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Vein Reflow Enhancement Strategies and Respiratory Rhythm Training: Can End-Stage Renal Disease Patients Walk-away from Hypotension during Hemodialysis

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Abstract **-** Patients with end-stage renal disease (ESRD) undergoing hemodialysis (HD) frequently experience intradialytic hypotension (IDH), a complication that not only compromises treatment stability and safety but also diminishes quality of life. While reducing ultrafiltration rates has traditionally been employed as a preventive measure, this approach can be impractical in clinical settings due to its adverse impact on fluid removal efficiency. To address these challenges, we propose an integrated solution, Smart External Pulsatile Compression (SEPC), which synergistically incorporates wearable physiological monitoring devices, lower extremity venous return facilitation via intermittent pneumatic compression (IPC), and respiratory rhythm training to maintain hemodynamic stability. Preliminary clinical findings suggest that SEPC significantly lowers the incidence of IDH without undermining ultrafiltration efficiency, thereby offering a viable alternative strategy for improving both the safety and comfort of HD treatments. By preserving dehydration efficacy while mitigating intradialytic hypotensive events, this multifaceted intervention holds considerable promise for advancing clinical outcomes and enhancing patient well-being in the management of ESRD.

Keywords**:** Intradialytic Hypotension, Hemodialysis, Smart External Pulsatile Compression (SEPC), Wearable Devices, Respiratory Rhythm Training

1. Introduction

Intradialytic hypotension (IDH) is one of the most common complications during hemodialysis [1]. Its existence not only affects the process of dialysis treatment, but is also closely related to a series of adverse outcomes, including cardiac dysfunction, arteriovenous fistula thrombosis, cerebral ischemia, and residual renal function damage [2]. However, there is currently no consensus on diagnostic criteria for IDH due to widespread heterogeneity in the definition of IDH worldwide. The Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines define IDH as a decrease in systolic blood pressure (SBP) of ≥20 mmHg or mean arterial pressure (MAP) of ≥10 mmHg, accompanied by symptoms of hypotension such as headache during dialysis, general fatigue, Convulsions, nausea, vomiting, and restlessness [3].

Patients with end-stage renal disease undergoing hemodialysis often face the problem of intradialytic hypotension (IDH) caused by insufficient circulating blood volume. This phenomenon directly affects the quality of dialysis, the stability of the program, and the overall living conditions of patients [4]. Traditional prevention methods focus on reducing the ultrafiltration rate (UFR), which may result in inefficient dehydration or prolonged treatment time. Recent research trends have shifted toward the goal of maintaining or even increasing effective circulating blood volume, to explore possible solutions that do not require sacrificing dehydration efficiency to reduce the risk of IDH proactively. Veins are a key player in the body, beat heart pumps blood throughout the body — thousands of miles of veins carry it back. Without veins, blood circulation could not happen. After our arteries deliver the goods, our blood must return to the lungs to pick up more oxygen, stock up on nutrients, get rid of carbon dioxide, and head back to the heart to be pumped out again. In this way, blood is in continuous motion, ensuring organs and tissues get what they need while waste products are removed. The vessels designed for the return trip are our veins.

Veins ensure roles in keeping up with the body's homeostasis and general well-being, that capability of blood returned to the heart, blood volume reservoirs, one-way valves, waste removal, and supplement and chemical transport. Veins ensure roles in keeping up with the body's homeostasis and general well-being, that capability of blood returned to the heart, blood volume reservoirs, one-way valves, waste removal, and supplement and chemical transport [5].

Veins help keep blood flowing back to the heart through several key systems, fortifying that veins are equipped with one-way valves, the muscle contraction surrounding the veins, blood flow in veins is driven by tension slope, breathing siphon helps with venous blood flow, and the sensory system guides venous tone to ensure smooth blood flow, especially in the lower part of the body [5].

Among the many strategies to improve venous return that are effective in preventing IDH, the application of intermittent pneumatic compression (IPC) to the lower extremities accompanied by moderate lower extremity muscle contractions is effective in promoting venous return to the center. Circulatory system [6][7]. At the same time, studies have shown that rhythmic deep breathing training can produce specific intrathoracic pressure changes, thereby affecting venous return and cardiac output, and has been recognized in cardiac rehabilitation and the treatment of chronic cardiopulmonary diseases [8]. In this study, the concept of respiratory rhythm control was integrated into the hemodialysis process together with a wearable multimodal physiological parameter monitoring device and a machine learning prediction model. When the system detects an increased risk of IDH, it not only immediately activates IPC and lower limb exercise reminders, but also strengthens venous return through specific respiratory rhythm training. This multiple-intervention strategy can maintain blood pressure within a safe range more continuously without reducing the dehydration rate, thereby balancing treatment efficiency and safety.

2. Method

2.1. SEPC system architecture

To effectively implement the above strategies, we first developed SEPC, an integrated wearable multimodal physiological signal monitoring platform. The wearable device continuously measures blood circulation and body fluid status, including continuous non-invasive blood pressure estimation through photoplethysmography (PPG) and pulse transit time (PTT), as well as simultaneous monitoring of heart rate and blood oxygen saturation, which can reflect the patient's real-time Hemodynamic status. By measuring the sympathetic nerve activity index through galvanic skin response and analyzing body fluid distribution through bioimpedance, the patient's blood circulation, and autonomic nerve regulation can be comprehensively assessed. All data is wirelessly uploaded to a cloud-based platform and encrypted and anonymized for subsequent analysis and decision support [9][10].

After quality control and noise filtering, the original signal is processed through multi-level feature extraction. In the time domain, blood pressure and heart rate are obtained; in the frequency domain, the spectral characteristics of heart rate variability (HRV), such as low frequency/high-frequency ratio, are used to explore the function of autonomic regulation; and nonlinear analysis is added, such as sample entropy (SampEn) and Hurst index to present the dynamic complexity and variability of physiological signals more deeply [11].

To predict the risk of IDH immediately, this study combined machine learning technologies such as Gradient Boosting, Random Forest, and Deep Learning to construct a model that can predict the possibility of IDH occurring in the next 10-20 minutes [12]. When a high risk of IDH is detected, the system will automatically activate the IPC compression device to accelerate the venous blood return to the center by periodically inflating the lower limbs. At the same time, the SEPC system will prompt the patient through the display interface or voice to perform isometric contraction exercises of the lower limbs (such as ankle rotation, plantar plate depression, etc.) to increase the reflux effect. Most importantly, specific rhythmic deep breathing exercises (such as 2 seconds of inhalation and 3 seconds of exhalation) are introduced at this time to promote venous blood return to the right atrium and increase cardiac output through rhythmic fluctuations in intrathoracic pressure. quantity [1]. The synergistic effect of SEPC action combined with respiratory rhythm can achieve a more significant stabilizing effect.

This study also established an immediate feedback mechanism. The predicted IDH risk, SEPC operating status, lower limb movement indications, and respiratory training rhythm are displayed in real-time through the clinical decision support system (CDSS). Patients can perform exercises directly based on visual and auditory commands. Clinical staff can also adjust treatment strategies based on real-time information, such as appropriate changes in body position or small amounts of fluid replacement, to maintain the stability of dialysis treatment.

2.2. General procedures

Patients

This was a randomized, controlled, single-center retrospective cohort study. We recruited 50 adult uremic patients who received routine hemodialysis (4 hours/time, 3 times/week) at the New Taipei Hemodialysis Center in Taiwan from May 1, 2024, to July 31, 2024 (Table 1 Baseline description and comparison). Patients with the following conditions were excluded from the study: (1) short life expectancy (< 1 year); (2) potential for short-term renal function recovery or other renal replacement therapy (< 6 months); (3) organ failure (Except kidney); (4) Untreated solid tumors or hematological tumors diagnosed within the past 5 years; (5) Active gastrointestinal bleeding diagnosed within the past 1 month; (6) Uncorrected or uncorrectable congestive disease Heart failure; (7) Have a history of myocardial infarction, cerebral infarction, or cerebral hemorrhage in the past three months; (8) Have dementia or be unable/refuse to measure upper arm blood pressure; (9) Unable to cooperate with the research or refuse to sign the informed consent form. This study was approved by the Medical Ethics Committee of the National Defense Medical Center, Taiwan (IRB No. KY2021-609).

The following data were collected for each patient: average interdialytic weight gain, actual ultrafiltration volume, predialysis systolic blood pressure, quality of life, etc. Patients in this study completed the scale either on their own or with assistance following hemodialysis. The scale consists of 36 items, covering five dimensions: symptoms and discomforts of kidney disease, the impact of kidney disease on life, the burden of kidney disease on life, physical health, and mental health. QoL scores were determined based on the scoring criteria provided by the KDQOL™-36 scale. Higher scores indicate better quality of life. Routine blood and biochemical tests and quality of life assessments were performed at baseline (before follow-up) and three months after follow-up.

Research proposal

Blood pressure was measured before and after dialysis for all participants in this study using an upper arm cuff sphygmomanometer. Measurements are taken automatically every 30 minutes during each dialysis session. The Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines define IDH as a decrease in systolic blood pressure (SBP) of ≥20 mmHg or mean arterial pressure (MAP) of ≥10 mmHg, accompanied by symptoms of hypotension such as headache during dialysis, general fatigue, Convulsions, nausea, vomiting, and restlessness [4].

Statistical analysis

Baseline patient characteristics were analyzed descriptively and differences between patients with and without frequent IDH were compared using independent t-tests, Kruskal-Wallis tests, or chi-square tests. The association between QoL and IDH was examined by comparing between-group differences in KDQOL™-36 scores during follow-up (using SEPC vs. using SEPC). This association was explored using a repeated-measures mixed-effects model in which the dependent variable was the KDQOL™-36 score and adjusted for confounding by sex, age, cause of ESRD (with chronic glomerulonephritis as reference), VA type (with animal Venous fistula as reference), dialysis duration, mean interdialytic weight gain, serum creatinine (Scr), heme (Hb), visit (considered as a random effect), and the interaction of IDH group and visit. Effects were measured as the least square mean difference (LSMD) and its 95% confidence interval (CI).

Table 1: Baseline description and comparison-SEPC

Factor	Classification	Yes (n = 25)	No (n = 25)	Chi2/t	P
Gender, n (%)	Female	4 (16.0%)	4 (16.0%)		
	Male	21 (84.0%)	21 (84.0%)		
Age (year)	(m ± sd)	61.6 ± 11.0	64.0 ± 11.7	1.23	0.2188
HD sessions		36	36		

IDWG%	(m ± sd)	3.5 ± 1.3	3.9 ± 1.0	1.77	0.0800
uf (L)	(m ± sd)	2.3 ± 0.9	2.4 ± 0.7	0.72	0.4755
Pre-SBP (mmHg)	(m ± sd)	144.5 ± 14.9	133.5 ± 23.8	2.97	0.0042
Pre-DBP (mmHg)	(m ± sd)	80.3 ± 8.7	75.6 ± 12.1	2.46	0.0165
Kt/V	(m ± sd)	1.3 ± 0.3	1.4 ± 0.3	1.09	0.2777
BMI(Kg/m2)	(m ± sd)	21.9 ± 3.3	21.6 ± 2.8	0.51	0.6097

Abbreviations: ESRD = end-stage renal disease, idwg = interdialysis weight gain, uf = average reality ultrafiltration volume, BMI = body mass index, Pre-SBP = predialysis Systolic Blood Pressure, Pre-DBP = predialysis Diastolic Blood Pressure, Kt/V: Urea clearance index

3. Experiments and results

This study recruited 50 ESRD patients aged between 40 and 75 years old, divided into SEPC group and control group, with 25 patients in each group, for a 3-month clinical trial. The control group maintained the conventional dialysis program without SEPC, respiratory rhythm training, and lower limb contraction exercise intervention, while the experimental group adopted the above comprehensive strategies while systematically predicting an increased risk of IDH.

3.1. Predialysis SBP distribution and IDH incidence

Figure 1 illustrates the distribution of predialysis Systolic Blood Pressure (SBP) across various intervals (80-200 mmHg), highlighting the substantial heterogeneity in patients' blood pressure before hemodialysis. The frequency of patients in each SBP interval increases or decreases between the hypotensive and hypertensive ranges, reflecting the diverse hemodynamic profiles of patients before initiating dialysis. Of particular note, the 120–160 mmHg range shows a markedly higher proportion of patients. In contrast, the proportion of patients with extreme hypotension (80 mmHg) or extreme hypertension (200 mmHg) is substantially lower, indicating that relatively few cases fall within these extreme SBP categories.

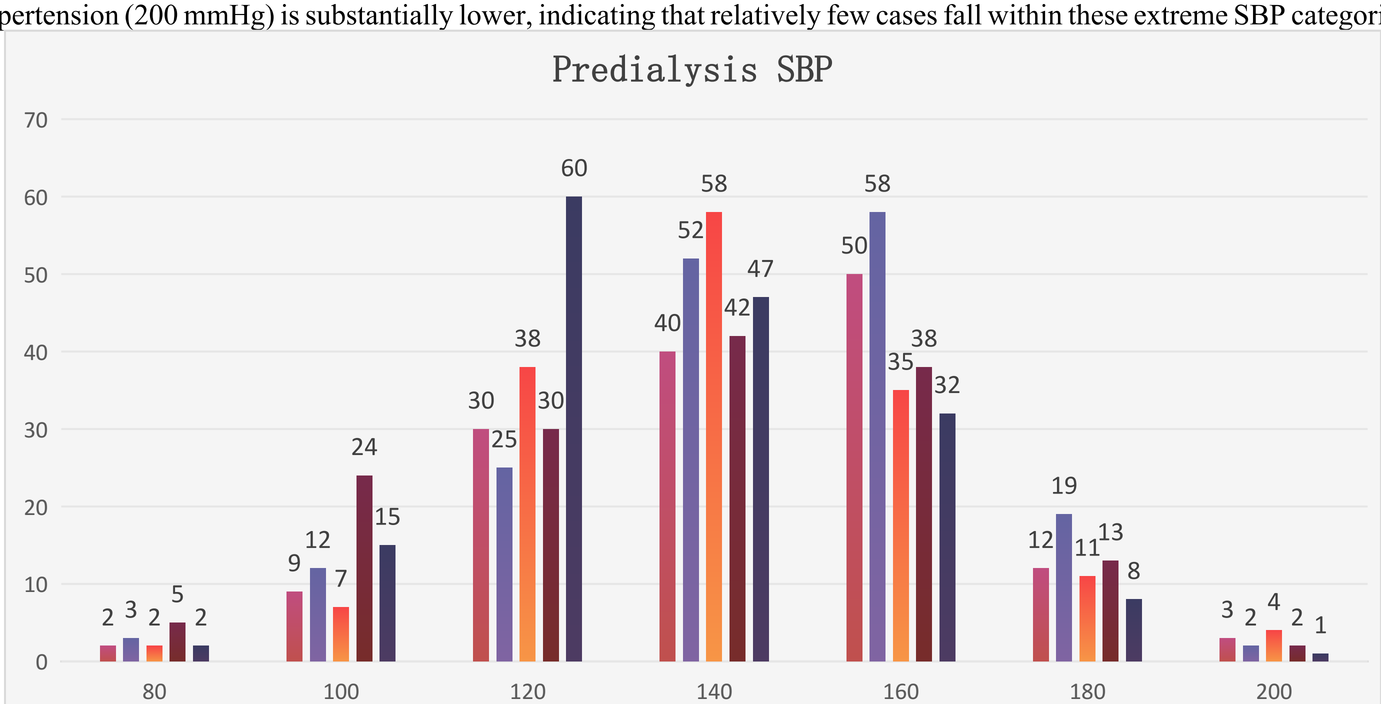

Fig. 1: This figure shows the distribution of the predialysis SBP in the patients of our dataset. Red lines mark the 50% interquartile range (IQR).

Figure 2 illustrates the incidence of intradialytic hypotension (IDH) among hemodialysis (HD) sessions, categorized by four distinct definitions and presented as both the percentage of HD sessions and the percentage of affected patients. Specifically:Nadir90 (lowest systolic blood pressure [SBP] < 90 mmHg) occurred in 18.80% of HD sessions and affected 44.52% of patients.Nadir100_90 (lowest SBP 90–100 mmHg) was observed in 20.75% of sessions, with 45.64% of patients meeting this criterion.Delta_SBP40 (an SBP drop ≥ 40 mmHg from baseline) was noted in 22.90% of sessions, affecting 61.38% of patients.DeltaSBP30_Nadir90 (an SBP drop ≥ 30 mmHg combined with a nadir < 90 mmHg) was identified in 10.24% of sessions and affected 34.45% of patients.

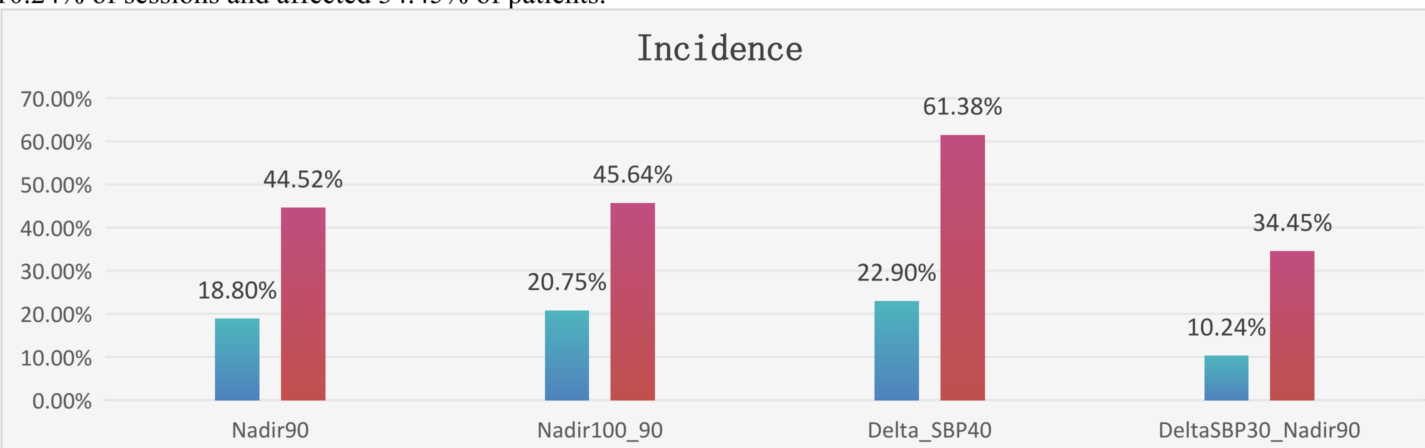

Fig. 2: Incidence of IDH. This graph shows the percentage of HD sessions and patients affected by IDH events.

Figure 2 findings underscore the varying frequency of IDH when different diagnostic thresholds are applied. While the Delta_SBP40 definition detects the highest proportion of affected patients, the DeltaSBP30_Nadir90 definition captures fewer events. This variation highlights the importance of standardized IDH criteria in clinical practice and research, as it can significantly influence the reported incidence and subsequent management strategies.

3.2. Time of occurrence of IDH event

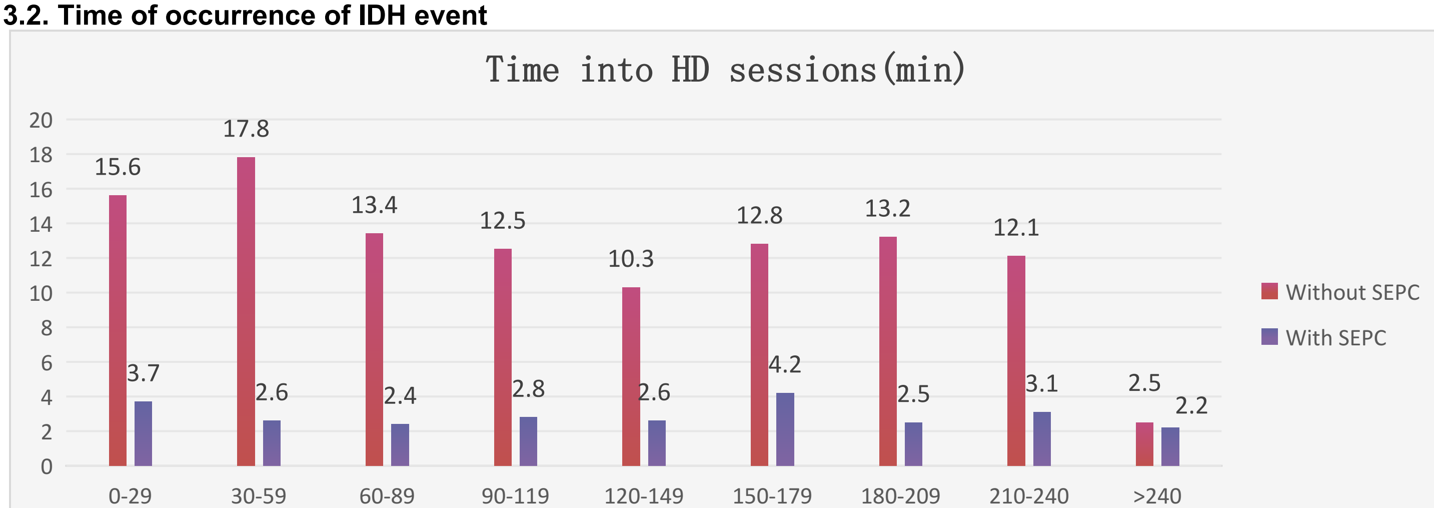

Fig. 3: Timing of IDH events. The risk of IDH for each time interval calculated by the placebo method is shown in blue, and the risk of IDH calculated by the SEPC method is shown in red.

Figure 3 illustrates the timing of intradialytic hypotension (IDH) events across successive time intervals, comparing two approaches - “Without SEPC” (placebo method, shown in blue) and “With SEPC” (SEPC method, shown in red). The horizontal axis denotes time intervals (in minutes), while the vertical axis reflects the percentage risk of IDH in each interval.

In the early treatment period (0–59 minutes), the placebo method demonstrates a relatively high risk of IDH, with 15.6% in the first 30 minutes (0–29 minutes) and a peak of 17.8% between 30–59 minutes. By contrast, the SEPC method substantially reduces the IDH risk in these early phases, reaching only 3.7% at 0–29 minutes and 2.6% at 30–59 minutes, underscoring its protective effect during the initial stage of dialysis.

During the mid-treatment phase (60–179 minutes), the placebo method maintains a moderate risk level, ranging from around 10.3% to 13.4%. Notably, there is a slight rise to 12.8% between 150–179 minutes. Meanwhile, under the SEPC approach, IDH risk remains within a lower band of 2.4%–4.2% in this period. Although the risk at 150–179 minutes with SEPC (4.2%) is higher than in the earlier intervals, it still represents a marked reduction compared to the placebo method.

In the late treatment period (≥180 minutes), IDH risk under the placebo method gradually decreases from 13.2% (180–209 minutes) to 2.5% beyond 240 minutes. However, the SEPC group consistently reports lower values, ranging from 2.5% to 3.1% in these later intervals. This finding indicates that SEPC continues to help maintain a reduced IDH risk as dialysis proceeds.

These data emphasize that SEPC offers a meaningful advantage in lowering the incidence of IDH throughout the dialysis session. The greatest difference emerges in the early phase, when patients are most susceptible to rapid changes in blood pressure, suggesting that SEPC may play a key role in enhancing patient stability and safety during hemodialysis.

3.3. Differences in quality of life

We explored mean between-group differences in QoL scores over time and the variability in between-group differences over time between those with and without SEPC. Results showed that patients who did not undergo SEPC had significantly worse quality of life in terms of symptoms and discomfort from kidney disease and the impact of kidney disease on their lives compared with patients who had less frequent IDH. Detailed information is shown in Table 2.

Table 2: Overall differences in quality of life between patients with and without SEPC.

Overall test	Overall test	F value	P value
Symptoms and discomfort of kidney disease	Group (With or without frequent IDH) [a]	8.14	0.0046
Impact of kidney disease on life	Group (With or without frequent IDH) [a]	7.83	0.0079
Burden kidney disease brings on life	Group (With or without frequent IDH) [a]	0.66	0.5665
Physiological health	Group (With or without frequent IDH) [a]	5.69	0.0185
Mental health	Group (With or without frequent IDH) [a]	0.25	0.6435

Intradialytic hypotension (IDH) is often accompanied by symptoms of nausea, dizziness, fatigue, muscle cramps, and cardiac arrhythmias, which can adversely affect the daily life of patients undergoing hemodialysis and may lead to a decrease in quality of life (QoL). This study used the KDQOL™-36 scale to assess the impact of frequent IDH on patients' quality of life, as defined by predialysis blood pressure (BP) and nadir systolic blood pressure (SBP) thresholds.

Compared with patients with SEPC at baseline, patients without SEPC had significantly lower scores on the kidney disease symptoms and discomfort dimensions at all follow-up points ($P<0.05$). The symptoms and discomfort of the kidney disease dimension without SEPC are more severe. People without SEPC had significantly poorer quality of life in terms of symptoms and levels of discomfort from kidney disease and the impact of kidney disease on life.

Over 3600 hours of dialysis data were accumulated over 3 months. Analysis of the results showed that the incidence of IDH in the experimental group was significantly lower than that in the control group ($p < 0.05$), indicating that this multiple-intervention method has the potential to reduce the incidence of IDH in clinical settings. More importantly, there was no significant difference in the efficiency of achieving the target dehydration goals between the SEPC and control groups, confirming that the strategy did not come at the expense of dehydration efficiency. The IDH prediction model exhibits approximately 88% sensitivity, 92% specificity, and 90% overall accuracy, and can provide early warning of IDH events 10-15 minutes before they occur. The synergistic effect of initiating SEPC and respiratory training at this time should produce more significant venous return, increase central blood volume, and prevent a rapid drop in blood pressure, thereby ensuring the safety of the treatment.

4. Discussion

SEPC compression leg veins assist with respiratory siphon, venous tone, pressure angle, muscle constrictions, and one-way valves keeping blood streaming back to the heart through a few key systems, notwithstanding neutralizing gravity.

4.1. Risk factors for hypotension during hemodialysis

1. Decreased cardiac output

CKD is an independent, non-modifiable risk factor for cardiovascular disease (CVD). Among patients with ESRD, CVD-related morbidity and mortality are high, even in young adults. Multiple cardiac manifestations are common in patients with ESRD, including low ejection fraction, diastolic dysfunction, valvular disease, and arrhythmias. Heart failure and loss of contractility predispose patients to IDH due to reduced cardiac output. Frequent episodes of IDH can also cause myocardial stunning, leading to progressive heart failure and an increased risk of cardiovascular death.

2. Autonomic nervous system dysfunction

The autonomic nervous system is a major component of endogenous defense mechanisms that prevent hypotension. Autonomic dysfunction is prevalent in diabetes, paraproteinaemia, and other comorbidities associated with CKD and ESRD, and impairs sympathetic activation during intravascular volume reduction during HD. This results in impaired compensatory arteriolar vasoconstriction and increases the risk of IDH. In addition, vascular calcification due to abnormal mineral metabolism is common in chronic dialysis patients. The resulting arterial stiffness and associated endothelial dysfunction led to an inadequate vascular response to volume changes, thereby increasing the risk of IDH. Patients with vascular calcification and IDH are at higher risk for cardiovascular events.

3. Changes in visceral blood flow

Food intake during hemodialysis treatment temporarily reduces blood volume in large vessels and may cause splanchnic sequestration and vasodilation, predisposing patients to IDH. This effect is less pronounced with high-protein diets but is more common in cases of pre-existing autonomic dysfunction.

4.2. Is SEPC clinically useful in preventing hypotension in HD?

In this SEPC study, real-time monitoring and analysis of multimodal physiological signals, supplemented by the predictive power of machine learning models, enabled early intervention before the onset of IDH to enhance venous return and stabilize blood pressure during dialysis. Combine respiratory rhythm training with lower extremity SEPC pressor and retractor actions to coordinate hemodynamic changes between the chest and lower extremities to increase central circulation. This multi-strategy approach does not reduce dehydration efficiency and provides a novel, effective, and clinically promising approach to preventing IDH. In the future, the universality of this method can be proven in larger-scale clinical trials, and more advanced artificial intelligence technology can be used to optimize personalized intervention plans, and is expected to be widely promoted in clinical practice.

Clinical symptoms are the most intuitive indicator to determine whether there is IDH. The KDQOL™-36 scale measures two dimensions of clinical symptoms, symptoms and discomfort and physical health, and a broad dimension of the impact of kidney disease on life. Pathophysiological studies have shown that when the fluid clearance rate exceeds the plasma refill rate during dialysis, the reduction in effective arterial blood volume will lead to cardiac dysfunction and reduced cardiac output; subsequently, cardiovascular and neurohormonal compensatory reactions occur during dialysis, eventually leading to the emergence of overt IDH. Hemodialysis can also cause ischemic events in multiple organs, such as the heart, intestines, brain, and kidneys. Organ ischemia or hemodynamic instability may manifest as nausea, dizziness, or cramps.

This study has some limitations. First, as an observational study, there may be confounding factors that lead to confounding bias. To provide more accurate effect estimates, we adjusted for potential confounders such as age, ESRD etiology, VA type, and dialysis duration in comparative analyses. However, due to the small sample size, it was not possible to consider all potential confounders. Second, the design of a single-center retrospective study with a limited sample size may introduce selection bias. Third, we used the KDQOL™-36 scale in this study, which lacks investigation of subjects' recovery time from fatigue.

5. Conclusion

In this SEPC study, we developed and validated an integrated system that combines point-of-care monitoring with a wearable device, compression measures, lower limb contraction exercises, and respiratory rhythm training to effectively improve the performance of ESRD patients during hemodialysis. Hemodynamic stability significantly reduces the incidence of IDH and maintains existing dehydration efficiency. This SEPC strategy brings new and practical solutions to the field of clinical hemodialysis and demonstrates the synergistic value of smart medical care and physiological regulation intervention, which will help improve the safety and comfort of renal replacement therapy.

SEPC compression for legs, so that users feel comfortable wearing them. For made-to-measure compression stockings, compression is graduated with the most pressure at the ankle and the least at the knee, this way it improves the blood to return up the legs to the heart.

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