA group. Analysed according to NT-proBNP improvement, the difference between leg oedema index and whole-body oedema index continued to be greater in the aggravation group.

Table 3 Pearson correlation analysis

		Change in Log (NT-proBNP)	*P*-value
Change in EI of whole-body	Coefficient of correlation (r)		.544
	P-value		.002
Change in EI of trunk	Coefficient of correlation (r)		.535
	P-value		.002
Change in EI of both leg	Coefficient of correlation (r)		.576
	P-value		.001
Change in difference between both leg EI and whole-body EI	Coefficient of correlation (r)		.500
	P-value		.004
Change in body weight	Coefficient of correlation (r)		.237
	P-value		.147
Change in creatinine	Coefficient of correlation (r)		−.152
	P-value		.357
Age	Coefficient of correlation (r)		−.018
	P-value		.915
LVEF	Coefficient of correlation (r)		.253
	P-value		.120

EI, oedema index; LVEF, left ventricular ejection fraction.

Discussion

This pilot study tested the hypothesis that continuous body water monitoring using BIA could enable early detection of changes in extracellular volume status in HF patients. The primary goal was to assess the feasibility of managing HF through home-based BIA monitoring, complemented by tailored interventions based on individual body water data.

The key findings of this study were (i) the home BIA body water monitoring system was feasible, acceptable, and safe for HF patients; (ii) the aggravation in the NYHA class from baseline was less pronounced in the home BIA group than in the control group; and (iii) while changes in body weight did not correlate with NT-proBNP level changes, changes in the oedema index did show a correlation with NT-proBNP levels.

BIA monitoring in HF patients

For patients with HF discharged from the hospital, monitoring prognostic biomarkers such as symptoms, body weight, and fluid status is just as crucial as pharmacological treatment in reducing re-admissions. Numerous trials have explored various strategies to monitor chronic HF patients after discharge to prevent HF-related re-hospitalizations. Although diverse biomarker- and haemodynamic-guided strategies have been explored, their clinical effectiveness in heart failure management has remained limited and inconsistent.[7,14–17]

In comparison, BIA is a non-invasive, easy-to-use method that has gained increasing use in HF patients.[8] Previous studies have shown that BIA, when combined with serum BNP, is an effective tool for diagnosing acute decompensated HF.[18] Martínez *et al.* also reported a significant correlation between the NYHA functional class for dyspnoea and bioimpedance parameters obtained through BIA in HF patients.[19]

This study demonstrates the feasibility and safety of body water monitoring using a home BIA system with pre-emptive management,

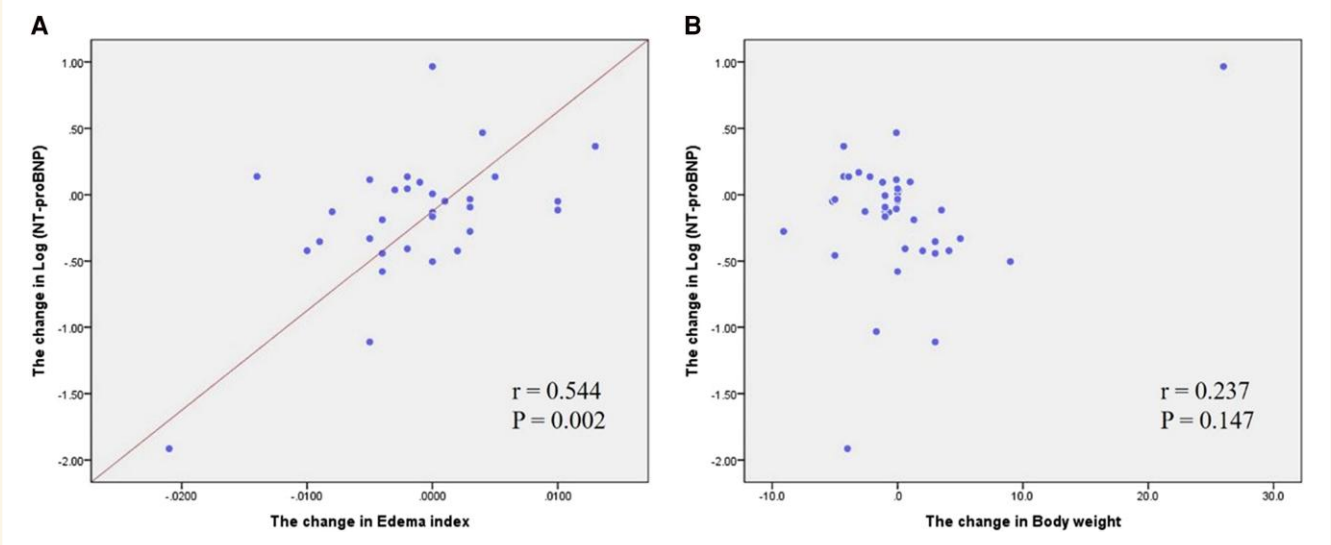

Figure 3 (*A*) Correlation plots between the change in whole-body oedema index and the change in Log (NT-proBNP) in total population. (*B*) Correlation plots between the change in body weight and the change in Log (NT-proBNP) in total population

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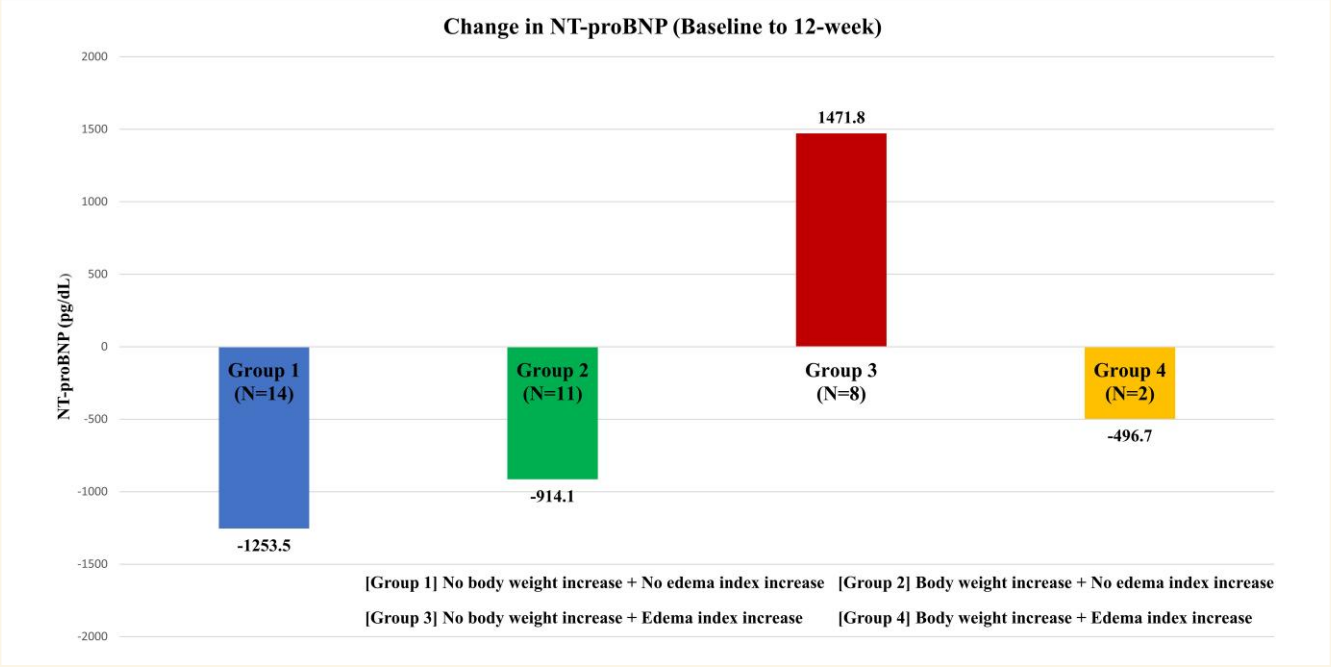

Figure 4 The change in NT-proBNP according to 4 subgroups by change in body weight and whole-body oedema index

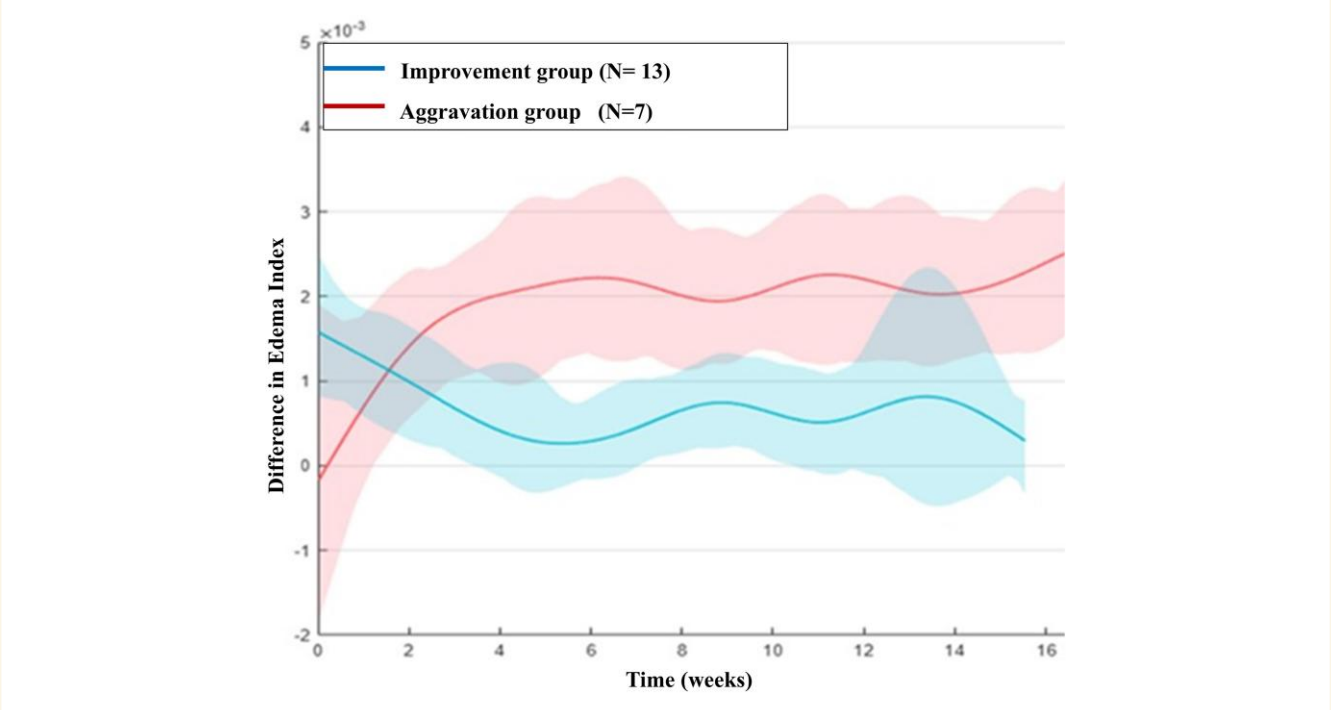

Figure 5 Continuous trend of difference between leg oedema index and whole-body oedema index according to NT-proBNP improvement in the home BIA group

including additional diuretic use. Despite the short follow-up period, 100% of patients in the home BIA group completed the study, and the adherence rate was high. In survey results (Supplementary Table S1), particularly the usability scores for the device (Q1, 4.65 ± 0.67) and satisfaction scores (Q19, 4.20 ± 0.77) were notably high, reinforcing the feasibility and acceptability of the system.

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Oedema index as a parameter reflecting NT-proBNP

Among the various BIA-derived parameters, the oedema index serves as a key surrogate marker for extracellular volume status.[20] The oedema index has prognostic value, with higher levels correlating with increased BNP levels and higher HF-related re-hospitalization rates in patients with acute decompensated HF.[21] This study demonstrated that changes in the oedema index significantly correlated with changes in NT-proBNP levels, while other parameters like body weight change, creatinine change, age, and LVEF showed no significant correlation with NT-proBNP (*Table 3*). Notably, body weight, a traditional and widely used indicator of volume status, did not correlate significantly with NT-proBNP levels (*Figure 3*). Changes in NT-proBNP levels were analysed across four subgroups based on changes in body weight and oedema index as measured using BIA in this study (*Figure 4*). Patients who experienced weight gain without an increase in the oedema index (Group 2) had a decrease in NT-proBNP levels. In contrast, patients with an increase in the oedema index but no weight gain (Group 3) had elevated NT-proBNP levels. This suggests that the oedema index may be a more sensitive and reliable indicator of a patient's volume status than body weight alone. Continuous trends were observed in the daily oedema index patterns (*Figure 5*), analysed in relation to NT-proBNP improvements. The difference between the leg oedema index and whole-body oedema index was consistently smaller in the improvement group than in the aggravation group. While the underlying mechanisms are still unclear, correlation analysis (*Table 3*) revealed that changes in the oedema index of the legs were the strongest predictors of NT-proBNP variation among the body segments measured. Furthermore, physical signs and changes in body weight often precede symptomatic manifestations like dyspnoea in the pathophysiology of congestion.[6] We propose that the difference between the leg and whole-body oedema indices could reflect early, sensitive changes in volume status, with leg oedema serving as a more responsive marker of fluid accumulation.

BIA monitoring and clinical implications

There were no significant differences between the groups in the change in log (NT-proBNP) and the oedema index (Supplementary Table S2). However, the home BIA group showed a lower, although not statistically significant, rate of symptom aggravation compared with the control group (*Figure 2*). Notably, approximately half of the participants (21, 53.8%) were in NYHA functional class I, representing a relatively stable clinical state. Subgroup analysis within the home BIA group (Supplementary Table S3) indicated that patients with NYHA class II or III had a numerically higher rate of home BIA measurements and greater use of additional diuretics. These patients also exhibited more pronounced reductions in log (NT-proBNP) and the oedema index.

A notable implication of this pilot study is that it demonstrates the potential for self-monitoring and self-care using the home BIA system for HF as a chronic disease during the 'Untact Era.' During the study period, a higher proportion of patients in the home BIA group used additional diuretics (40.0% vs 15.8%; $P = .093$) (Supplementary Table S4). This suggests that daily body water monitoring using home BIA enhances patients' capacity for self-monitoring and self-care. Furthermore, previous research has shown that intensive treatment approaches combined with close follow-up can improve symptoms, quality of life, and clinical outcomes in HF cases.[22] Similarly, this study suggests that proactive monitoring and timely intervention may contribute to better symptom management and improved clinical outcomes in patients with chronic HF.

Limitations

First, this was a small pilot study. The assessment of clinical outcomes, such as HF hospitalization and mortality, is limited by the small sample size and short follow-up period. Despite this, this pilot study successfully demonstrated the feasibility and acceptability of a home BIA system and pre-emptive management based on patient volume status. Second, this study did not find a significant difference in changes in NT-proBNP levels between the two groups. As a small pilot study, there was limited use of additional diuretics because the study protocol prioritized safety. Moreover, most patients were in a stable chronic phase with NYHA functional class I and were not experiencing acute exacerbations, which may have contributed to the lack of significant differences in clinical outcomes. Third, while patients in the home BIA group measured their body water daily, analysis of data and providing directions for diuretics were only performed once a week. The study protocol was designed by the investigators to minimize variability in BIA measurements and potential errors, and it was determined that it would be safer and more effective to respond to changes in body water and adjust diuretic use on a weekly basis rather than daily.

Conclusions

Home-based body water monitoring, combined with pre-emptive management using a home BIA device and a linked application system, is both feasible and acceptable in chronic ambulatory HF patients who require diuretics. Changes in the oedema index significantly correlated with changes in NT-proBNP levels in HF patients.

Supplementary data

Supplementary data are available at *ESC Heart Failure* online.

Declarations

Disclosure of Interest

All authors declare no disclosure of interest for this contribution.

Data Availability

No data were generated or analysed for this manuscript.

Funding

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Ethical Approval

Ethical approval was obtained from the institutional review board of each participating centre, and all patients provided written informed consent. And the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

Pre-registered Clinical Trial Number

None supplied.

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