Mass General Brigham

Study Protocol

Protocol Title:	Comparison of Outcomes with Relative Blood Volume Monitoring Added to the Best Clinical Practice versus the Best Clinical Practice Alone among Volume Overloaded Hospitalized Patients Treated with Maintenance Hemodialysis
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Sites:	Massachusetts General Hospital (MGH) Brigham and Women's Hospital (BWH)
Sponsor:	Pending
Version:	Original protocol
IRB Protocol ID:	2024P003473
IRB Approval Date:	December 9, 2024

GCP Statement
This study will be conducted in compliance with the protocol, Good Clinical Practice and all other applicable regulatory requirements, including the archiving of essential documents.

Confidential Information
This document contains confidential information which should not be copied, referred to, released or published without written approval.

Statement of Compliance
This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to the Common Rule at 45CFR46 (human subjects) and other applicable government regulations and Institutional research policies and procedures.

TABLE OF CONTENTS

1. BACKGROUND AND RATIONALE….....3
2. METHODS AND ANALYSES.....3
    2.1. Objectives.....3
    2.2. Selection of Study Participants.....4
    2.3. Intervention…….....5
    2.4. Outcome Measures.....6
    2.5. Data Collection.....7
    2.6. Sample Size Considerations.....8
    2.7. Analytical Plan..... 8
3. ETHICS AND DISSEMINATION.....9
4. POTENTIAL LIMITATIONS AND FUTURE DIRECTIONS.....9
5. REFERENCES.....10
6. TABLES AND FIGURES.....…11
7. APPENDIX.....…….19

1. BACKGROUND AND RATIONALE

In the United States, over half a million adults with end-stage kidney disease (ESKD) rely on maintenance hemodialysis (MHD) for survival.[1,2] Caring for these patients is expensive, with Medicare spending approximately $28 billion annually on total MHD care.[2] Hospital care accounts for around 45% of this total cost, as these patients experience frequent hospitalizations with an average length of stay of hospitalization 11 days per year.[3] Volume overload is a major factor in these hospitalizations, accounting for 25-35% of all cases and often leading to a 30-day rehospitalization rate of about 33%.[4] Effective management of volume overload is crucial for patients on MHD. However, current methods for assessing fluid status often provide inaccurate and/or incomplete assessments, making it challenging to determine the optimal fluid removal during dialysis. This can lead to persistent hypervolemia or hypovolemia, causing complications like intradialytic hypotension (hypovolemia) or respiratory distress from pulmonary congestion (hypervolemia).

Relative Blood Volume Monitoring (RBVM) offers a potential solution by providing real-time, non-invasive monitoring of intravascular volume.[5] This technology allows clinicians to optimize fluid removal during dialysis, potentially reducing the risks of both hypervolemia and hypovolemia. While prior studies have examined the benefits of RBVM, these studies have shown mixed results with some studies showing that RBVM reduces intradialytic hypotension and improves fluid management, while the others have found no significant benefit (**Table 1: Summary of Prior Studies of Relative Blood Volume Monitoring**).[6-16] The prior studies of MHD patients were conducted only in an outpatient setting and did not address the potential benefits of RBVM among MHD patients hospitalized for or with volume overload leaving **a major knowledge gap** in clinical care.

Our **preliminary data**, obtained retrospectively and analyzed using inverse probability treatment weighted analyses, from patients requiring MHD who were hospitalized for heart failure exacerbation (n=262) suggests that the length of stay is shorter (by ~2 days; effect size 0.3) and 90-day rehospitalization rate lower (by ~64%) in patients admitted to a hospital where RBVM guidance is added to the best clinical practice compared with patients admitted to another hospital where RBVM is not added to the best clinical practice (**Appendix: Preliminary Data [manuscript under review]**). Interestingly, prior to the addition of RBVM to the best clinical practice, the same hospitals had similar length of stay and 90-day rehospitalization rates with favorable differences in these outcomes emerging only after the routine application of RBVM began at one hospital. Based on these intriguing preliminary data, we now propose a prospective natural experiment study in a broader group of hospitalized MHD patients with volume overload.

Additionally, successful implementation of the RBVM among hospitalized patients may face several challenges, from physician expertise and staff training to familiarity, staff turnover, and integrating the monitor's data with clinical observations. Semi-structured interviews, exploring key themes related to training gaps and concerns regarding RBVM use, may help uncover obstacles to future optimal utilization by informing the development of effective training and implementation strategies to improve RBVM use during hemodialysis, ultimately enhancing the clinical and patient reported outcomes for patients with ESKD.

2. METHODS AND ANALYSES

2.1 Objectives

Aim 1: To examine the effect of addition of RBVM to the best clinical practice on clinical and patient reported outcomes among MHD patients hospitalized for or with volume overload

Hypothesis: Addition of RBVM guidance to the best clinical practice improves dialytic fluid removal and reduces morbidity among MHD patients hospitalized with volume overload.

The above hypothesis will be examined by conducting a prospective non-randomized natural experiment cohort study that will recruit 400 patients in total from the Massachusetts General Hospital (MGH) and the Brigham and Women's Hospital (BWH). Both hospitals treat patients with similar case-mix and have similar capabilities for clinical care with one key difference— the rate and volume of dialytic fluid removal is guided by RBVM in addition to the best clinical practice at MGH whereas fluid removal is guided only by the best clinical practice at BWH. This key difference allows us to conduct instrumental variable analysis where differences in treatment are based on quasi-random variation in practice pattern in the 2 participating hospitals. The primary outcome will be the length of Index hospitalization and secondary outcome will be 90-day rehospitalization rate for or with volume overload. Exploratory outcomes will be percentage of hemodialysis sessions complicated by: intradialytic hypotension, requirement of saline/albumin infusion, requirement of blood flow lowering, or adverse symptoms such as cramps. Intradialytic hypotension will be defined as an absolute nadir systolic blood pressure

of <90 mmHg (for patients with pre-dialysis systolic blood pressure <160 mmHg) and absolute nadir systolic blood pressure of <100 mmHg (for patients with pre-dialysis systolic blood pressure ≥160 mmHg).[17]

Aim 2: To define perceptions of nurses and nephrologists regarding managing volume overload and RBVM application in hospitalized MHD patients

Hypothesis: Real time graphic and alphanumeric outputs provided by RBVM increases the confidence of clinical staff for safe and effective dialytic fluid removal.

The above hypothesis will be examined by conducting semi-structured interviews with 20 participants from the in-hospital dialysis teams at MGH and BWH to investigate current practices and identify gaps and barriers to the application of the RBVM in patients with ESKD treated with MHD. We aim to recruit 10 nephrologists (5 from each hospital) and 10 nursing staff (5 from each hospital). This will be done through purposive sampling to ensure diverse experiences and perspectives on RBVM use. Interviews will be conducted in a private setting at the hospital, audio-recorded, and transcribed verbatim. An interview guide will be used to ensure consistency across interviews while allowing flexibility to explore emergent themes. Thematic analysis will be used to identify key themes and patterns in the interview data. Ethical research guidelines will be followed, with all participants able to opt out and confidentiality maintained throughout the study. Our work will inform what are the perceptions of nurses and nephrologists regarding managing volume overload and RBVM in hospitalized MHD patients and whether these perceptions differ between members from MGH compared to BWH.

2.2 Selection of Study Participants

Aim 1. Patient selection

Patients will be enrolled from July 1st 2025 to June 30th 2026. Admission records of patients will be reviewed prospectively within 24 hours of admission to determine their eligibility to participate in this study.

Inclusion criteria

All adult (≥18 years) MHD-dependent ESKD patients hospitalized for or with volume overload at either MGH or BWH will be potentially eligible to participate in this cohort study. Patient should have received at least one hemodialysis session during the index hospitalization and meet the following previously published criteria for volume overload:[4]

a) Clinical impression of volume overload and/or an acute heart failure exacerbation, or

b) Respiratory compromise defined as subjective dyspnea or presenting oxygen saturation <92% on room air plus ≥2 of the following signs:

i) Jugular venous distension,
ii) Third heart sound,
iii) Bibasilar lung rales or crackles,
iv) Pulmonary edema on chest imaging,
v) Reported bilateral pulmonary infiltrates on chest imaging without fever,
vi) Reported pleural effusion on chest imaging,
vii) Reported abdominal ascites on abdominal imaging,
viii) Documented central venous pressure >12 mmHg,
ix) Documented pulmonary capillary wedge pressure >12 mmHg

The variables for which information is not available through medical record review because a particular test was not done (e.g. abdominal imaging to detect ascites was not obtained) will be recorded as not available.

Exclusion criteria

Patients with acute kidney injury requiring dialysis, those hospitalized for the initiation of hemodialysis, those requiring continuous kidney replacement therapy at admission, those under observation status, and those with liver cirrhosis will be excluded.

Recruitment feasibility

MGH and BWH on average hospitalize ~30 patients with ESKD treated with MHD per month per location for or with volume overload (~720 in total/per year for both hospitals combined). We anticipate that at least 75% of these patients will meet the eligibility criteria outlined above allowing us to complete the target recruitment (n=400

patients) for our proposed prospective natural experiment study within one year from the study initiation. The study protocol has been evaluated and approved by the Mass General Brigham Institutional Review Board and the board has granted a waiver of patient consent (Protocol ID: 2024P003473).

Aim 2. Staff selection

The staff will be enrolled from January 1st, 2026, to June 30th, 2026. We will approach staff employed at both BWH and MGH and introduce the study to them stating our aims, how the semi-structured interviews will be conducted, confidentiality and the ability to opt-out at any time.

Inclusion criteria

All dialysis nurses and attending nephrologists who work in an inpatient setting either at MGH or BWH will be potentially eligible to participate in this study. Nephrologists should at least have covered dialysis service at either hospital for 2 weeks within the prior year at enrollment. Dialysis nurses should have worked at least 14 dialysis shifts in the prior year at enrollment.

Exclusion criteria

Fellows in training and dialysis technicians will not be eligible for enrollment. Nephrology attendings and dialysis nurses who do not meet the required experience mentioned under the inclusion criteria section above will be excluded.

2.3 Intervention

Intervention of interest for this prospective study is guidance obtained by RBVM using Crit-Line® IV Monitor or CLiC™ device. Application of RBVM versus no application of RBVM during inpatient hemodialysis sessions will be according to the standard of care at the participating hospital (MGH regularly applies RBVM for all inpatient hemodialysis sessions and BWH never applies RBVM for inpatient hemodialysis sessions).

The MGH has access to both the CLiC™ device and Crit-Line® IV Monitor. Information from the Crit-Line® IV Monitor or CLiC™ device is used to adjust the ultrafiltration rate based on the profile change. All staff at the MGH are trained for the application of CLiC™ device and Crit-Line® IV Monitor and for interpreting data available from these devices.

The Crit-Line® IV Monitor is designed to optimize hemodialysis treatment through real-time, non-invasive monitoring of key physiological parameters. Utilizing photo-optical technology, the device continuously measures hematocrit, percent change in blood volume, and oxygen saturation. This data is displayed on a screen, providing clinicians with both graphic and alphanumeric outputs that facilitate a comprehensive understanding of the patient's fluid status and response to treatment (**Figure 1: Crit-Line® IV Monitor Guidance**). By monitoring these parameters, clinicians can make data-driven adjustments to ultrafiltration rates, maximizing fluid removal while mitigating common complications such as nausea, vomiting, and cramping. The Crit-Line® IV Monitor empowers clinicians to fine-tune treatment strategies, promoting patient comfort, and optimizing the effectiveness of hemodialysis.

The Crit-Line® IV monitor is a touch screen display device. The monitor mounts to the IV pole of the hemodialysis machine by means of the pole mount. The monitor is operated by touching buttons on the display. Menus are navigated by pressing buttons which allows the operator to:

- Display the hematocrit, oxygen saturation, and percent change in blood volume measurements in real time
- Review and print previous treatment data, and
- Perform setup activities to control basic features of the Crit-Line® IV Monitor

The CLiC™ device connects via a cable with a USB connector to the port on the bottom left of the Crit-Line® IV Monitor (**Figure 2: CLiC™ Device**). The CLiC™ device is a sensor that when placed on the Crit-Line® Blood Chamber, located between the arterial bloodline and the blood inlet port of the hemodialyzer, monitors the patient's hematocrit, oxygen saturation and percent change in blood volume. The CLiC™ device clips onto the Crit-Line® Blood Chamber and shines light through the lens of the Crit-Line® Blood Chamber onto a sensor on the opposite side of the blood chamber. This sensor detects the level of absorption and scattering of the light as it is transmitted through the patient's blood as it flows through the blood chamber.

RBVM protocol

Hemodialysis treatments at MGH are actively monitored and adjusted according to the RBVM data following a protocol similar to prior publication[8] and is outlined below:

Monitoring for changes in relative blood volume begins at 30 minutes after the initiation of dialysis and includes dynamics of blood volume changes in profiles. Profile A is displayed when measurements taken over the previous 15 minutes result in a profile of ≤ 3% per hour and is represented as a flat or upward slope. Profile A indicates that the patient's plasma refill rate is occurring at the same or greater rate than the ultrafiltration rate and suggests the ultrafiltration rate might be increased without intradialytic symptoms. Profile B is displayed when measurements taken over the previous 15 minutes result in a profile that is >3% to ≤ 6.5% per hour and is the ideal profile. Profile B is a gradual slope and is ideal as it finds the best compromise between a higher ultrafiltration rate and prevention of intradialytic symptoms. Profile C is displayed when the measurements taken over the previous 15 minutes result in a profile of >6.5% per hour. Profile C is a steep slope and indicates a rapid decrease in blood volume and suggests a higher risk for intradialytic symptoms and suggest that the ultrafiltration rate should be lowered. After assessing the patient for symptoms and vital signs, nurses make changes to the ultrafiltration goal until the patient converts to Profile B. For profile C, ultrafiltration goal is lowered by 200 mL and the blood volume profile is checked every 15 minutes after the ultrafiltration goal is lowered. Ultrafiltration goal continues to be lowered by 200 mL every 30 minutes until the curve converted to Profile B. If the patient develops hypotension, standard of are interventions including placing the patient in modified Trendelenburg position and turning the ultrafiltration rate to minimum are applied. Normal saline or albumin bolus are administered if hypotension persists. Blood pressure is monitored and treated every 5 minutes until any symptoms related to hypotension are relieved.

2.4 Outcome Measures

Objectives	Endpoints
Aim 1: To examine the effect of addition of RBVM to the best clinical practice on clinical and patient reported outcomes among MHD patients hospitalized for or with volume overload	
Primary	
Compare the length of Index hospitalization according to RBVM application versus no RBVM application among MHD patients hospitalized for or with volume overload	• Length of index hospital stay
Secondary	
Compare rehospitalization rate according to RBVM application versus no RBVM application among MHD patients hospitalized for or with volume overload within 90 days of index discharge	• Rehospitalization rates for or with volume overload within 90 days of discharge after the index hospitalization
Exploratory	
Compare the rates of complications according to RBVM application versus no RBVM application among MHD patients hospitalized for or with volume overload	Percentage of dialysis sessions during index hospitalization complicated by: • Intradialytic hypotension episodes • Requirement of saline/albumin infusion • Requirement of blood flow reduction • Requirement of vasopressor support • Hemodialysis session duration or frequency increase • Adverse symptoms such as cramps
Aim 2: To define perceptions of nurses and nephrologists regarding managing volume overload and RBVM application in hospitalized MHD patients.	
Understand the current practices, gaps, and barriers hindering effective volume management and RBVM use among MHD patients hospitalized for or with volume overload and compare these parameters between providers affiliated with MGH versus BWH	• Knowledge gaps and barriers regarding volume management and RBVM

2.5 Data Collection

Data collection for Aim 1

Measurements of explanatory and outcome variables for the study participants will be obtained from the electronic medical files from each of the participating centers (**Table 2: List of Demographic and Clinical Variables for Aim 1 of the Proposed Study**). We will review the electronic medical records fitted with the dialysis kidney consult alert system for potentially eligible hemodialysis patients. We will examine whether the patient fulfills our enrollment criteria and if they do, we will follow these patients throughout their index hospital stay (for primary and exploratory outcomes) and up to 90 days post discharge (for secondary outcome).

Recordings will also be made of parameters that influence the volume removal during the hemodialysis session. These parameters will be recorded for patients hospitalized at MGH and at BWH and will include the documented estimated dry weight, blood pressure, jugular venous distension, pulmonary edema, third heart sound, bibasilar lung rales or crackles, peripheral edema, pulmonary edema on chest imaging, bilateral pulmonary infiltrates on chest imaging without fever, pleural effusion on chest imaging, abdominal ascites on abdominal imaging, central venous pressure >12 mmHg, and pulmonary capillary wedge pressure >12 mmHg. The variables for which information is not available through medical record review because a particular test was not done (e.g. abdominal imaging to detect ascites was not obtained) will be recorded as not available.

For MGH patients, in addition, RBVM profiles at the beginning of hemodialysis session(s) and changes to the RBVM profile during hemodialysis session(s) and the corresponding oxygen saturations will be recorded.

Details of hemodialysis equipment and prescriptions for each inpatient hemodialysis session during the index hospitalization will be decided by the treating nephrologist (including target ultrafiltration volume, target ultrafiltration rate, sodium profiling, dialysate temperature, and dialysate sodium) and will be recorded along with achieved ultrafiltration volume, intradialytic hypotension, requirement of saline/albumin infusion, requirement of blood flow reduction, increasing dialysis frequency, increasing dialysis session duration, requirement of vasopressor support, and adverse symptoms such as cramps for each inpatient hemodialysis session for patients enrolled in the study.

We will appoint **independent** Clinical Research Coordinators (one at MGH and one at BWH) who will have access to patient data in compliance with the data management policy of the Massachusetts General Brigham health system and Good Clinical Practice guidelines for electronic data collection. All data will be stored in a research folder that can only be accessed by the Principal Investigator, Co-investigator, Clinical Research Coordinators, and biostatistician. Data will be pseudonymized and a file to decode these data will be stored in a research folder only accessible by the study staff.

Data collection for Aim 2

Semi-structured interviews will help provide a flexible framework for understanding dialysis nurses' and attending nephrologists' perspectives on RBVM use. First, we will identify the staff members that meet our eligibility criteria and agree to participate in an interview. The Clinical Research Coordinators will introduce themselves, the purpose of the study, obtain consent, ensure confidentiality, and decide with the interviewee on a suitable location and time to meet in person or virtually. Interviews will be audio-recorded, and we will make sure the interviewee are informed and agreeable. In order to make sure that our interviews have a dynamic flow, while maintaining a degree of structure we will adhere to the following outline:

1. Introduction: This includes explanatory materials and consent along with the first couple of questions.
2. Exploration of the core phenomenon: This is the heart of the interview and will include questions such as: Can you describe your current approach to managing fluid overload in patients receiving MHD? What are some of your concerns when it comes to determining the appropriate amount of fluid to remove during dialysis? How has the use of RBVM influenced your decision-making process during dialysis and do you feel it has impacted your confidence in achieving safe and effective fluid removal? (MGH staff specific), If you had access to RBVM, how do you think it might change your approach to fluid management? (BWH staff specific).
3. Final reflections: This allows for the most abstract questions, an opportunity for any comment the interviewee might care to make.

We will start our interviews with predetermined open-ended questions that guide the interview while allowing for flexibility and adaptability. This will help us adjust the order, rephrase questions, and probe for deeper insights, fostering a conversational flow. We will help encourage participants to express themselves freely, facilitating the exploration of complex topics. After the interview, the recording will be transcribed verbatim and analyzed using

thematic analysis to identify key themes related to challenges and opportunities in managing volume overload in hospitalized MHD patients and whether and how RBVM addresses them and then explore whether themes differ between BWH and MGH staff members.

2.6 Sample Size Considerations

Aim 1. Sample size

Sample size calculations and power estimations were conducted for the primary outcome of length of stay of index hospitalization using G*Power software. Our preliminary retrospective data obtained using inverse probability treatment weighted analyses (**Appendix: Preliminary Data [manuscript under review]**), from patients requiring MHD who were hospitalized for heart failure exacerbation (n=262) suggests that the length of stay is shorter (by ~2 days; effect size 0.3) in patients admitted to a hospital where RBVM is available for application during clinical care (MGH) compared with patients admitted to another hospital where RBVM is not available (BWH). With **conservative estimation approach**, to detect a 2-day difference in the index length of stay for MHD patients hospitalized for or with volume overload with a power of 80%, two-sided alpha of 0.05, and 10% loss, the total number of patients needed is approximately **400**. Propensity matching will reduce the variability and may allow 80% power even with a smaller sample size. We will aim to recruit equal number of participants (200 from MGH and 200 from BWH). As mentioned in the feasibility section above, we expect to reach the required sample size within one year of study initiation.

Aim 2. Sample size

Unlike quantitative studies with fixed formulas, qualitative research relies on an iterative approach to determining the appropriate sample size as it is a nuanced process guided by the research objectives and the principle of data saturation. We will aim for a diverse, heterogeneous participant group to capture the breadth of their perspectives. We will begin with recruiting **20** participants and continue data collection until thematic saturation is achieved, the point at which new interviews no longer yield significant new information to ensure comprehensive coverage of participants' perspectives.

2.7 Analytical Plan

Aim 1. Statistical analysis

For all tests, a two-sided alpha value of 0.05 will be considered statistically significant. All analyses will be performed using R (version 4.3.0, R Foundation for Statistical Computing, Vienna, Austria).

Baseline characteristics will be presented as proportions for categorical variables and means (standard deviation) or median (interquartile range) for continuous variables, as appropriate. Differences in distributions of baseline characteristics between the study groups will be quantified by means of standardized differences.

We will conduct **propensity score matching** to limit possible confounding bias by controlling for baseline demographic and clinical characteristics focusing on known variables associated with clinical decision-making regarding volume management in MHD patients admitted for or with volume overload. The propensity score will be estimated using binary logistic regression analysis, with RBVM as the dependent variable and age, gender, race, zip code of patient's residence, primary insurance, vascular access, and Charlson Comorbidity Index will be included as covariates in the model. A 1:1 nearest neighbor matching will be performed, with a maximum caliper of 0.15 of the standard deviation of the logit of the propensity score using the Matchit() algorithm in R software. After propensity score matching, the distributions of baseline characteristics will be compared between the study groups and quantified using standardized differences.

The primary analysis will be a test for superiority and will test the null hypothesis that there is no difference between RBVM application added to the best clinical practice versus best clinical practice alone for the length of index hospitalization. The analyses will be conducted within the dataset of propensity-matched subjects and will assess the relationship between the RBVM and the length of index hospitalization (primary outcome) using linear regression, while rehospitalization for or with volume overload will be assessed by Poison regression (secondary outcomes). The relationship between the RBVM and exploratory outcomes will also be assessed using regression models.

We will minimize missingness of data by conducting comprehensive review of records and will apply multiple imputations to address if any missingness.

Subgroup and sensitivity analyses

The above analyses will be repeated in subgroups of (1) patients admitted specifically for (and not only with) volume overload and (2) patients with history of heart failure. Because of multiple comparisons, findings for subgroup analyses will be interpreted as exploratory. A competing risk analysis using Fine-Gray modeling will be performed as a sensitivity analysis to determine whether death is a competing event in assessing time to first rehospitalization for or with volume overload within 90 days of index discharge.

Aim 2. Data synthesis and analyses

We will start with transcribing and organizing data post interview ensuring that the nuances of participants' responses are captured in detail. To ensure accurate and meaningful analysis, we will use a reliable audio recording device, the transcription will occur in a quiet environment to maintain focus and reduce distractions. We will use an automated tool to convert the audio to text and then go over transcripts checking for errors or omissions. We will also listen to the recordings multiple times to ensure the context is preserved, especially for nuanced statements.

Once transcribed, we will organize the data systematically based on themes, concepts, or questions that emerged during the interviews to facilitate effective analysis. We will be using digital tools or spreadsheet applications to sort and store this data to enhances retrieval and aid in comparative analysis. We will also employ coding techniques and assign labels to various segments of data to better understand the underlying trends. To effectively conduct qualitative coding, we will first familiarize ourselves with the data to understand the context of participants' answers. Next, we will develop a coding scheme that reflects our research objectives and emerging themes. We will continually refine our scheme to ensure it captures the nuances of the data.

To deepen the analysis, we will employ thematic analysis to interpret the coded data. The thematic approach focuses on overarching themes, summarizing key insights related to research objectives. The interview transcripts will be analyzed using principles of thematic analysis, with the assistance of NVivo software to facilitate the process. We will iteratively establish and revise a set of basic and organizing codes independently by two members from the research team, applying this coding framework across all interview transcripts. The researcher-derived codes will be organized under global themes that are pertinent to the research questions. Following the coding process, we will identify candidate themes meant to encapsulate patterned responses or meanings within the dataset. These themes will undergo further refinement as we explore relationships between themes particularly those that capture perceptions of RBVM use information deemed most relevant and impactful. To enhance the rigor and quality of the analysis, the research team members, including the Principal Investigator, Clinical Research Coordinators, and qualitative research expert will meet regularly to review, refine, and establish consensus on the codes and analytic themes identified during multiple passes through the data. Throughout the analytical process, the research team will consistently make comparisons within and across interview transcripts, actively seeking atypical cases to enhance and refine ongoing interpretation.

3. ETHICS AND DISSEMINATION

The study protocol has been evaluated and approved by Massachusetts General Brigham Institutional Review Board. The Institutional Review Board approved a waiver of consent (reference number: 2024P003473). Results from our proposed study will be submitted to the American Society of Nephrology's 2026 Kidney Week Meeting and for a peer review publication in a high impact nephrology specialty journal.

4. POTENTIAL LIMITATIONS AND FUTURE DIRECTIONS

The observational nature of the proposed study (Aim 1) limits causal inferences. However, a quasi-randomized natural experimentation that leverages clinical practice variation at the 2 participating hospitals with similar case-mix, prospective enrollment, independent coordinators recording data from the 2 participating hospitals, and propensity score matching will minimize the influence of measured and unmeasured confounders. Findings, if positive, will set the stage for a multi-center cluster randomized controlled trial to examine the clinical, patient-level benefit of adding RBVM to the best clinical practice among hospitalized MHD patients with or for volume overload. Design and conduct of such a trial— the first one dedicated to examining the role of RBVM among hospitalized MHD patients— as well as future best clinical practice that routinely incorporates RBVM will be informed by our findings from Aim 1 and Aim 2.

Considering the potential cost-savings from lower hospital length of stay and reduced rehospitalization rates, it will be important to assess the cost-effectiveness of RBVM in future. Results from our Aim 1 analysis, will be foundational for future cost-effective analyses.

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TABLES AND FIGURES

Table 1: Summary of Prior Studies of Relative Blood Volume Monitoring

Table 2: List of Demographic and Clinical Variables for Aim 1 of the Proposed Study

Figure 1: Crit-Line® IV Monitor Guidance

Figure 2: CLiC™ Device

Table 1: Summary of Prior Studies of Relative Blood Volume Monitoring

Publication	Design	Methods	Population	Outcome	Limitations
Santoro et al, 2002[10]	Randomized multicenter crossover trial	Patients randomized to study sequences that included either blood volume tracking or conventional hemodialysis, each sequence lasting for 4 months	Hypotension-prone hemodialysis-dependent outpatients (n=36)	-Reduction in IDH events with blood volume tracking -Reduction in interdialytic symptoms with blood volume tracking -Weight gain, pre-dialysis blood pressure, intradialytic weight loss, and dialysis adequacy did not differ between the two treatments	-Small sample size -Limited to patients prone to hypotension -Relevance to hemodialysis dependent inpatients with volume overload unclear
Bégin et al, 2002[11]	Prospective single center cross-over trial	Prospective cross-over analysis comparing RBVM versus traditional hemodialysis over 12-week period	Hypotension-prone hemodialysis-dependent outpatients (n=7)	-74% increase in dialysis sessions not requiring therapeutic interventions to treat hypotension with RBVM -No difference in mean pre-dialysis blood pressure between the two groups	-Small sample size -Limited to patients prone to hypotension -Short study duration -Single center -No randomization -Relevance to hemodialysis dependent inpatients with volume overload unclear
McIntyre et al, 2003[9]	Prospective single center observational study	Standard hemodialysis for 3 weeks followed by 2-week optimization period then RBVM biofeedback-controlled hemodialysis for 3 weeks	Stable hemodialysis-dependent outpatients (n=15)	-Symptomatic intradialytic hypotension episodes reduced with RBVM biofeedback -Reduction in interdialytic weight gains with RBVM biofeedback	-Small sample size -Single center -Short study duration -No randomization -Relevance to hemodialysis dependent inpatients with volume overload unclear
Reddan et al, 2005[7]	Randomized multicenter trial	Random assignment to RBVM using Crit-Line or conventional hemodialysis for 6 months	Hemodialysis-dependent outpatients (n=443)	-No differences in weight, blood pressure, or dialysis-related complications between the study groups -Higher rates of non-access-related hospitalizations and access-related hospitalizations in RBVM group -Higher mortality in RBVM group	-Study design did not follow a strict protocol -Study did not selectively enroll patients with volume overload -Relevance to hemodialysis dependent inpatients with volume overload unclear

Rodriguez et al, 2005[14]	Prospective single center observational study	One component of study evaluated the extent of dry weight changes following the application of RBVM over 3-5 hemodialysis sessions	Stable hemodialysis-dependent outpatients (n=15)	-Most (~68%) of patients had their dry weight reduced	-Single arm -Observational study -Small sample size -Dry weight was estimated and not measured -No randomization -Relevance to hemodialysis dependent inpatients with volume overload unclear
Déziel et al, 2007[12]	Randomized single center trial	Run in period of 4 weeks followed by randomly assigning patients to RBVM with Hemocontrol or standard hemodialysis for 6 months	Hemodialysis-dependent outpatients (n=57)	-No improvement in blood pressure control -Improvement in patient tolerability to dialysis with RBVM	-Small sample size -Short study duration -Single center -Missingness of data -Relevance to hemodialysis dependent inpatients with volume overload unclear
Balter et al, 2015[6]	Quality improvement single center study	RBVM assessed as part of clinic-wide, fluid management program over 12 months	Hemodialysis-dependent outpatients (n=45)	-Decrease in post-dialysis blood pressure -Increase in dialysis adequacy -Increases in dialysis treatment time	-Small sample size -Short study duration -Single center -No control arm -No randomization -Relevance to hemodialysis dependent inpatients with volume overload unclear
Antlanger et al, 2017[15]	Randomized multicenter crossover trial	RBVM regulation of ultrafiltration and dialysate conductivity and/or regulation of ultrafiltration and temperature versus conventional dialysis assessed over 12 hemodialysis sessions	Hemodialysis-dependent outpatients with volume overload (n=50)	-Intra- and post-dialytic complications reduced with RBVM regulation of regulation of ultrafiltration and temperature -Magnitude of dry weight reduction larger with RBVM regulation of regulation of ultrafiltration and temperature	-Small sample size -Poor technical execution of RBVM regulation of ultrafiltration and dialysate conductivity -Relevance to hemodialysis dependent inpatients with volume overload unclear
Leung et al, 2017[13]	Randomized multi-center crossover trial	Run-in phase of 4 weeks followed by two 8-week treatment periods of RBVM guided biofeedback versus	Hypotension-prone hemodialysis-dependent outpatients (n=32)	-No difference in symptomatic intra-dialytic hypotension rate between RBVM guided biofeedback and control periods - No difference in asymptomatic intra-dialytic hypotension,	-Small sample size -Strict eligibility criteria limiting generalizability -Relevance to hemodialysis dependent inpatients with volume overload unclear

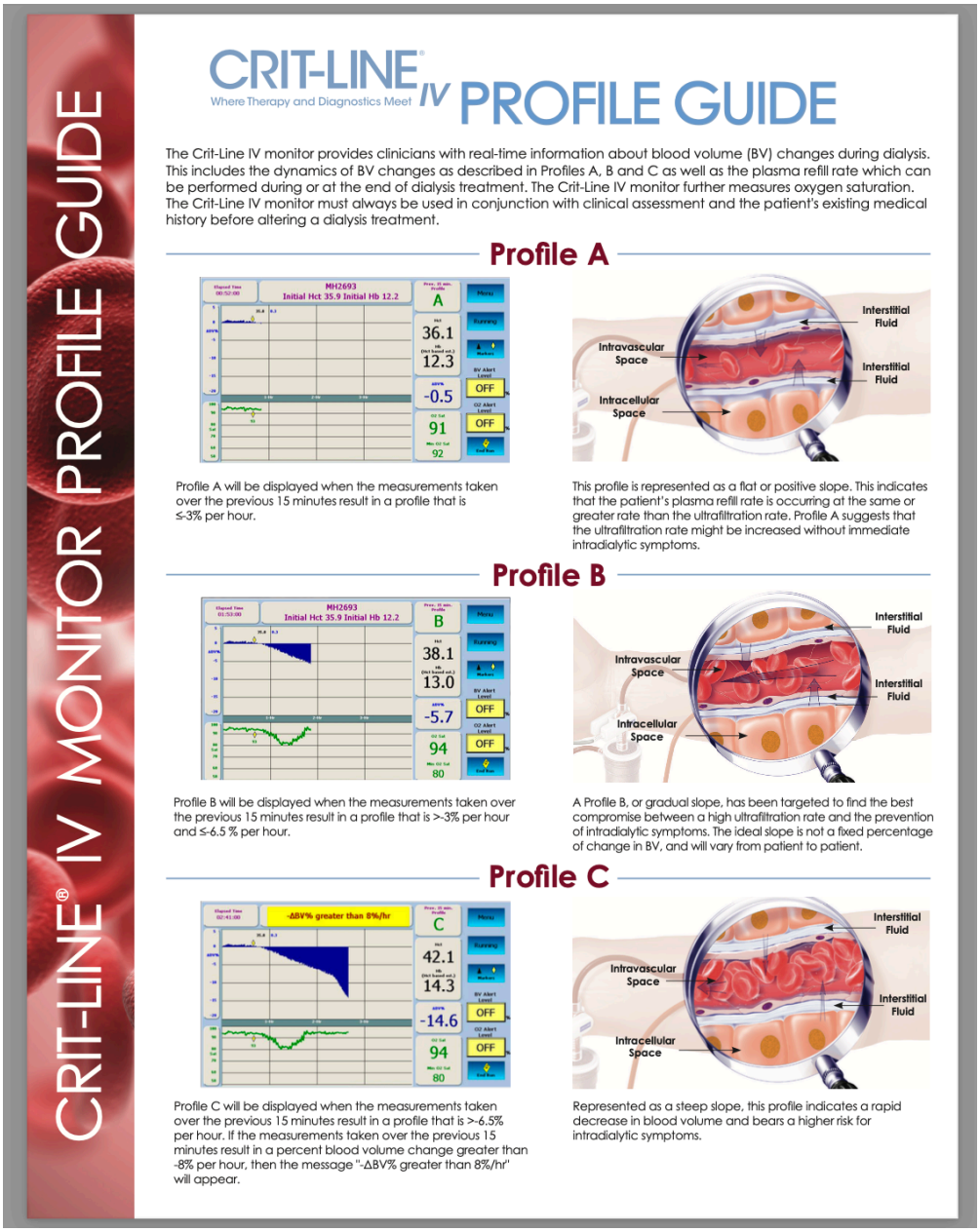
		control separated by a 2-week washout phase		symptoms rate, interdialytic weight gain, brain natriuretic peptide, troponins, extracellular/intracellular water ratio, ultrafiltration rate, and dialysis recovery time	
Martin et al, 2022[8]	Quality improvement single center study	Time series comprising of periods (each 3 months in duration) prior to and during RBVM application	Hospitalized patients with acute kidney injury and end-stage kidney disease patients requiring hemodialysis (n=328)	-Overall, no difference in intradialytic hypotension between the two periods -Reduction in intradialytic hypotension rate with RBVM use in patients admitted to the intensive care unit -Hospital stay longer in the RBVM group	-Intervention period was not done over 3 consecutive months due to COVID-19 pandemic -Relevance to hemodialysis dependent inpatients with volume overload unclear as study population was mixed (acute kidney injury and end-stage kidney disease)
Ficociello et al, 2023[16]	Retrospective multicenter observational study	Comparison of outcomes in Fresenius Kidney Care clinics that have high utilization of RBVM versus no RBVM in propensity score matched analyses	Hemodialysis-dependent outpatients (n=25,083)	-Lower rate of all-cause and fluid-related hospitalizations with RBVM use -Trend toward lower 30-day readmissions with RBVM use	-Retrospective approach -No randomization -Relevance to hemodialysis dependent inpatients with volume overload unclear

Table 2: List of Demographic and Clinical Variables for Aim 1 of the Proposed Study

Demographics	- Age - Race - Gender - Zip code - Primary insurance
Hospitalization related variables	- Admitting hospital for index hospitalization - Admitting diagnosis for index hospitalization and 90-day rehospitalization - Admission for index hospitalization from Emergency Department or transfer from another hospital - Length of index hospitalization stay - Rehospitalization within 90 days of discharge after index hospitalization
Comorbid conditions	- Hypertension - Diabetes mellitus - History of coronary artery disease - History of congestive heart failure - History of myocardial infarction - History of cerebrovascular disease - History of chronic obstructive pulmonary disease - History of peripheral vascular disease - History of cognitive deficit - History of connective tissue disease - History of liver disease - History of hemiplegia - History of human immunodeficiency virus or acquired immunodeficiency syndrome - History of malignancy
Hemodialysis related factors	- Hemodialysis vintage - Hemodialysis access (arteriovenous fistula, arteriovenous graft, tunneled dialysis catheter) - RBVM profile changes during each hemodialysis session during the index hospitalization - Changes in oxygen saturation corresponding to RBVM profile changes during each hemodialysis session during the index hospitalization - Weight at admission, prior, and post each hemodialysis session throughout index hospitalization - Blood pressure pre and post hemodialysis sessions during the index hospitalization - Heart rate pre and post hemodialysis sessions during the index hospitalization - Episodes of intradialytic hypotension defined as - The use of intradialytic medications to raise blood pressure such as normal saline, albumin, and midodrine at each hemodialysis session during the index hospitalization - The use of intradialytic or post hemodialysis medications (on hemodialysis days) to lower blood pressure such as beta blockers, calcium channel blockers during each hemodialysis session throughout index hospitalization - Ultrafiltration, blood flow and dialysate flow rates during each hemodialysis session throughout index hospitalization - Hemodialysis machine model and manufacturer
Laboratory values (recorded at admission)	- Hemoglobin - Hematocrit - Serum or plasma sodium - Serum albumin - Serum bicarbonate

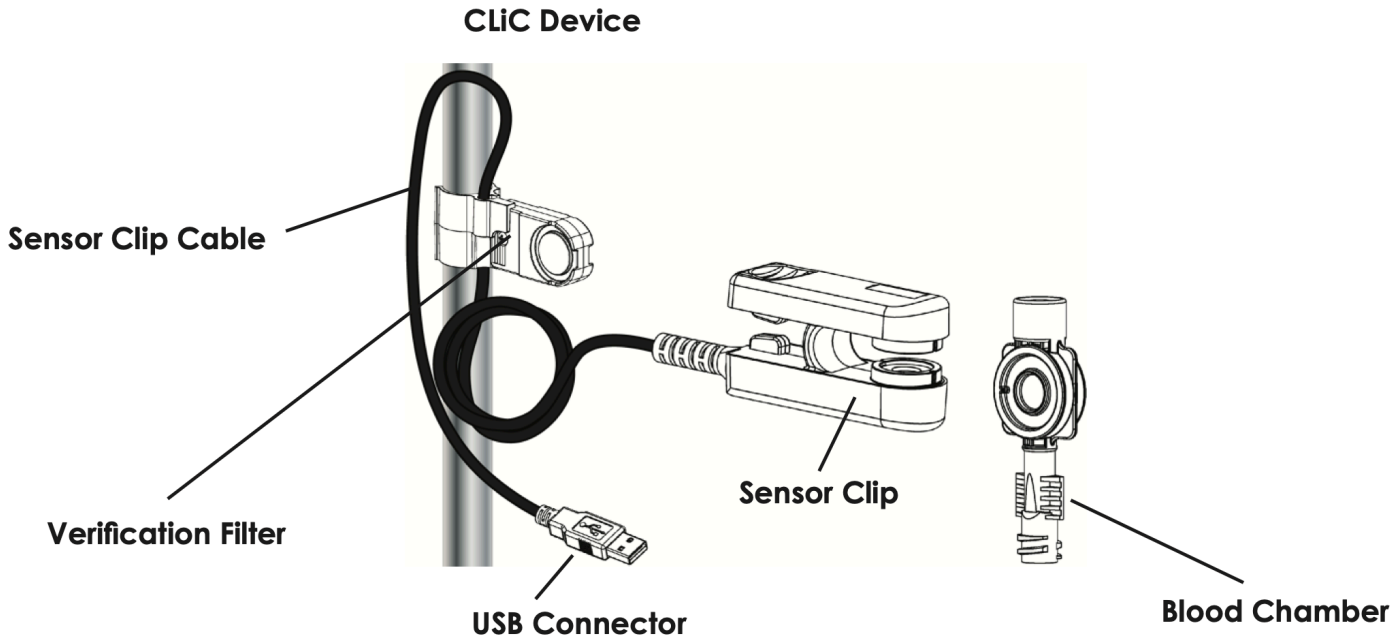
	- N-terminal pro-B-type natriuretic peptide (NT-pro-BNP)
Physical exam findings (recorded at admission)	- Jugular venous distension - Third heart sound - Bibasilar lung rales or crackles - Abdominal Distention - Lower extremity edema
Additional data points (recorded at admission, if available)	- Pulmonary capillary wedge pressure - Central venous pressure - Chest X-ray - Abdominal X-ray - Echocardiogram

Figure 1: Crit-Line® IV Monitor Guidance



Source:https://fmcna.com/content/dam/fmcna/live/support/documents/fluid-management/crit-line-iv/Crit-Line%20IV%20Profile%20Guide.pdf

Figure 2: CLiC™ Device



Source:https://fmcna.com/content/dam/fmcna/live/support/documents/fluidmanagement/clic/CLiC_TraintheTrainer.pdf

Appendix: Preliminary Data [manuscript under review]

Comparison of Outcomes with and without Blood Volume Monitoring among Hospitalized Patients with Heart Failure on Maintenance Hemodialysis

Abstract

Background:
Heart failure (HF) is the leading cause of hospitalization and rehospitalization among patients on maintenance hemodialysis (HD). Difficulties in accurate volume status assessment and incorrect ultrafiltration targets negatively influence clinical outcomes. This study examined whether the application of blood volume monitoring (BVM) to guide ultrafiltration target associates with better clinical outcomes among patients on HD hospitalized for HF.

Methods:
Our retrospective cohort study from two Boston area hospitals included adults on maintenance HD hospitalized for HF exacerbation. One hospital consistently applied BVM, while the other did not according to the admitting hospital's protocols. Demographics, clinical parameters, and outcomes were extracted from the electronic health records and adjudicated by two nephrologists. The primary outcome was length of index hospitalization. The secondary outcomes were time to HF rehospitalization, number of HF rehospitalizations within 90 and 180 days, and time to decongestion during the index hospitalization.

Results:
During the study period (2017-2019), 278 patients met eligibility criteria (mean age [± SD]: 70 ± 12 years, 58% males, and 62% white). 58% were dialyzed with BVM and 42% were dialyzed without BVM during the index hospitalization. The average index hospitalization was 7 days [interquartile range (IQR): 4.00 to 11.75 days]. After adjusting for baseline characteristics with inverse probability treatment weighting, BVM guided HD was associated with a shorter length of hospital stay (difference of -2.00 days, 95% confidence intervals: -4.20 to -0.30 days). There was no difference in time to rehospitalization between BVM and non-BVM groups. Rates of 90 and 180-days rehospitalization and time to decongestion were lower in the BVM group. In the period prior to BVM availability, primary and secondary outcomes were similar between the two hospitals.

Conclusion:
BVM was associated with shorter length of stay, faster time to decongestion, and lower rehospitalization rate among patients on HD hospitalized for HF.

Introduction:

Approximately 45% of patients with ESKD on maintenance hemodialysis (HD) also have heart failure (HF).[1] HF exacerbations in individuals with end-stage kidney disease (ESKD) have a high rate of hospitalization and ~1/3rd patients on HD hospitalized for HF require a rehospitalization in 30 days.[2] Hospitalizations and rehospitalizations for HF exacerbation significantly contribute to the overall economic burden of clinical care.[3] There is a substantial unmet need to identify strategies to reduce the risk of hospitalizations and rehospitalizations in patients living with ESKD to improve quality of life as well as reduce the healthcare costs associated with these hospitalizations.

Establishing and achieving dry weight is the cornerstone of volume management in patients on HD. The dry weight guides the amount of ultrafiltration that is targeted during each HD session. Dry weight in patients with ESKD is currently established on clinical basis in most dialysis centers and is commonly defined as the lowest body weight a patient can tolerate without developing hypotension or becoming symptomatic from volume depletion.[4] The clinical findings, however, are unable to detect changes in hydration status especially if those were subtle and frequently lead to an inaccurate estimation of dry weight. If estimated dry weight is higher than the true dry weight, then the ultrafiltration volume will be insufficient, and patient may develop volume overload and heart failure exacerbation. On the other hand, if estimated dry weight is lower than the true dry weight then patient may receive overly aggressive volume removal leading to intradialytic hypotension, cardiac arrhythmias, and myocardial stunning.[5]

Blood volume monitoring (BVM) technology provides continuous readings of the changes in hematocrit via optic transmission in response to ultrafiltration.[6] It was developed to assist with volume removal by providing real-time data on the patient's intradialytic volume status. Continuous monitoring of changes in blood volume during HD have been reported to allow the prediction of intradialytic hypotension, to assist in obtaining an improved assessment of a patient's intravascular volume status, and to optimize intravascular volume management—a critical component particularly for patients admitted for HF exacerbation.[7] To the best of our knowledge, however, none of the prior studies of BVM have focused on patients treated with HD who were hospitalized for HF exacerbation and BVM is not routinely applied during the HD treatments for patients on HD who are hospitalized.

We planned the present study to examine the potential impact of BVM monitoring on clinical outcomes among patients with ESKD on maintenance HD who were hospitalized for HF exacerbation.

Methods:

Study Design:

This retrospective two-center cohort study examined outcomes in adult patients (age ≥18 years) with ESKD undergoing HD who were hospitalized for HF exacerbation. International Classification of Diseases (ICD)-9/10 code on admission and discharge were used to identify the primary cause of hospitalization. The study period spanned from January 1, 2015 to January ,1, 2020, and encompassed admissions to two large academic hospitals in Boston, Massachusetts (Hospitals A and B). During the period I (January 1, 2015- August 1, 2017), both hospitals did not employ BVM during HD sessions as that period coincided with the period during which there was a recall of BVM necessitating the conventional practice of HD at both academic hospitals. The recall was due to the potential for misinterpretation of the Blood Volume slope graphic display and the possibility of the screen freezing, which could cause the blood pump to stop. The interruption in BVM implementation persisted until its reintroduction in end of August 2017. Data collection done during this period was to help assess whether the differences seen between the two hospitals is attributable to BVM use or to differences in management that are separate from BVM. During the subsequent period II (September 1, 2017-January 1,2020) Hospital A integrated BVM into their HD treatment protocols and data from September 2017 to January 2020 was subsequently gathered to ensure comprehensive analysis. (Figure. 1)

The study is reported according to the STROBE guidelines. The study was approved by the Massachusetts General Brigham Institutional Review Board, which waived the informed consent.

Data Source and Study Population:

Individuals meeting eligibility criteria were identified using the Research Patient Data Registry (RPDR), a shared centralized clinical data registry of both hospitals. Each electronic chart was manually reviewed to confirm the eligibility and accuracy of group assignment. Two nephrologists reviewed and unanimously agreed that the cases met the primary diagnosis of HF exacerbation. Upon abstraction of the relevant information from patient charts, the data elements were entered into the Research Electronic Data Capture (REDCap) secure web application.

Hospitalized adults were included if they met the initial screening of ICD 9/10 codes on admission and or discharge and (1) were 18 years of age or older, (2) had a confirmed diagnosis of ESKD (at least one value of a glomerular filtration rate (GFR) ≤ 15 ml/min/1.73m^2 estimated by the Chronic Kidney Disease Epidemiology Collaboration(CKD-EPI) formula within six months and a diagnosis of ESKD recorded in the patient's chart), (3) were on maintenance HD for at least three months, (4) had a history of HF, (5) were admitted for HF exacerbation as defined by increased oxygen requirement, elevation of N-terminal-prohormone B-type natriuretic peptide (NT-proBNP) compared to prior chart baseline or worsening or new findings on imaging such as pleural effusion, Kerley lines, peribronchial cuffing as read by radiology or physical exam findings such as new or worsening lower extremity edema, and/or crackles, (6) underwent ward admission with ability to receive HD in the hospital dialysis unit, and had (7) primary care, nephrology, or cardiology follow-up within the Massachusetts General Brigham system documented in the electronic health record.

Exclusion criteria included (1) acute kidney injury leading to the initiation of HD during hospitalization, (2) hospitalizations for the initiation of HD, (3) hospitalized under observation (non-inpatient) status, (4) admitted to the intensive care unit, (5) lung, heart, or liver transplant recipients, (6) those with a diagnosis of cancer within the past 12 months, and (7) those with a history of liver cirrhosis.

Data Collection and Definitions of Variables of Interest:

The exposure of interest was the application of the BVM (using Crit-Line^{TM}) which was adjudicated based on which center the patients were admitted to as well as the year of hospitalization and confirmed by reviewing nursing notes. HD was exclusively done with BVM at one participating hospital and exclusively without it at the other center during period II.

The clinical data collected included age, gender, race, cardiovascular comorbidities, dialysis vintage, and type of HD access. Laboratory data included hemoglobin, NT-proBNP, iron, ferritin, total iron binding capacity (TIBC), and transferrin saturation (TSAT). Acute myocardial injury was assessed using troponin T, high sensitivity troponin. Manual chart review of decongestion-related parameters included i) estimated dry weight, ii) weight on admission, iii) oxygen requirement compared to baseline, and iv) physical examination findings (orthopnea, edema, and jugular vein distention).

The severity of HF was graded using the Get With the Guidelines–Heart Failure (GWTG-HF) risk score, which estimates all cause in-hospital mortality and provides prognostic prediction during the acute phase of hospitalization as well as the chronic phase post-discharge.[8] The score, which has been validated in ESKD, includes systolic blood pressure, blood urea nitrogen, black race, serum or plasma sodium, age, heart rate, and chronic obstructive pulmonary disease. The values of the score range between 0 and 100.[8,9] The score was calculated using an online calculator. [10] The GWTG-HF risk score has been identified as an independent predictor of adverse cardiac events (defined as hospitalization for HF exacerbation and or cardiac mortality) in patients with HF. [11,12] Higher GWTG-HF risk scores are significantly associated with an increased likelihood of HF related hospitalization in both preserved and reduced ejection fraction. [11,12]

The data collected to evaluate primary and secondary outcomes included (1) date of index hospitalization, (2) date of discharge, (3) date of resolution of increased oxygen requirement, (4) date of first rehospitalization, (5) number of rehospitalizations at 90 days and 180 days, and (6) date of death. Two independent nephrology reviewers adjudicated the outcomes. Patients where adequate documentation was not available as independently determined by both nephrology reviewers were excluded. To calculate the number of HF exacerbation rehospitalizations, each patient with HF and ESKD had their medical record assessed for the number of rehospitalizations that hold one of the following ICD codes 9/10: volume overload, shortness of breath, and HF exacerbation.

Outcomes of interest:

The primary outcome of interest was the length of index hospital stay. The secondary outcomes of interest were a) the time to first rehospitalization for HF exacerbation, b) the number of rehospitalizations for HF exacerbation within 90 and 180 days of discharge and c) the time to decongestion during the index admission. Decongestion-related parameters were monitored throughout the patient's index hospital stay. The time for decongestion was determined from the point of resolution of increased oxygen requirement to baseline, along with supportive physical exam findings indicating no edema or a return to pre-admission status.

Statistical Analysis:

Continuous variables are summarized as means (± standard deviation) for normally distributed data and medians (interquartile range [IQR]) for not normally distributed data. Categorical variables are summarized as frequency counts (percentages). We compared baseline characteristics between BVM and non-BVM groups using the

Wilcoxon rank-sum test and the Chi-square test for continuous and categorical variables, respectively. We applied inverse probability treatment weighting (IPTW) to period II to account for confounding and balance the baseline characteristics between BVM and non-BVM groups. Secondary analysis was done for period I to compare patient demographics, clinical parameters, and outcomes pre-BVM.

Linear regression analysis was performed to examine the association between the institute of index hospitalization and length of stay during period I (preceding BVM use) and then to examine the association between BVM use and length of stay during period II (period where Hospital A consistently applied BVM during all HD treatments and Hospital B did not apply BVM during any HD treatments). Linear regression was used to investigate the number of rehospitalizations within 90 and 180 days at both hospitals during period II. Rehospitalization was also assessed as a binary outcome by logistic regression. The number of rehospitalizations were separated into binary outcomes analyzed via two separate binary logistic models with model 1 comparing binary outcome of one or more versus no rehospitalizations, and model 2 comparing two or more versus less than two (0 or 1) hospitalizations. This approach allowed us to estimate the odds ratio for rehospitalizations associated with BVM use compared to non-BVM group, adjusting for relevant covariates. The association between BVM use and time to first rehospitalization as well as time to first rehospitalization rates at both hospitals from 2017 to 2019 were examined using the Cox proportional hazards model as it met the proportional hazards assumption. Multivariable models were performed to adjust for age, gender, race, hypertension, diabetes mellitus, coronary artery disease (CAD), dialysis vintage, and HF score.

Two sensitivity analyses were conducted for the main findings. First, to minimize the loss of power when fitting multivariable models and assuming data were missing at random, we performed multiple imputation for missing covariates. Second, competing risks analysis using Fine-Gray modeling was performed to determine whether death is a competing event in assessing time to first rehospitalization providing a more accurate estimate of the event probability.

For all tests, a two-sided alpha value of 0.05 was considered statistically significant. All analyses were performed using R (version 4.3.0, R Foundation for Statistical Computing, Vienna, Austria).

Results:

Study Population

For our primary analysis, we collected data for study period II. 278 individuals met our study's inclusion criteria of whom 160 were dialyzed by BVM guidance at Hospital A and 118 at Hospital B were dialyzed without BVM guidance. For our secondary analysis, data from study period I was collected, and 100 individuals met our study's inclusion criteria with 33 receiving dialysis at Hospital A and 67 at Hospital B. (Figure.2)

Clinical Characteristics of the Study Cohort According to BVM Use

Table 1 shows the characteristics of the cohort stratified by study period and further sub-stratified in study period II by BVM use. Age, gender, and race distributions were similar between the study periods. Prevalence of hypertension, diabetes mellitus, and CAD were comparable between the two study periods and the BVM and non-BVM HD groups.

During study period II, patients dialyzed without BVM had a higher HF score and had a lower prevalence of arteriovenous fistula as the dialysis access compared with the non-BVM group. Patients dialyzed with BVM were more likely to be emergency department admissions (as opposed to hospital transfers) and to have a higher hematocrit at discharge.

Table 2 shows the demographic and clinical characteristics of patients with ESKD on HD admitted for HF exacerbation before and after the IPTW. Differences noted prior applying IPTW were no longer noted after applying IPTW.

BVM Use and Length of Stay

The median length of stay for the index HF exacerbation during study period II was 7 days [IQR: 4.00, 11.75 days]. Patients dialyzed with BVM (Hospital A) had a shorter length of stay compared to those dialyzed without BVM (Hospital B) (difference of -2.30 days, 95% confidence interval -4.30 to -0.38 days, P = 0.020) (Table 3). Multivariable analyses showed that BVM use was associated with shorter length of stay (difference of -2.00 days, 95% confidence interval -3.90 to -0.13 days, P = 0.037). (Figure. 3)

BVM Use and Time to First Rehospitalization

Both univariable and multivariable Cox proportional hazard analyses showed no difference in time to rehospitalization according to the BVM use during study period II (univariable: HR: 0.74, 95% CI: 0.51-1.06, P = 0.101 and multivariable analysis: HR: 0.69, 95% CI: 0.47-1.01, P = 0.058) (Table 4).

BVM Use and Number of Rehospitalizations

During study period II, BVM use was associated with fewer rehospitalizations within the first 90 days compared to non-BVM guided HD (unadjusted Beta coefficient: -0.24 95% CI: -0.45, -0.03, *P=0.027*, and adjusted Beta coefficient: -0.27, 95% CI: -0.48, -0.06, *P=0.013,* respectively) (Table 5).

Similar results were seen within 180 days (unadjusted Beta coefficient: 0.56, 95% CI: 0.40, 0.79, *P<0.001* and adjusted Beta coefficient: 0.41, 95% CI: 0.23, 0.70, *P=0.001*) (Table 6).

In logistic regression analyses, BVM use was associated with lower odds of rehospitalizations compared to non-BVM guided HD within 90 days (unadjusted analyses: odd ratio (OR)=0.39, 95% CI: 0.18, 0.79, *P=0.011* and multivariable adjusted analyses: OR= 0.36, 95% CI: 0.16, 0.80, *P=0.013*) (Table S1).

Similar results were seen for rehospitalization within 180 days (unadjusted analysis: OR=0.41, 95% CI: 0.23, 0.72, *P=0.002* and multivariable adjusted analysis: OR= 0.36, 95% CI: 0.19, 0.66, *P=0.001*) (Table S2).

BVM Use and Time to Decongestion

BVM use was associated with shorter time to decongestion compared to non-BVM guided HD. (unadjusted Beta coefficient: -1.00, 95% CI: -160, -0.48, *P<0.001* and adjusted Beta Coefficient: -1.10, 95% CI: -1.60, -0.50*, P<0.001).* (Table S3) (Figure S.1).

Secondary analysis of period I

Baseline characteristics in the pre-BVM era between individuals treated at two hospitals were comparable (Table S3). On secondary analysis, there was no association between admission hospital and length of stay, time to rehospitalization, number of rehospitalizations at 90 and 180 days or time to decongestion. (Table S4-S8).

Discussion:

In this study, we observed that patients with ESKD and HF who were hospitalized for HF exacerbation and were dialyzed using BVM had a shorter length of stay, faster time to decongestion, and lower rehospitalization rate compared to those who got conventional dialysis.

In the outpatient setting, BVM guided HD of patients with ESKD has shown conflicting results. [21–23] Studies conducted in the inpatient setting mostly included critically ill patients already prone to hemodynamic instability, multiorgan dysfunction and ischemic complications.[24] Inpatient studies also focused on patients with either 1) severe AKI requiring HD or 2) ESKD receiving HD in the ICU.[24,25–28] What distinguishes our study is that it only included patients with ESKD and coexisting HF in the non-intensive care unit inpatient setting whose primary reason for hospitalization was HF decompensation.

A prospective study by Martin et al investigated whether the use of blood volume monitoring (BVM) during acute hemodialysis sessions could reduce the occurrence of intradialytic hypotension (IDH) in hospitalized patients. The study included 328 patients, with 161 in the control group (no RBVM) and 167 in the intervention group (with BVM). 42% of the control group had ESKD, 39% had cardiovascular disease (CVD), and 21% were in the intensive care unit (ICU). While in the BVM group, 53% had ESKD, 41% had CVD and 24% were in the ICU. They concluded that BVM use did not lead to a statistically significant reduction in intradialytic hypotension (IDH) across all hospitalized patients receiving dialysis. However, in a subgroup of 72 patients receiving HD, BVM was associated with a 29% reduction in the odds of IDH. The group also noted that the length of hospital stay was significantly longer in the BVM group, although the reason for this was unclear. [24] While our study revealed that patients undergoing BVM-guided HD had a shorter hospital stay. The reason behind this discrepancy may be due to differences in the studied populations, as patients in the study by Martin et al. were more likely to be hemodynamically unstable, less likely to have pre-existing CVD, and prone to intradialytic hypotension compared to our cohort.

Similarly, our study found lower rehospitalization rates for HF exacerbation within 90 and 180 days among BVM-guided HD patients, consistent with prior research by Goldstein et al. and a quality improvement study showing BVM-guidance associated with lower rate of hospitalization in ESKD patients. [21,29] However, the CLIMB Study reported higher hospitalization rates for BVM-guided HD, possibly due to differences in patient characteristics and study settings. [23] Our study, conducted in quaternary care hospital dialysis units with HF patient population, contrasts with the outpatient setting of the CLIMB Study, where only a 18% had HF among the BVM-guided dialysis group.[23]

The strengths of this study include 1) its assessment of only patients with HF and ESKD which were not previously evaluated in prior studies of BVM-guided HD, 2) the collection of data through manual review of the electronic health records, 3) including only patients with follow-up with primary care team, cardiologist, or nephrologist within the healthcare network, aiming to standardize outpatient care practices, 4) inverse probability

treatment weighting to control for potential confounders, 5) sensitivity analyses including Fine and Gray competing risks regression to address death as a competing event in assessing rehospitalization, and 6) the *quasi-randomization* provided by the design of the experiment making it more informative than traditional observational studies. Moreover, the observation of comparable outcomes between the 2 hospitals during study period I (when both hospitals did not apply BVM) further bolsters our conclusions regarding better outcomes with BVM application compared to no BVM application during study period II (during which one hospital always applied the BVM and the other hospital did not apply BVM at all).

The study has some limitations. The observational nature and retrospective cohort design can only suggest an association but cannot establish a causal relationship between the BVM use and the observed outcomes. The residual kidney function of patients on HD was not accounted for and neither were the factors once patients were discharged from the hospital, such as diet and adherence to HD and medications. Clinical competency in using the BVM by staff was only assessed by supervisors and not by written knowledge testing.

In conclusion, we found that among patients on HD hospitalized for HF exacerbation, BVM use is associated with a shorter length of stay, a lower number of rehospitalizations for HF exacerbation, and shorter time to decongestion. These findings need to be confirmed in future rigorous prospective studies.

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I. Tables:

Table 1. Baseline characteristics in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation dialyzed without BVM or via BVM between September 2017 and January 2020

	Hemodialysis period II			
Characteristics	**Overall (n=278)**	**Non-Blood Volume Monitoring (n=118)**	**Blood Volume Monitoring (n=160)**	**P**
Age (years)	69.50(±12.24)	68.00 (±13.23)	71.00 (±11.36)	0.078
Male Gender	161 (57.90)	64 (54.20)	97 (60.60)	0.345
Race				
White	173 (62.20)	66 (55.90)	107 (66.90)	0.110
Black	53 (19.10)	28 (23.70)	25 (15.60)	
Asian	16 (5.80)	5 (4.20)	11 (6.90)	
Hispanic/Other	36 (12.90)	19 (16.10)	17 (10.60)	
Comorbidities				
Hypertension	271(96.80)	116(98.30)	155(97.00)	0.454
Diabetes Mellitus	213(76.70)	94(79.70)	119(74.40)	0.305
Coronary Artery Disease	243 (87.41)	103 (87.28)	140(87.50)	0.999
Dialysis related Factors				
Ultrafiltration rate (mL/Kg/hr)	9.46 [6.78, 12.78]	9.52 [6.17, 12.80]	9.46 [6.84, 12.74]	0.850
Estimated Dry Weight (Kg)	74.25 [62.33, 89.75]	74.90 [60.00, 87.30]	72.20 [64.58, 92.63]	0.463
Admit Weight (Kg)	77.60 [65.83, 93.53]	77.70 [63.63, 90.15]	77.15 [67.90, 97.23]	0.423
∆ Weight (Kg)	-3.50[-5.00, -2.20]	-3.40[-4.93, -2.03]	-3.55[-5.53, -2.30]	0.175
Dialysis vintage (years)	2.00 [1.00, 4.00]	2.00 [1.00, 4.00]	2.00 [1.00, 4.00]	0.364
Access type (%)				
AVF	181 (65.10%)	88 (74.60%)	93 (58.10%)	**0.013**
AVG	30 (10.80%)	7 (5.90%)	23 (14.40%)	
TDC	67 (24.10%)	23 (19.50%)	44 (27.50%)	
Heart Failure:				
Low	78(28.00%)	29(24.60%)	49(30.60%)	0.085
Moderate	74(26.60%)	28(23.70%)	46(28.80%)	
High	126(45.40%)	61(51.70%)	65(40.60%)	
GWTG-HF Score	41.00[39.00-42.00]	42.50[40.00,44.00]	40.00[38.00,41.00]	**0.013**
Location				
Emergency Department	226 (81.29%)	83 (70.34%)	143 (89.38%)	**<0.001**
F-F transfer	52 (18.71%)	35(29.66%)	17 (10.62%)	
Length of stay (days)	7.00 [4.00, 11.75]	7.50 [4.25, 13.50]	7.00 [4.00, 11.00]	0.230
Labs:				
Hemoglobin (g/dL)	9.95 [8.90, 11.10]	9.80 [8.93, 10.80]	10.00 [8.90, 11.23]	0.420
HCT admit (L/L)	31.30 [28.10, 35.18]	31.15 [28.10, 34.40]	31.45 [28.08, 35.33]	0.435
HCT discharge (L/L)	29.80 [27.03, 32.38]	28.95 [26.60, 31.68]	30.40 [27.50, 33.20]	**0.009**
∆ HCT	2.60 [1.20, 4.60]	2.95 [0.90, 4.90]	2.40 [1.20, 4.30]	0.728
Iron (mcg/dL)	45.00 [32.40, 63.30]	49.00 [37.50, 67.00]	44.00 [31.00, 60.00]	0.091
Ferritin (mg/dL)	806.00 [368.00, 1373.00]	785.00 [325.50, 1433.00]	817.50 [437.50, 1314.30]	0.859
Transferrin saturation (SI units)	23.00 [17.00, 34.00]	18.50 [16.50, 28.00]	25.00 [17.50, 34.00]	0.325
NT-proBNP (pg/mL)	32349.50 [14689.00, 64924.30]	35214.50 [15869.80, 70000.00]	31547.00 [14360.30, 58331.50]	0.594
troponin T (ng/mL)	0.12 [0.10, 0.30]	0.16 [0.10, 0.30]	0.11 [0.10, 0.20]	0.116

AVF: arteriovenous fistula, AVG: arteriovenous graft, TDC: tunneled dialysis catheter, HCT: hematocrit, F-F: floor to floor, NT-proBNP: N-terminal pro b-type natriuretic peptide, ∆: delta, GTWG: Get with The Guidelines-Heart Failure Score

Table 2. Demographic and Clinical Characteristics of admissions for Heart Failure exacerbation on Hemodialysis with a history of Heart Failure Before and After the Inverse Probability of Treatment Weighting.

	Hemodialysis period II					
	Unweighted Cohort			Weighted Cohort		
Characteristics	**Non-Blood Volume Monitoring (n=118)**	**Blood Volume Monitoring (n=160)**	**SMD**	**Non-Blood Volume Monitoring (n=110)**	**Blood Volume Monitoring (n=152)**	**SMD**
Age (years), mean ± SD	68.00 (±13.23)	71.00 (±11.36)	**0.217**	69.50 (±13.12)	69.50 (±11.86)	0.000
Male Gender	54.20	60.60	0.064	58.94	58.97	0.0003
Race (%)						
White	55.90	66.90	**0.109**	62.51	62.33	-0.002
Black	23.70	15.60	-0.081	19.79	19.82	0.0003
Asian	4.20	6.90	0.026	4.94	5.55	0.006
Hispanic/Other	16.10	10.60	-0.055	12.76	12.30	-0.005
Comorbidities (%)						
Hypertension	98.30	96.90	-0.014	97.43	97.48	0.0004
Diabetes Mellitus	79.70	74.40	-0.053	77.08	76.93	-0.002
Coronary Artery Disease	87.29	87.50	0.002	87.52	87.34	-0.002
Dialysis related Factors						
Dialysis vintage (years) mean ± SD	3.35(± 4.55)	3.39 (±3.39)	0.012	3.42(± 5.02)	3.41 (±3.43)	-0.003
Heart Failure: (%)						
Low	24.58	30.62	0.061	27.26	27.75	0.005
Moderate	23.73	28.75	0.050	25.60	26.06	0.005
High	51.69	40.62	-0.111	47.14	46.19	-0.009

SMD: Standard Mean Difference, SD: standard deviation, HF: GTWG: Get with The Guidelines-Heart Failure Score

Table 3. Length of stay in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis via Blood Volume Monitoring vs non-Blood Volume Monitoring between September 2017 and January 2020

Length of Stay	Univariable Analysis			Multivariable Analysis			Multivariable Analysis		
Characteristic	**β- Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**
Group									
BVM	-2.3	-4.3, -0.38	**0.020**	-2.2	-4.1, -0.29	**0.025**	-2.0	-3.9, -0.13	**0.037**
Age	-0.01	-0.08, 0.07	0.893	-0.03	-0.11, 0.05	0.440	-0.05	-0.14, 0.03	0.207
Gender									
Male	1.1	-0.88, 3.1	0.278	0.73	-1.3, 2.7	0.474	0.00	-2.0, 2.0	0.998
Race Group									
White	-	-	-				-	-	-
Black	-3.2	-5.7, -0.66	**0.014**	-3.4	-6.1, -0.81	**0.011**	-2.9	-5.5, -0.27	**0.031**
Asian	-4.5	-9.1, 0.01	0.051	-4.1	-8.7, 0.39	0.075	-3.7	-8.1, 0.74	0.104
Hispanic/Other	-2.9	-5.9, 0.00	0.051	-2.7	-5.7, 0.27	0.076	-2.6	-5.5, 0.42	0.093
Hypertension									
Yes	-4.6	-11, 2.2	0.187				-3.8	-10, 2.8	0.266
Diabetes Mellitus									
Yes	1.5	-0.82, 3.9	0.205				1.6	-0.84, 4.1	0.198
Coronary Artery Disease									
Yes	4.3	1.4, 7.3	**0.004**				3.3	0.21, 6.5	**0.038**
Dialysis Vintage	0.20	0.01, 0.38	**0.041**				0.25	0.06, 0.44	**0.012**
Heart Failure score									
Low	-	-	-				-	-	-
Moderate	0.22	-2.2, 2.7	0.859				0.09	-2.4, 2.5	0.943
Severe	2.6	0.27, 4.9	**0.029**				2.6	0.29, 5.0	**0.028**

BVM: Blood Volume Monitoring. Linear Regression used to show length of stay.

Table 4. Time to readmit in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis via Blood Volume Monitoring vs non-Blood Volume Monitoring between September 2017 and January 2020

Time to first Readmit	Univariable Analysis			Multivariable Analysis		
Characteristic	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Group						
BVM	0.74	0.51, 1.06	0.101	0.69	0.47, 1.01	0.058
Age	0.99	0.98, 1.01	0.226	0.99	0.98, 1.01	0.407
Gender						
Male	1.06	0.74, 1.53	0.750	1.11	0.74, 1.66	0.612
Race Group						
White	-	-	-	-	-	-
Black	1.40	0.88, 2.22	0.157	1.35	0.85, 2.14	0.201
Asian	1.25	0.61, 2.56	0.546	1.28	0.57, 2.85	0.552
Hispanic/Other	1.06	0.60, 1.88	0.839	1.07	0.59, 1.96	0.814
Hypertension						
Yes	0.68	0.31, 1.45	0.315	0.62	0.27, 1.43	0.267
Diabetes Mellitus						
Yes	1.22	0.77, 1.92	0.403	1.09	0.67, 1.77	0.725
Coronary Artery Disease						
Yes	0.88	0.53, 1.48	0.641	0.86	0.50, 1.50	0.602
Dialysis Vintage	0.94	0.90, 0.99	**0.011**	0.94	0.90, 0.99	**0.011**
Heart Failure score						
Low	-	-	-	-	-	-
Moderate	0.80	0.50, 1.29	0.369	0.82	0.48, 1.38	0.448
Severe	1.05	0.69, 1.62	0.815	0.98	0.60, 1.59	0.926

BVM: Blood Volume Monitoring. Cox proportional hazards regression used to show time to Heart Failure readmission.

Table 5. Number of readmits within 90 days in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis via Blood Volume Monitoring vs non-Blood Volume Monitoring between September 2017 and January 2020

Number of readmissions within 90 days	**Univariable Analysis**			**Multivariable Analysis**			**Multivariable Analysis**		
Characteristic	**β-Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**
Group									
BVM	-0.24	-0.45, -0.03	**0.027**	-0.25	-0.46, -0.04	**0.022**	-0.27	-0.48, -0.06	**0.013**
Age	-0.01	-0.02, 0.00	**0.022**	-0.01	-0.02, 0.00	0.146	-0.01	-0.01, 0.00	0.224
Gender									
Male	0.13	-0.09, 0.35	0.252	0.13	-0.09, 0.35	0.249	0.17	-0.06, 0.39	0.150
Race Group									
White	-	-	-				-	-	-
Black	0.39	0.12, 0.67	**0.006**	0.33	0.04, 0.62	**0.025**	0.32	0.03, 0.61	**0.033**
Asian	-0.05	-0.55, 0.45	0.842	0.01	-0.49, 0.51	0.967	-0.01	-0.51, 0.48	0.954
Hispanic/Other	0.13	-0.20, 0.45	0.439	0.16	-0.17, 0.49	0.346	0.14	-0.19, 0.48	0.403
Hypertension									
Yes	0.03	-0.71, 0.78	0.930				-0.06	-0.80, 0.68	0.874
Diabetes Mellitus									
Yes	0.08	-0.17, 0.34	0.520				-0.01	-0.29, 0.26	0.922
Coronary Artery Disease									
Yes	-0.10	-0.43, 0.23	0.547				-0.02	-0.37, 0.33	0.902
Dialysis Vintage	-0.02	-0.04, 0.00	0.040				-0.03	-0.05, 0.00	**0.021**
Heart Failure score									
Low	-	-	-	-	-	-	-	-	-
Moderate	-0.04	-0.30, 0.21	0.740				-0.18	-0.46, 0.09	0.190
Severe	-0.04	-0.30, 0.21	0.740				-0.07	-0.33, 0.19	0.590

BVM: Blood Volume Monitoring, Linear Regression used to show number of readmissions within 90 days

Table 6. Number of readmits within 180 days in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis via Blood Volume Monitoring vs non-Blood Volume Monitoring between September 2017 and January 2020

Number of readmissions within 180 days	**Univariable Analysis**			**Multivariable Analysis**			**Multivariable Analysis**		
Characteristic	**β-Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**
Group									
BVM	-0.42	-0.75, -0.09	**0.012**	-0.44	-0.76, -0.11	**0.009**	-0.47	-0.80, -0.15	**0.004**
Age	-0.02	-0.03, -0.01	**0.006**	-0.01	-0.03, 0.00	**0.042**	-0.01	-0.03, 0.00	0.059
Gender									
Male	0.02	-0.32, 0.35	0.909	0.00	-0.34, 0.34	0.994	0.05	-0.30, 0.39	0.790
Race Group									
White	-	-	-				-	-	-
Black	0.59	0.17, 1.0	**0.007**	0.02, 0.90	**0.043**	0.02, 0.90	0.46	0.02, 0.91	**0.043**
Asian	0.04	-0.73, 0.81	0.916	-0.61, 0.91	0.695	-0.61, 0.91	0.12	-0.64, 0.88	0.758
Hispanic/Other	0.16	-0.34, 0.65	0.537	-0.38, 0.63	0.617	-0.38, 0.63	0.13	-0.38, 0.64	0.621
Hypertension									
Yes	-0.23	-1.4, 0.92	0.697				-0.37	-1.5, 0.76	0.523
Diabetes Mellitus									
Yes	0.07	-0.33, 0.47	0.730				-0.10	-0.52, 0.33	0.658
Coronary Artery Disease									
Yes	-0.14	-0.65, 0.36	0.584				0.06	-0.48, 0.60	0.829
Dialysis Vintage	-0.04	-0.07, -0.01	0.020				-0.04	-0.08, -0.01	**0.010**
Heart Failure score									
Low									
Moderate	-0.25	-0.66, 0.17	0.249				-0.20	-0.62, 0.22	0.358
Severe	-0.06	-0.46, 0.33	0.748				-0.08	-0.48, 0.32	0.702

BVM: Blood Volume Monitoring, Linear Regression used to show number of readmissions within 180 days

II. FIGURES

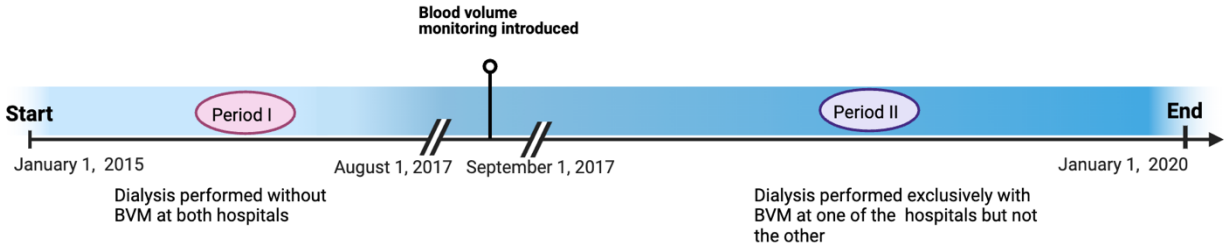

Figure 1. Timeline showing the data collection

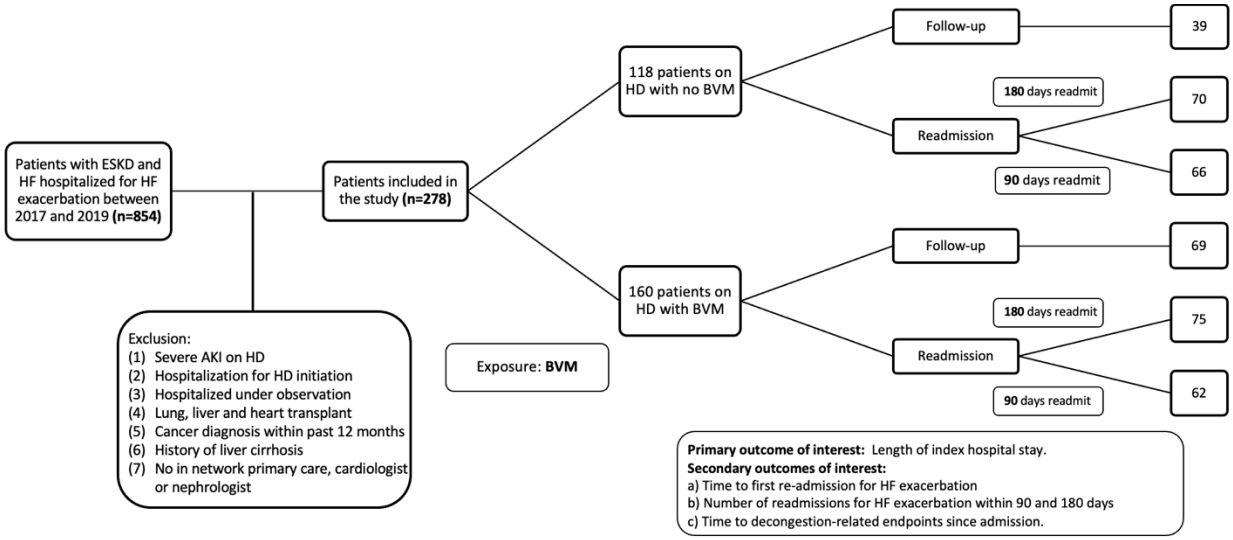

Figure 2. Flow diagram showing the data collection method between September 2017 and January 2020

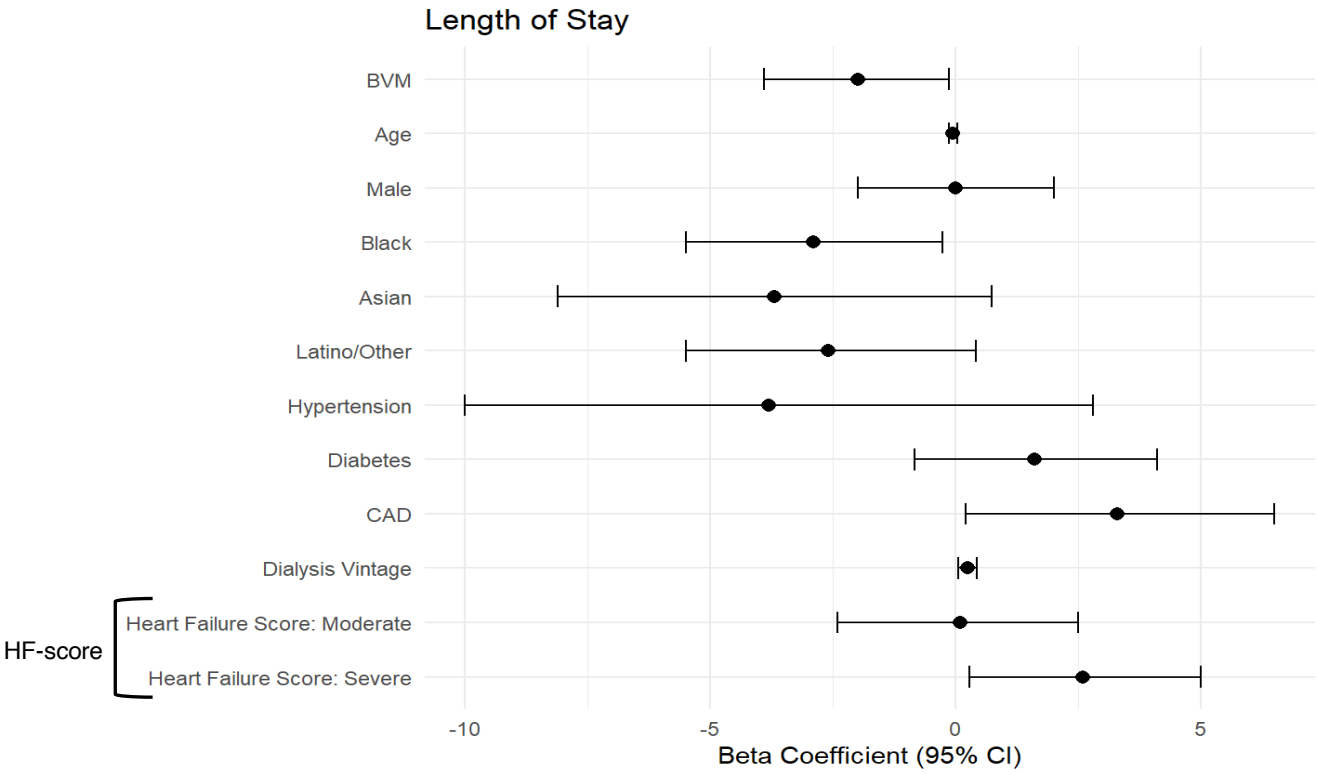

Figure 3: Multivariable linear regression model showing Beta coefficients of Length of Stay by patient characteristics. Filled diamond denotes point estimate of β-coefficient and error bars represent 95% CI. BVM: Blood Volume Monitoring, HTN: Hypertension, DM: Diabetes Mellitus, CAD: Coronary Artery Disease, HF-score: Heart Failure score

Supplementary

I. Tables
II. Figures

I. Supplementary Tables:

Table S1. Number of readmits within 90 days in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis via Blood Volume Monitoring vs conventional between September 2017 and January 2020.

Number of readmits within 90 days	Univariable (1 or more) vs 0			Multivariable (1 or more) vs 0			Univariable more vs (1/0)			Multivariable more vs (1/0)		
Characteristic	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Group												
BVM	0.56	0.40, 0.79	**<0.001**	0.49	0.34, 0.71	**<0.001**	0.53	0.32, 0.87	**0.013**	0.41	0.23, 0.70	**0.001**
Age	0.99	0.97, 1.00	**0.045**	0.98	0.97, 1.00	0.057	0.98	0.97, 1.00	0.105	0.99	0.97, 1.01	0.326
Gender												
Male	1.20	0.85, 1.69	0.292	1.19	0.81, 1.77	0.379	1.42	0.86, 2.39	0.179	1.71	0.95, 3.14	0.077
Race Group												
White	—	—		—	—							
Black	1.51	0.97, 2.34	0.066	1.24	0.74, 2.08	0.410	2.82	1.58, 4.99	**<0.001**	2.65	1.34, 5.24	**0.005**
Asian	0.85	0.37, 1.87	0.689	1.04	0.38, 2.74	0.932	1.17	0.27, 3.57	0.807	3.00	0.64, 10.7	0.114
Other	0.94	0.56, 1.57	0.821	0.90	0.51, 1.59	0.719	2.14	1.04, 4.19	**0.031**	2.29	1.03, 4.96	**0.038**
Hypertension												
Yes	1.14	0.35, 3.94	0.824	1.20	0.36, 4.26	0.770	0.64	0.17, 3.68	0.547	0.51	0.12, 3.22	0.408
Diabetes Mellitus												
Yes	1.15	0.77, 1.73	0.489	1.04	0.64, 1.68	0.887	1.25	0.70, 2.39	0.469	1.14	0.57, 2.41	0.725
Coronary Artery Disease												
Yes	0.90	0.54, 1.50	0.680	0.90	0.49, 1.66	0.730	0.66	0.35, 1.35	0.230	0.72	0.32, 1.68	0.434
Dialysis Vintage	0.91	0.86, 0.96	**<0.001**	0.90	0.85, 0.95	**<0.001**	0.92	0.84, 0.99	0.070	0.93	0.84, 1.01	0.144
Heart Failure score												
Low												
Moderate	0.80	0.52, 1.22	0.308	0.83	0.51, 1.34	0.444	0.50	0.25, 0.98	**0.049**	0.55	0.25, 1.14	0.112
Severe	0.90	0.60, 1.35	0.614	0.91	0.57, 1.43	0.671	1.07	0.62, 1.86	0.812	1.18	0.64, 2.22	0.595
BVM: Blood Volume Monitoring, Logistic Regression used to show number of readmissions within 90 days												

Table S2. Number of readmits within 180 days in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis via Blood Volume Monitoring vs conventional between September 2017 and January 2020.

Number of readmits within 180 days	Univariable (1 or more) vs 0			Multivariable (1 or more) vs 0			Univariable more vs (1/0)			Multivariable more vs (1/0)		
Characteristic	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Group												
BVM	0.68	0.49, 0.96	**0.026**	0.57	0.39, 0.82	**0.003**	0.51	0.34, 0.75	**<0.001**	0.41	0.27, 0.63	**<0.001**
Age	0.99	0.98, 1.00	0.196	0.99	0.97, 1.00	0.081	0.98	0.97, 1.00	0.051	0.98	0.96, 1.00	**0.021**
Gender												
Male	0.90	0.64, 1.26	0.524	0.81	0.54, 1.20	0.289	1.18	0.80, 1.74	0.414	1.04	0.67, 1.63	0.864
Race Group												
White	—	—		—	—							
Black	1.42	0.92, 2.22	0.117	1.30	0.77, 2.20	0.325	1.83	1.14, 2.91	**0.012**	1.64	0.94, 2.88	0.081
Asian	1.18	0.54, 2.63	0.684	1.87	0.71, 5.27	0.214	1.29	0.50, 2.99	0.572	1.70	0.52, 4.96	0.345
Other	0.75	0.45, 1.25	0.272	0.64	0.36, 1.12	0.121	0.99	0.53, 1.77	0.966	0.86	0.43, 1.65	0.659
Hypertension												
Yes	0.45	0.11, 1.48	0.211	0.49	0.12, 1.69	0.283	0.74	0.22, 2.93	0.631	0.71	0.19, 3.03	0.616
Diabetes Mellitus												
Yes	1.31	0.88, 1.96	0.184	1.25	0.77, 2.02	0.371	1.06	0.68, 1.70	0.796	0.98	0.56, 1.73	0.943
Coronary Artery Disease												
Yes	1.01	0.60, 1.69	0.966	1.00	0.54, 1.85	0.999	1.00	0.57, 1.84	0.993	1.27	0.64, 2.65	0.503
Dialysis Vintage	0.91	0.86, 0.95	**<0.001**	0.90	0.85, 0.95	**<0.001**	0.90	0.84, 0.96	**0.004**	0.91	0.84, 0.97	**0.008**
Heart Failure score												
Low												
Moderate	0.79	0.52, 1.20	0.270	0.86	0.53, 1.38	0.534	0.66	0.40, 1.08	0.103	0.69	0.40, 1.19	0.187
Severe	1.00	0.67, 1.50	0.989	1.01	0.64, 1.60	0.976	0.93	0.60, 1.46	0.763	0.92	0.56, 1.54	0.762

BVM: Blood Volume Monitoring, Logistic Regression used to show number of readmissions within 180 days

Table S3. Decongestion days in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis via Blood Volume Monitoring vs conventional between September 2017 and January 2020.

Time to Decongestion	Univariable Analysis			Multivariable Analysis			Multivariable Analysis		
Characteristic	**β-Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**	**β-Coefficient**	**95% CI**	**p-value**
Group									
BVM	-1.0	-1.6, -0.48	**<0.001**	-1.0	-1.6, -0.47	**<0.001**	-1.1	-1.6, -0.50	**<0.001**
Age	-0.01	-0.03, 0.02	0.486	-0.02	-0.04, 0.01	0.200	-0.02	-0.04, 0.01	0.140
Gender									
Male	-0.02	-0.61, 0.57	0.955	-0.15	-0.74, 0.44	0.628	-0.20	-0.80, 0.40	0.514
Race Group									
White	-	-	-				-	-	-
Black	-0.65	-1.4, 0.10	0.092	-0.78	-1.6, -0.01	**0.049**	-0.75	-1.5, 0.03	0.062
Asian	-1.0	-2.4, 0.36	0.152	-0.83	-2.2, 0.51	0.227	-0.84	-2.2, 0.49	0.218
Hispanic/Other	-0.71	-1.6, 0.17	0.115	-0.78	-1.7, 0.11	0.087	-0.86	-1.7, 0.03	0.060
HTN									
Y	-0.37	-2.4, 1.7	0.722				-0.08	-2.1, 1.9	0.938
DM									
Y	0.60	-0.09, 1.3	0.090				0.38	-0.36, 1.1	0.314
CAD									
Y	0.65	-0.24, 1.5	0.155				0.41	-0.53, 1.3	0.398
Dialysis Vintage	-0.05	-0.11, 0.00	0.056				-0.05	-0.11, 0.01	0.094
HF score									
Low									
Moderate	-0.09	-0.82, 0.65	0.818				-0.16	-0.90, 0.57	0.665
Severe	0.64	-0.06, 1.3	0.074				0.51	-0.19, 1.2	0.158

BVM: Blood Volume Monitoring, HTN: Hypertension, DM: Diabetes Mellitus, CAD: Coronary Artery Disease, HF: Heart Failure

S.4 Table: table showing dialysis patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation to Hospital A and Hospital B between January 2015 and August 2017

Characteristics	Overall (n=100)	Hospital A (n=67)	Hospital B (n=33)	P
Age (years)	73.00 [59.75, 83.00]	69.00 [58.50, 82.50]	73.00 [66.00, 83.00]	0.236
Male Gender	57 (57.00 %)	37 (55.20 %)	20 (60.60 %)	0.767
Race Group (%)				
White	50 (50.00)	31(46.27)	19 (57.58)	0.313
Black	27 (27.00)	21 (31.34)	6 (18.18)	
Asian	7 (7.00)	1 (1.49)	6 (18.18)	
Hispanic/Other	16 (16.00)	14 (20.90)	2 (6.06)	
Coexisting conditions				
Hypertension	97(97.00)	65(97.01)	32(96.97)	0.999
Diabetes Mellitus	80(80.00)	53(79.10)	27(81.82)	0.958
Coronary Artery Disease	94 (94.00)	65(97.01)	29(87.88)	0.174
Dialysis related factors				
Ultrafiltration rate (mL/Kg/hr)	8.81 [6.71, 11.38]	8.66 [6.98, 11.56]	8.93 [6.44,10.67]	0.945
Estimated Dry Weight (Kg)	71.85 [59.90, 81.83]	73.60[62.50, 86.60]	66.00 [56.00, 80.00]	0.125
Admit Weight (Kg)	74.60 [62.30, 86.30]	75.50 [64.50, 88.10]	70.00 [58.00, 74.60]	0.155
∆ Weight (Kg)	2.50[1.60,4.00]	2.10 [1.55,4.00]	2.60[1.90,4.40]	0.243
Dialysis vintage (years)	1.00 [1.00, 3.00]	1.00 [1.00, 3.00]	1.00 [1.00, 3.00]	0.810
Access type (%)				
AVF	41 (41.00%)	26(38.81%)	15 (45.46%)	0.192
AVG	4 (4.00%)	0 (0.00%)	4(12.12%)	
TDC	55 (55.00%)	41(61.19%)	14(42.42%)	
GWTG-HF- Severity (%)				
Low	28(28.00%)	19(28.36%)	9(27.27%)	0.846
Moderate	18(18.00%)	11(16.42%)	7(21.21%)	
Severe	54(54.00%)	37(55.22%)	17(51.52%)	
GWTG-HF Score	42.87	43.18	42.24	0.611
Admission Modality				
Emergency Department	74(74.00%)	48 (71.64%)	26(78.79%)	0.446
Floor to Floor Transfer	26(26.00%)	19(28.26%)	7(21.21%)	
Length of Stay	8.50[4.75,13.25]	8.00[4.00,13.50]	9.00[7.00,13.00]	0.382
Laboratory				
Hemoglobin (g/dL)	9.80 [9.10,11.03]	9.80 [8.95, 11.10]	10.10 [9.20, 10.90]	0.550
Hematocrit admit (L/L)	31.00 [28.05, 35.05]	30.80 [27.65, 35.50]	32.00 [29.20, 34.60]	0.514
Hematocrit discharge (L/L)	29.85 [26.80, 32.80]	29.70 [26.55, 33.30]	30.00 [26.80, 32.20]	0.798
∆Hematocrit	2.50 [1.60, 4.00]	2.10 [1.55, 4.00]	2.60 [1.90, 4.40]	0.243
Iron (mcg/dL)	43.00 [30.75, 69.00]	44.00 [32.50, 74.00]	42.00 [28.00, 53.00]	0.407
Ferritin (mg/dL)	708.00 [229.75, 1485.75]	522.00 [228.50, 1367.00]	833.00 [268.00, 1493.00]	0.310
TIBC (mcg/dL)	172.00 [110.00, 213.00]	173.00 [139.00, 192.00]	169.00 [42.00, 216.50]	0.797
NT-proBNP (pg/mL)	10372.00 [0.00, 36430.25]	9845.00 [0.00, 45050.00]	19488.00 [835.00, 35000.00]	0.594
troponin T (ng/mL)	0.10 [0.04, 0.22]	0.09 [0.04, 0.20]	0.11 [0.04, 0.25]	0.5153

Data summarized as mean (SD) or median (25th, 75th percentiles) for continuous variables or n (%) for categorical variables; GWTG-HF: Get with the guidelines heart failure score, TIBC: Total Iron Binding Capacity, NT-proBNP: N-terminal prohormone of brain natriuretic peptide ∆: Difference

Table S5. Length of Stay in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis at Hospital A and B between January 2015 and August 2017

Length of Stay	Univariable Analysis			Multivariable Analysis			Multivariable Analysis II		
Characteristic	**Beta Coefficient**	**95% CI**	**p-value**	**Beta Coefficient**	**95% CI**	**p-value**	**Beta Coefficient**	**95% CI**	**p-value**
Group									
Hospital B	-0.48	-4.2,3.35	0.819	-0.7	-4.6, 3.2	0.724	-0.92	-4.9, 3.1	0.651
Age	-0.13	-0.25, -0.0001	**0.049**	-0.18	-0.32, -0.05	**0.007**	-0.17	-0.31, -0.03	**0.013**
Gender									
Male	-0.33	-3.93,3.27	0.857	-0.92	-4.51, 2.67	0.612	-2.24	-6.17, 1.69	0.261
Race Group									
Asian									
Black	-1.53	-5.7, 2.6	0.47	-4.14	-8.7, 0.43	0.075	-3.28	-8.29, 1.73	0.197
Other	4.74	-11.8, 2.3	0.185	-4.13	-11.25, 3.00	0.253	-3.40	-10.82, 4.02	0.365
White	-5.79	-10.80, -0.77	**0.024**	-7.92	-13.12,-2.72	**0.003**	-7.64	-13.15, -2.14	**0.007**
Hypertension									
Yes	1.64	-8.8,12.1	0.755				-2.07	-14.39, 10.24	0.739
Diabetes Mellitus									
Yes	3.54	-0.86,7.94	0.114				4.81	-0.23, 9.85	0.061
Coronary Artery Disease									
Yes	-0.43	-7.94,7.08	0.910				-0.32	-9.10, 8.45	0.942
Dialysis Vintage	-0.43	-1.38,0.51	0.367				-0.65	-1.72, 0.43	0.233
HF-score	-0.08	-2.14,1.97	0.937				-0.24	-2.42, 1.93	0.823
HF-score: Heart Failure Score, Linear Regression to show length of stay									

Table S6. Time to first readmit post discharge for Heart Failure exacerbation in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis at Hospital A and B between January 2015 and August 2017

Time to first readmit		Univariable Analysis		Multivariable Analysis		
Characteristic	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Group						
Hospital B	0.76	0.41, 1.41	0.39	0.63	0.32, 1.26	0.199
Age	0.99	0.97, 1.00	0.065	0.98	0.95, 1.00	0.113
Gender						
Male	1.11	0.61,2.02	0.724	0.47	0.82, 1.68	0.089
Race Group						
Asian				—	—	
Black	2.61	1.24,5.50	**0.012**	2.09	0.88,4.96	0.094
Other	7.64	1.57,37.24	**0.012**	20.20	3.03, 134.62	**0.002**
White	1.28	0.63,2.60	0.492	1.11	0.49, 2.48	0.807
Hypertension						
Yes	0.13	0.015,1.05	0.06	0.09	0.006,1.49	0.094
Diabetes Mellitus						
Yes	1.53	0.69, 3.38	0.292	2.21	0.83, 5.83	0.110
Coronary Artery Disease						
Yes	1.76	0.54,5.71	0.347	1.82	0.44,7.51	0.408
Dialysis Vintage	0.99	0.83,1.21	0.992	0.837	0.65,1.08	0.168
Heart Failure score	1.14	0.79,1.65	0.485	1.26	0.80,1.98	0.314
Cox proportional hazards regression used to show time to Heart Failure readmission.						

Table S7.a. Number of readmissions for heart failure exacerbation within 90 in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis at Hospital A and B between January 2015 and August 2017

Number of readmits within 90	Univariable Analysis			Multivariable Analysis		
Characteristic	**Beta Coefficient**	**95% CI**	**p-value**	**Beta Coefficient**	**95% CI**	**p-value**
Group						
Hospital B	-0.22	-0.64,0.19	0.288	-0.19	-0.64,0.27	0.421
Age	-0.001	-0.02,0.01	0.853	0.0002	-0.02,0.02	0.982
Gender						
Male	-0.16	-0.55,0.24	0.435	-0.38	-0.83,0.07	0.094
Race Group						
Asian	-	-	-	-	-	-
Black	0.02	-0.45,0.48	0.943	0.146	-0.42,0.71	0.613
Other	0.27	-0.52,1.06	0.506	0.541	-0.30,1.38	0.206
White	0.48	-0.08,1.04	0.09	0.520	-0.30,1.38	0.101
Hypertension						
Yes	0.47	-0.68,1.62	0.422	-0.008	-1.41,1.39	0.991
Diabetes Mellitus						
Yes	0.15	-0.342,0.642	0.546	0.390	-0.18,0.96	0.179
Coronary Artery Disease						
Yes	0.66	-0.16,1.48	0.113	0.440	-0.56,1.43	0.388
Dialysis Vintage	-0.07	-0.17,0.03	0.181	-0.118	-0.24,0.004	0.059
Heart Failure score	0.08	-0.15,0.30	0.495	0.184	-0.06,0.43	0.141
Linear Regression used to show number of readmissions within 90 days						

Table S7.b. Number of readmissions for heart failure exacerbation within 180 in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis at Hospital A and B between January 2015 and August 2017

Number of readmits within 180	Univariable Analysis			Multivariable Analysis		
Characteristic	**Beta Coefficient**	**95% CI**	**p-value**	**Beta Coefficient**	**95% CI**	**p-value**
Group						
Hospital B	-0.22	-0.81,0.37	0.466	-0.021	-0.65,0.61	0.948
Age	-0.01	-0.03,0.01	0.453	-0.002	-0.02,0.02	0.889
Gender						
Male	-0.15	-0.71,0.41	0.601	-0.271	-0.89,0.35	0.385
Race Group						
Asian				—	—	
Black	0.28	-0.36,0.93	0.387	0.475	-0.89,0.35	0.234
Other	0.15	-0.94,1.25	0.784	0.484	-0.31,1.26	0.412
White	0.96	0.18,1.73	**0.020**	0.940	-0.68,1.65	**0.034**
Hypertension						
Yes	1.71	0.13,3.30	**0.035**	0.989	0.08,1.81	0.313
Diabetes Mellitus						
Yes	0.14	-0.55,0.83	0.694	0.236	-0.95,2.93	0.555
Coronary Artery Disease						
Yes	1.41	0.28,2.54	**0.015**	0.883	-0.50,2.26	0.207
Dialysis Vintage	-0.10	-0.25,0.04	0.168	-0.133	-0.30,0.04	0.120
Heart Failure score	-0.07	-0.39,0.25	0.670	0.114	-0.23,0.46	0.509
Linear Regression used to show number of readmissions within 180 days						

Table S8. Time to decongestion during heart failure exacerbation in patients on hemodialysis with Heart Failure admitted for Heart Failure exacerbation undergoing dialysis at Hospital A and B between January 2015 and August 2017

Time to decongestion	Univariable Analysis			Multivariable Analysis		
Characteristic	**Beta Coefficient**	**95% CI**	**p-value**	**Beta Coefficient**	**95% CI**	**p-value**
Group						
Hospital B	-0.13	-0.63,0.38	0.619	0.03	-0.65,0.61	0.914
Age	-0.01	-0.03,0.01	0.303	-0.01	-0.02,0.02	0.184
Gender						
Male	0.11	-0.36,0.59	0.637	0.04	-0.89,0.35	0.875
Race Group						
Asian				—	—	
Black	0.07	-0.46,0.61	0.792	0.03	-0.89,0.35	0.920
Other	-1.21	-2.12, -0.29	**0.01**	-1.15	-0.31,1.26	**0.024**
White	-0.72	-1.37, -0.07	**0.03**	-0.64	-0.68,1.65	0.090
Hypertension						
Yes	-0.07	-1.46,1.32	0.922	-0.27	0.08,1.81	0.743
Diabetes Mellitus						
Yes	0.38	-0.21, 0.96	0.209	0.32	-0.95,2.93	0.342
Coronary Artery Disease						
Yes	0.11	-0.89,1.10	0.833	0.07	-0.50,2.26	0.905
Dialysis Vintage	0.05	-0.08,0.17	0.475	0.02	-0.30,0.04	0.753
Heart Failure score	0.24	-0.02,0.51	0.07	0.22	-0.23,0.46	0.129

I. Supplementary Figure:

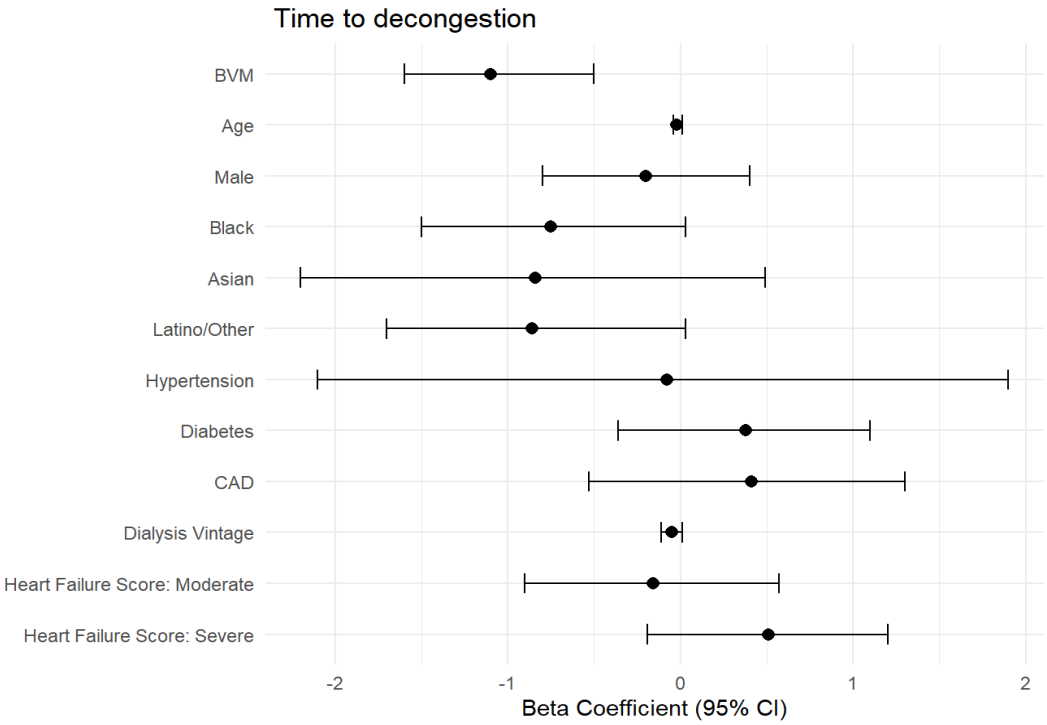

Figure SI: Multivariable linear regression model showing Beta coefficients of time to decongestion by patient characteristics. Filled diamond denotes point estimate of β-coefficient and error bars represent 95% CI. BVM: Blood Volume Monitoring, HTN: Hypertension, DM: Diabetes Mellitus, CAD: Coronary Artery Disease, HF-score: Heart Failure score