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Comparative Retrospective Analysis Assessment Of Extracellular Volume Excess In Hypertensive Hemodialysis Patients

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COMPARATIVE RETROSPECTIVE ANALYSIS: ASSESSMENT OF EXTRACELLULAR VOLUME EXCESS IN HYPERTENSIVE HEMODIALYSIS PATIENTS

by

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ABSTRACT

Cardiovascular disease, including hypertension, accounts for almost 50% of the deaths in patients with end stage renal disease (ESRD) on hemodialysis (HD) yet hypertension remains very poorly controlled in this population. The purpose of this study was to retrospectively compare control of hypertension in hemodialysis (HD) patients when extracellular volume (ECV) was assessed and managed by clinical parameters and physical assessment data alone with control of hypertension when data from blood volume monitoring (BVM) technology was also used to assess and manage ECV in a freestanding outpatient hemodialysis unit. The main cause of hypertension in the ESRD population has been identified as increased ECV most likely secondary to increased interdialytic weight gain and failure to attain and maintain patient's dry weight. HD nurses often employ clinical parameters along with physical examination to determine a patient's pre, intra, and post dialytic fluid status and this approach can have a high index of error. BVM technology is being used in many hemodialysis units to assist with assessment of ECV. A comparative retrospective chart review was used to collect data for this project. A descriptive, cross-sectional design was employed to answer the question: "Are hypertensive hemodialysis patients who dialyze in a freestanding dialysis unit, where BVM technology is utilized, more likely to be normotensive as defined by a pre dialysis blood pressure of less than 140/90 and post dialysis blood pressure less than 130/80"? A pilot study was conducted to determine if the patient population and data were available in existing patient records for extrapolation. Approval for the study was obtained from the University IRB. A convenience sample was obtained from the records of patients meeting the inclusion criteria. Variables were measured and analyzed using

descriptive statistics such as sampled paired T-test to compare pre and post BVM systolic, diastolic blood pressures, intradialytic weight gain, serum Albumin and sodium levels, and hemoglobin. A *p-value* of 0.05 was assigned for statistical significance. Data analysis showed there were statisticaly significant differences in the pre dialysis systolic blood pressure, post BVM, and the serum sodium pre and post BVM when the two groups were compared These statistically significant findings support a correlation between reduction in the HD patient's ECV and improved blood pressure control. The reduction of pre-dialysis SBP was significant because many patients on hemodialysis have systolic hypertension that may or may not coexist with diastolic hypertension. The findings of this study may be used to formulate a protocol to be used in the HD units where the BVM is available. The protocol would rely on accurate nursing assessment of clinical parameters, patient verbalizations of symptoms, and the routine use of the BVM in order to continuously assess the patient's fluid status. Future research recommendations include conducting the study in a population closer to the national sample, a study where glucose readings and /or hemoglobin A1C levels are measured to assess the impact of glucose on ECV, and which antihypertensive class of medication works best with BVM technology to effectively manage hypertension in this population.

This project is dedicated to memories of my father, Nana Osei-Asibey-Bonsu (Ohene-Nananomhene, Ashanti Tribe, Ghana West Africa), and also to my brother, Nana Owusu Osei Asibey-Bonsu (Asantehene of Dallas Texas). To my husband, Raymond Moe, you are my rock. This is for all of you to fulfill my promise and commitment to help those who cannot help themselves.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1: INTRODUCTION

Outline for Thesis

This chapter will discuss the current assessment models and management of HTN and ECV in the HD patient. The purpose of Chapter 2 is to present the research reports and evidence based recommendations. Chapter 3 will describe the design and implementation of the project. Chapter 4 will present and discuss the results and Chapter 5 will present conclusions and suggestions for future studies.

Problem/Significance

According to the United States Renal Data System (USRDS; National Institute of Diabetes and Digestive and Kidney Diseases [NIDDKD], 2008) there were 360,000 ESRD patients in the U.S. of which 93% receive hemodialysis and 7% receive peritoneal dialysis (PD). Hypertension (HTN) is the second leading cause of chronic kidney disease (CKD) and ESRD (NIDDKD, 2008) yet HTN remains widely uncontrolled even once the patient makes the transition to ESRD (Aggarwal, 2003). It is estimated that 87% of diabetic HD patients and 67% of non-diabetic HD patients have inadequate blood pressure control (Mailloux, 2001). Hypertension is the leading and undisputed leading cause of cardiovascular disease (CVD; Zoccali, Mallamaci, & Tripepi, 2000). In the ESRD population, CVD is the predominant cause of morbidity and mortality.

The mortality rate for dialysis patients in the United States is 20 % approximately 50% of which is from CVD (Hlebovy, 2006) The most common cause of hospital admissions for HD patients is CVD related diagnoses. CVD related diagnoses account for 49% of chronic and 40% of acute admissions of that pulmonary edema being the most

common admitting diagnosis (Hlebovy, 2006). The use of antihypertensive medications is not as effective in CKD Stage 5 and ESRD because the cause hypertension in this population is most likely camouflaged volume retention (Hlebovy, 2006). The use of Thiazide and Loop diuretics in late stages of CKD and ESRD has a diminished effect secondary to the severely decreased glomelular filtration rate (GFR) and potassium sparring diuretics are contraindicated due to the increased risk of hyperkalemia (Izzo, Sica, & Black, 2008).

The pathophysiological cause of HTN in ESRD, after secondary causes have been ruled out, is extracellular volume (ECV) expansion (Hlebovy, 2006). Total body water is contained within 2 compartments: intracellular (within the cells) and extracellular (outside the cells). The intracellular compartment holds about 60% of total body water and the ECV holds about 40% of which 20% is within the plasma volume (Mitchell, 2002). ECV is the fluid contained in the interstitial, transcellular, and the intravascular spaces (Mitchell, 2002).

As renal failure worsens, the ability of the kidneys to balance sodium and water output dramatically decreases leading to sodium and water excess that may abet HTN by expanding the ECV and increasing ventricular wall stress (cardiac output) during systolic ejection. The foundations of managing HTN in HD patients are achieving appropriate dry body weight through dialysis, interdialytic fluid restriction, attending HD sessions, adhering to prescribed dietary guidelines and medication therapy (Denhaerynck et al., 2007).

Background of Hypertension in HD Patients

Hypertension is estimated to be present in up to 80% of ESRD patients sometimes as the primary cause of renal failure but more often as a secondary complication ESRD where inaccurate patient assessment of ECV status or patient complications during HD (i.e. hypotensive episodes) leads to decreased fluid removal (Savage, Fabbian, Gibbs, Tomson, & Raine 1997). The result of decreased fluid removal is increased ECV which may lead to hypertension. Hlebovy (2006) concluded that 90% of HD patients could become normotensive by lowering the ECV and focusing on the patient's dry weight.

Assessment of the patient's fluid status is based on the patient's dry weight (DW). DW, as it pertains to the ESRD population, is defined as the lowest weight a patient can tolerate without the development of symptoms (i.e. cramping) or hypotension in the absence of antihypertensive medications (Rodriguez, Domenici, Diroll and Goykhman, 2005). Appropriate DW is directly correlated with control of blood pressure and notably increased HD patient survival rates (Hlebovy, 2006).

In many dialysis units, DW is assessed by the presence or absence of clinical parameters and physical exam such as dyspnea, headache, periorbital and pre-tibial edema, postural dizziness, cramps, hypotension and hypertension. Raimann, Lui, Ulloa, Kotanko, and Levin (2008) found that none of these clinical parameters and physical findings were sufficiently specific or sensitive to DW and fluid assessment and may exhibit a large margin of error due to patient variability.

The problem with DW assessment based on purely clinical grounds is that dry weight cannot be assessed by a single parameter (Locatelli et al., 2004). Factors such as the patient's residual renal function as evidenced by urinary output, other sources of fluid

loss such as diarrhea and emesis, and interdialytic well being such as appetite and energy levels, should be incorporated and reassessed at least every 2 weeks to assure the patient's post dialysis weight reflects an accurate DW and management of ECV (Locatelli et al., 2004). Jaeger and Mehta (1999) studied the current methods of ECV/DW assessment method of dry weight and concluded that it was difficult to determine whether a patient was over-hydrated or under-hydrated even when these assessment methods are properly employed.

Four emerging technological methods that show promise are being used and have gained popularity in recent years within the HD community. These methods include the use of biochemical markers, vena cava diameter, bioimpedence, and blood volume monitoring (BVM). Of the 4 methods discussed, BVM, which has been available since 1992, has become the most widely used and accepted method of assisting in the determination of a patient's ECV fluid status in both in- and outpatient settings (Rodriguez, Domenici, Diroll and Goykhman, 2005).

BVM determines ideal body weight non-invasively by directly measuring the change in blood volume by monitoring the fluid volume and oxygenation in the intra-vascular space. BVM monitors the patient's real time hematocrit because red blood cells (RBC) are too large to pass through the dialyzer. RBC mass remains constant during the dialysis treatment (Donauer, 2004) but hematocrit levels have an inverse relationship with hydration status within the human body. An increased hematocrit, per BVM, is highly representative of reduction of the ECV and the decreased hematocrit represents increased in ECV (Donauer, 2004).

The BVM displays a picture of the patient's volume status based on the variability of the patient's real time hematocrit and Oxygen levels. The clinician is able to adjust the DW and rate of fluid removal by monitoring the patient and BVM every 15 minutes. The BVM has the ability to notify the clinician of impending intradialytic complications such as hypotension and cramping by displaying changes in the patient's hematocrit and oxygenation levels for which the clinician has been trained to observe and intervene appropriately (Donauer, 2004).

Many dialysis personnel involved in the assessment of the patient's BP and fluid status rely on the patient's past post dialysis weights, complaints, or lack of complaints of symptoms such as muscular cramping, post HD fatigue, and pre-dialysis blood pressure to determine the patient's target fluid removal. Some clinics use BVM along with clinical parameters and physical exam to assist in determining the patient's ECV status. The an education of Nephrology nurses and ancillary staff such as certified dialysis technicians on the clinically significant link between HTN and ECV status may lead to an improved knowledge base and eventually improved overall outcomes.

Hypertension in HD Patients: The Nursing Community Takes Action

The reported prevalence of HTN in HD patients is estimated to be between 50%-90% (Purcell, Williams, & Walker, 2004). Antihypertensive medications do not reduce the blood pressure effectively in this population because the most likely etiology of HTN in HD patients is increased ECV. Therefore The American Nephrology Nurses Association (ANNA) viewed fluid management as an area of concern and convened a special interest group (SIG) in 2004. The goal of the SIG was "to supply information

about accurate dry weight measurement and the effects of inaccurate measurement " to the nephrology nursing community.

The objectives of the SIG included reviewing the long-term complications of hemodialysis related to fluid volume excess and fluid volume deficit and to assess the effectiveness of the BVM as a tool to assist in obtaining the ideal DW. The SIG concurred BVM would be helpful in managing ECV but stated more studies were needed (Purcell, Williams, & Walker, 2004). CVD is the leading cause of morbidity and mortality in the HD patient. Long term HTN not only affects the patient's morbidity and mortality but also the patient and their families/ loved ones quality of life. Another issue is that long term HTN may hinder the patient's chances of possible kidney (living or cadaver) transplant as the heart of a patient with uncontrolled HTN may be enlarged and have left ventricular hypertrophy which may hinder cardiac output and may not have enough cardiac output to sustain the needed blood flow to the transplanted kidney.

Nephrology practitioners now have 4 decades of clinical and physical assessment knowledge and, in some facilities, the assistance of technology to manage fluid volume and HTN. Improving BP control in this vulnerable population is a collaborative effort among the nursing, medical, dietary, and social work providers involved in the patient's care. The ANNA SIG on fluid management position statement announced it is time for nephrology nurses and the nephrology industry to accept accountability and include fluid management (clinical parameters, physical exam and available tools such as BVM) as part of the HD standards of care which may be located within the National Kidney Foundation's Kidney Dialysis Outcomes Quality Initiatives (NKF-KDOQI) guidelines (2006).

The SIG continued by stating the goal of fluid management should be in line with dialysis pioneers such as Dr. Scribner's who defined DW as the post dialysis weight that allows the BP to remain normal (less than 130/80 mm/hg) until the next dialysis session, without the use of antihypertensives, and despite interdialytic weight gain (NKF-KDOQI, 2006). In 1961 Dr. Belman Scribner, the father of chronic dialysis, made the observation HTN may be controlled by low sodium diet and fluid removal during HD (Shaldon, 2002). The first patients were dialyzed for 6-8 hours three times a week. The long dialysis sessions allowed for the removal of increased fluid volume and toxin removal. In the first 3 out of 4 long-term HD patients treated by Dr. Scribner, anti-hypertensive medications were stopped secondary to hypotensive episodes (Shaldon, 2002).

Objectives/Aims

This review of the current state of science revealed the potential benefit of managing HTN in the HD patient by assessing the ECV status and attaining euvlomemia using clinical parameters and BVM technology as an adjunctive tool. Effective HTN and fluid circumspection is directly related to decreased CVD associated morbidity and mortality. The NKF-KDOQI guidelines regarding the management of HTN in HD patients emphasize attention to the patient's fluid status (Clinical Practice Guidelines, 2006). Kidney Disease: Improving Global Outcomes (KDIGO), the international consortium HTN management guidelines recommend gradual reduction of the patient's DW as antihypertensive medications are withdrawn. Therefore, HTN management in the HD patient through approximating the ECV status is recommended by both the KDOQI and KDIGO guidelines in attempt to decrease CVD associated morbidity and mortality.

1. Provide data to support the use of tools such as the BVM will effectively manage the ECV thereby assist in control of hypertension in HD patients.
2. Improving the patient and/or their families/loved ones quality of life by decreasing CVD associated morbidity and mortality by effectively controlling ECV status.

This study aims to answer the question "Are HD patients who dialyze in a freestanding HD unit where BVM technology is used as an adjunctive tool along with assessment of clinical parameters more likely to be normotensive (BP < 140/90 pre-dialysis. 130/80 post-dialysis) secondary to achieving and maintaining an adequate dry weight?" The feasible, interesting, novel, ethical, and relevant (FINER) criteria was used to determine the research question. The author deems the project to be feasible based on the availability and appropriateness of records on which to evaluate the impact of the use of the BVM in addition to clinical parameters The completed project will contribute to the literature, which supports the belief that HTN may be managed in HD patients with appraisal of clinical parameters and fluid management utilizing BVM technology. This project is ethical as the researcher adhered to the ethical principles of respect for persons, beneficence, and justice as outlined in the Belmont Report. Lastly, the relevance of this project has been attested by previous studies and reports that document that a large percentage of HTN is HD patients secondary to excess ECV status.

Variables

The patient records reviewed were records of hypertensive HD patients in which secondary causes of HTN have been excluded and reflected use of BVM within the past 12 months. The records were reviewed to obtain pre and post dialysis weights, blood

pressure measurements, albumin, hemoglobin and sodium levels. The identified variables were pre and post intervention systolic and diastolic blood pressure, interdialytic weight gains, albumin, hemoglobin and sodium measurements. The variables were statistically analyzed to reveal relationships, where and if available. The data collection tool was developed to obtain the necessary data from the patient's record to meet the project's objectives and complete statistical analysis to positively or negatively answer the research question. The research question stated: Are HD patients who dialyze in a freestanding HD unit where BVM technology is available and used as an adjunctive tool along with assessment of clinical parameters more likely to be normotensive (BP < 140/90 pre-dialysis. 130/80 post-dialysis) by attaining and maintaining a euvolemic state?

Definition of Terms

1. Antihypertensive medications: Medications prescribed by the patient's provider(s) to control hypertension. Medications must be current and information will be collected on the data collection tool according to classification. Categories include: ACE-I, ARB, beta-blocker, calcium channel Blocker, central adrenergic blockers, alpha blockers, alpha-beta blockers, vasodilators, diuretics
2. Clinical parameters: Assessment of weight, blood pressure, presence or absence of fluid deficit or excess before and after dialysis
3. Co-morbidities: Any chronic illness that may affect the patient and their quality of life. This information taken from the 2728 form.
4. Euvolemia The state of fluid equilibrium. The fluid state at which there are no signs of extracellular fluid deficit (hypovolemia) or extracellular fluid excess (hypervolemia).

5. Hypertension (HTN) in hemodialysis (HD) patients: Pre-dialysis blood pressure (BP) greater than 140/90 mm/hg and post-dialysis BP greater than 130/80 mm/hg.
6. Increased IDWG: Greater than 3000 ml gained in between prescribed dialysis sessions.
7. Interdialytic weight gain (IDWG): Weight change calculated by subtracting post weight from pre-dialysis weight. Was measured in ml
8. Prescribed treatment time: Time prescribed to be spent on dialysis, measured in minutes, prescribed by the provider to ensure dialysis adequacy and safe fluid removal.
9. Primary cause of renal failure: The cause of decreased renal function necessitating the initiation of dialysis. This data will be taken from the 2728 form (see Appendix A), which is a standardized form every patient is required to have as part of his or her chart.
10. Sodium profile: HD machine setting that allows for an increase amount of sodium to be delivered through the dialysate:
    - Hemoglobin 10-12 mg/dl
    - Serum albumin 3.5-5.0
    - Serum glucose 60-100 mg/dl
    - Serum sodium: 135-145 mEq/L.
11. Ultrafiltration (UF) profile: HD machine setting that allows for fluid removal at different rates.

The primary cause of end stage renal disease was obtained from the patient's 2728 form (see Appendix A). The Centers for Medicare and Medicaid Services (CMS)

requires the form for all newly diagnosed ESRD patients, regardless of their Medicare status or treatment modality. The 2728 form serves two purposes. The purposes are to provide medical evidence of an end-stage renal condition for Medicare entitlement, and to register the patient in a national renal registry. CMS provides the data to the USRDS for public reference and use in research. The patient's co-morbidities was obtained from the 2728 and listed on the data collection tool (see Appendix B).

Assumptions

- There will be adequate patient population meeting inclusion criteria.
- The recorded data will be accurate and reliable.
- Correct analysis of data to answer the research question

Importance of Proposed Project

The proposed project will help fill gaps in nursing/medical knowledge regarding HTN and management of ECV in the hypertensive HD patient by promoting the need for ongoing ECV status and adjustment of DW. The obtained knowledge will contribute to nursing/medical knowledge by dispelling myths and supporting facts about that effectively managing the ECV status to improve control of HTN and may lead to the discontinuation of antihypertensive medication in some patients. The conducted research sought to lead to the implementation of best clinical practices in addition to KDOQI and KDIGO guidelines.

Benefits of standardization would include an improvement in the clinical staff's ability to assess a patient's volemic state and improve the chances of achieving and maintaining the DW without experiences complications such as inter and intradialytic

hypotension, cramps, nausea and/or vomiting, The study's results may positively impact the practice of healthcare providers by assisting them to help meet the conditions of coverage (COC) as defined by CMS. The COC state "the principal goal of these conditions is to improve cardiovascular outcomes by optimizing fluid management practices and strategies during hemodialysis" (Hlebovy, 2008, p. 442). The conditions may be met by decreasing or preventing hospitalizations, decreasing morbidity and mortality rates associated with cardiac events by astute assessment and maintenance of the patient's fluid status. Patient benefits include improved quality of life as evidenced by reduction in left ventricular mass that has been shown to decrease incidences of arrthymias and sudden cardiac death. The benefit of increased quality of life and patient longevity are priceless.

CHAPTER 2: LITERATURE REVIEW

Purpose

The purpose of this literature review is to consider the discussions and data surrounding assessing extracellular volume (ECV) volume in hypertensive HD patients. The literature and guidelines reviewed indicate that HTN in the ESRD population is largely attributed to increase ECV and HTN, which remains uncontrolled despite accurate nursing assessment and provider intervention. The expected increase in the number of patients dependent on HD, along with economic impact of providing competent care, has increased the need to control HTN in this population.

Background

Investigators have concluded that cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the ESRD population (Locatelli et al., 2004). The distinguishing CVD risk factors in the ESRD populations are: volume overload with consequent hypertension, anemia, deranged calcium-phosphorus metabolism, accumulation of specific uremic toxins, and chronic inflammatory processes (Locatelli et al, 2004). Unresolved hypertension contributes to the increased workload of the heart by affecting preload and afterload. Purcell, Manias, Williams, and Walker (2004) concluded hypertension particularly increases afterload.

The main etiology of HTN in the ESRD population is ECV expansion (Purcell, Manias, Williams, and Walker, 2004). Guyton et al. established the significant role the kidneys play in the homeostasis of sodium and ECV (Purcell, Manias, Williams, and

Walker, 2004). An individual with normal kidney function balances salt and water intake through the gut and salt and water output through the kidneys that ultimately maintains the size of the ECV (Charra, 2007).

As renal failure worsens the ability of the kidneys to excrete sodium decreases thereby leading to sodium excess that may abet HTN by expanding the ECV and increasing ventricular wall stress (cardiac output) during systolic ejection. This ventricular wall stress is known as afterload (Purcell, Manias, Williams, and Walker, 2004)

Afterload refers to factors that augment ventricular wall stress during systolic ejection (Purcell, Manias, Williams, and Walker, 2004). Sustained hypertension increases afterload and may result in left ventricular hypertrophy (LVH; 2004). LVH increases oxygen demands of the myocardium leading to increased risk of ischemic heart disease and possibly fatal arrhythmias. Foley et al. (1996) authenticated a lineal relationship between longstanding hypertension and the development of LVH. Horl and Horl (2002) established that LVH is a common characteristic of patients with kidney failure and significantly reduces their life expectancy. Foley (1996) documented that for every 10mm/hg increase in mean arterial pressure (MAP) there was a 48% increased risk of LVH. The state of euvolemia is known as achieving a patient's dry weight (DW). The definition of a patient's dry weight was formulated based on multiple ideations but best stated by Charra (2007) as the lowest weight a patient can tolerate without intra and interdialytic symptoms such as hypotension and with no to minimal antihypertensive agents. Assessment of DW in HD patients relies heavily on clinical parameters (i.e. vital signs, patient comments, and physical exam). This imprecise method fails to take into

account the dynamic nature of DW. DW may change during any period of illness, wellness, depression, gain and loss of lean body weight that may affect DW (Purcell, Manias, Williams, and Walker, 2004).

The pillar of managing uncontrolled HTN in HD patients, after secondary causes have been eliminated, is achieving appropriate DW. Secondary causes of HTN in dialysis patients include activation of sympathetic nervous system, increased blood viscosity, stimulation of the Renin-Angiotensin system, and electrolyte shifts (Stankus, 2010). The problem of assessing dry weight on purely clinical grounds is rooted in the fact dry weight cannot be assessed by a single parameter (Purcell, Manias, Williams, and Walker, 2004). Providers in the HD unit estimate DW. Factors such as the patient's interdialytic well being, including appetite and energy level, should be incorporated and reassessed at least every 2 weeks to assure the patient's post dialysis weight reflects an accurate DW (Purcell, Manias, Williams, and Walker, 2004).

Hypertension is the leading and undisputed leading cause of CVD (Zoccali, Mallamaci, & Tripepi, 2002). In the ESRD population CVD mortality is the predominant cause of death. The USRDS annual report (NIDDKD, 2008) noted approximately 45% of overall mortality in ESRD patients receiving HD are attributed to cardiac events. The NKF-KDOQI guidelines state the HD prescription should be individualized to help the patient achieve euvolemic and normotensive states utilizing fluid control (2006). The need to provide clinicians with improved assessment skills in the field of ECV assessment is imperative to improve patient outcomes, patient quality of life, and decreased morbidity and mortality associated with uncontrolled HTN secondary to ECV excess.

Blood Pressure Guidelines in Hemodialysis Patients

The NKF-KDQOI were first published in 2002, and revised in 2006, provide the framework for the treatment of uncontrolled hypertension in the ESRD patient. The NKF KDQOI guidelines are categorized into blood pressure management and management of hypertension (NKF-KDQOI, 2006). Blood pressure management in the ESRD patient is based on pre-dialysis blood pressure to guide antihypertensive therapy since blood pressure varies significantly upon the timing of the measurement.

These guidelines state that it is difficult to relate usual BP readings to the ESRD patient because studies have shown both pre and post dialysis readings to measure 14 points higher systolically and 5 points diastolically as compared to the non-ESRD patient (NKF-KDQOI, 2006). The guidelines also cite the availability of enough current data to define optimal blood pressure in ESRD patients so the committee selected 140/90 mm/hg as a pre-dialysis blood pressure target and 130/80 mm/hg as a post dialysis target.

The guidelines clearly support the benefit of a lower target blood pressure but cite the increased morbidity and mortality of lower blood pressures in the ESRD population. This may be explained by reverse epidemiology according to Borsboom et al. (2006). The investigators found that long term uncontrolled hypertension coupled with increased ECV led to LVH, systolic, and diastolic dysfunction. The ESRD patient with severe cardiac failure presents as hypotensive in spite of their fluid status. The ESRD patient with this severe form of cardiac failure has a 1.5-3 times higher probability of death in the next 3-7 years as compared to the hypertensive ESRD patient (Borsboom et al, 2006).

The NKF-KDQOI guidelines (2006) also cite dietary and nutritional management recommendations of HTN in the HD patient. The first recommendation states the

patient's dietary sodium intake should be limited to 80 to 100 mEq/d. Tomson (2001) suggested that the nephrology community should concentrate on advising and helping dialysis patients to limit their salt intake which will help limit their thirst. Tomson continued by stating that patients drink for one of two reasons: thirst and because they feel like a drink (2001). Therefore, asking a patient to adhere to a fluid restriction without a sodium restriction is useless because if a patient's sodium intake exceeds their output the stimulus to drink will be present due the body's drive to maintain serum osmolarity (2001).

In 2008 the Department of Health and Human Services, Centers for Medicare and Medicaid (CMS) published new guidelines for condition of coverage (COC) for establishing minimum health and safety standards for improving care and protecting Medicare and Medicaid beneficiaries (CMS, 2008). The conditions of coverage state "the adverse effects of ESRD, many patients experience labiality of blood pressure and fluid management, the management of which may require reassessment of medication needs, adjustments in target weight, and changes to the plan of care. The comprehensive assessment should include evaluation of the patient's pre/intra/post and interdialytic blood pressures, interdialytic weight gains, target weight, and related intradialytic symptoms (e.g., hypertension, hypotension, muscular cramping) along with an analysis for potential root causes". Both in and out patient dialysis facilities must meet the standards in order to be paid by CMS and since CMS is the major payer for those receiving HD. (CMS, 2008). Under the conditions of coverage an interdisciplinary team, consisting of the patient, registered nurse, physician, advanced practitioner, social worker, and dietician, are to convene to develop an appropriate plan of care.

Therefore, successful blood pressure and fluid management is mandated in order for dialysis units, physicians, and allied health professionals to be reimbursed (CMS, 2008).

Assessment of volume status in the HD patient involves the multi-disciplinary team approach of HD nurses, dieticians, patients and their caregivers. Although ECV assessment is not a precise science the perceptive HD nurse may employ various assessment methods including clinical parameters, physical exam, and in certain cases technology to assist in ECV management.

Assessment of Volume Status

Dry weight (DW), as it pertains to the ESRD population, is defined as the lowest weight a patient can tolerate without the development of symptoms (i.e. cramping) or hypotension in the absence of antihypertensive medications (Charra, 2007). In many dialysis units around the world DW is assessed by the presence or absence of symptoms such as dyspnea, headache, periorbital and pre-tibial edema, postural dizziness, cramps, hypotension and hypertension. Raimann, Lui, Ulloa, Kotanko, and Levin (2008) found that none of these symptoms were sufficiently specific or sensitive and exhibit a large inter and intra-individual variability. The earliest finding of fluid overload is jugular vein distention (JVD) and it is rarely assessed in dialysis units (Raimann, Lui, Ulloa, Kotanko, and Levin, 2008).

Historically, assessment of volume status in the hypertensive HD patient has been elicited by measurement of clinical parameters and physical exam pre, intra, and post HD. Jaegar and Mehta (1999) found clinical assessment of ECV is crude and imprecise due to overestimation and underestimation of DW. Overestimation of DW leads to HTN,

cerebral vascular accidents (CVA), and congestive heart failure (CHF) that have been identified as the leading causes of death in the HD patient (Jaegar and Mehta, 1999). Underestimation of DW frequently leads to persistent hypotensive episodes, which may cause patient alienation from their HD caregivers by affecting delivery of dialysis through decreasing or missing HD sessions.

Mitchell concluded (2002) pre-dialysis clinical assessment of ECV and DW is highly dependent on vital signs such as blood pressure, heart rate, temperature and in the case of HD patients their pre-dialysis weight. Pre-dialysis HTN may be secondary to excessive intra-dialytic weight gain (>3 kgs) (Reams and Elder, 2003). Reams and Elder also stressed the importance of assessing pre-dialysis HTN was not secondary to missed or held anti-hypertensive therapy. The importance of accurate pre-dialysis weight measurement should never be underestimated (Mitchell, 2002). Charra (2007) concluded, based on his clinical studies, that errors in weighing are frequent and may adversely impact the dialysis tolerance and the estimation of DW. Simple measures should be employed such as ensuring the scale is calibrated to zero pre and post treatment and educating the patient to wear similar clothing to every HD session to maintain pre-HD weight consistency.

One of the most important pre-dialysis clinical assessment tools is determining the patient's residual renal volume. The residual renal volume is the amount of interdialytic urine volume along with extrarenal water losses such as diarrhea, vomitus, and nasogastric secretions (Pace, 2007). Pace, concluded, a HD patient's fluid allowance is 600 ml additional per 24 hours in addition to the patient's urine output and extrarenal

water losses. Consistent assessment of a HD patient's fluid allowance is paramount in preventing overestimation and underestimation of the patient's volume status.

Pre-dialytic and intra-dialytic volume assessment continues with physical exam and eliciting patient comments regarding interdialytic and intradialytic quality of life and general wellbeing (Mitchell, 2002). Purcell, Manias, Williams, and Walker (2004) found that the patient in the HD unit who attracts the most attention by experiencing hypotensive episodes, nausea and vomiting, or cramping during or after their dialysis treatment are more likely to report a perceived decrease in their quality of life. Intra-dialytic patient complaints of fatigue, edema, or dyspnea that may lead to the inability of the patient to carry out activities of daily living are vital to astute volume assessment. The clinician should also refer to treatment history, preferably 2 weeks' worth of treatment data, to assist in determination of volume status (Mitchell, 2002).

The patient's post dialysis weight coupled with the presence or absence of orthostatic hypotension may lead the HD nurse towards determining whether the DW is accurate or in need of adjustment. Charra (2007) found predialysis, interdialysis, and post dialysis assessment of edema often points to ECV excess but HD nurses must also assess the patient's cardiac function and serum albumin.

HD patients are often malnourished and a low albumin level leads to leakage of intravascular fluid into interstitial spaces, which leads to visible edema (Mitchell, 2002). Agarwal, Andersen, and Pratt (2008) undertook a study to answer the question "What is the role of pedal edema in the HD patient"? The cross-sectional study of asymptomatic HD patients' deduced assessment of volume state is an important component of day-to-day treatment of HD patients. The study concluded lower extremity edema correlates

with cardiovascular risk factors such as age, body mass index, and left ventricular mass but does not reflect volume in HD patients. Clinical parameters such as vital signs, patient's complaints, and physical exam are critical components to assessment of ECV status but nursing knowledge is crucial in executing efficient and effective patient outcomes. Coupled with the need for keen nursing assessment is the advent of technology to assist with ECV management.

Blood Volume Monitoring

Assessment of ECV in HD has long depended on edema, presence or absence of dyspnea, HTN, fatigue and patient complaints. This imprecise method fails to take into account the dynamic nature of DW in which any period of illness, depression, gain or loss of lean body weight may affect ECV (Purcell, Manias, Williams, and Walker 2004). Of all the advancements in dialysis therapy the use of the blood volume monitor (BVM) has proven to be the most useful tool in DW attainment with little risk of hypotensive episodes in the ESRD patient (Heerspink et al., 2009). BVM is a non-invasive method, which monitors the fluid available in the intravascular space against the rate of fluid removal during dialysis.

This is accomplished by measuring plasma refill during the hemodialysis process. Plasma refill is the shift of poisons and fluids from the intracellular space to the extracellular space into the intravascular space/circulating blood volume. During the dialysis session, excess fluids and toxins are removed from the circulating blood volume and if there is excess fluid or toxins in either the intracellular or extracellular compartments it is shifted to the intravascular space. This process is known as plasma refill (Heerspink et al, 2009).

The BVM utilizes the patient's hematocrit (HCT) increased or decreased ECV has a direct inverse relationship with a increase or decrease blood volume measured through real time HCT (Leypoldt et al., 2002). Steuer, Germain, Leypoldt, and Cheung (1998) concluded that the use of BVM during HD facilitated the identification of patients with increased ECV while permitting greater removal of excess body fluids without a substantial increase symptom during treatment.

BVM allows the HD nurse to utilize clinical parameters and physical exam to predict and avoid interdialytic morbidity such as hypotensive episodes. Charra (2007) concluded BVM in conjunction with discerning nursing judgment might result in decreased patient morbidity and mortality. BVM is particularly useful when assessing ECV status in hypertensive elder patients that have decreased body water related to increased body fat, decreased muscle mass and decreased ability to regulate water and sodium balance (McCance & Huether, 1998).

The advantages of the BVM are that HD nurses and staff are able to make immediate changes to the rate and volume of fluid removal before an adverse patient event. The disadvantages of BVM use are lack of access to the majority of HD patients secondary to economic factors and accurate interpretation of the data by nursing staff. Purcell, Manias, Williams, and Walker (2004) looked at whether clinical parameters and physical exam used alone or in conjunction with BVM yielded improved outcomes. They found the most important component is seasoned nursing judgment.

The autonomy of the dialysis nurse is well known within the health care community. Dialysis nurses autonomy may be secondary to the highly technical nature of their practice and the need to make immediate decisions regarding the patient's treatment

often without the presence of a physician or advanced practitioner. Bonner and Walker (2004) examined nephrology nurses and their role in the blurring of boundaries as it relates to patient care. The study's participants included 6 novice nephrology nurses and 11 expert nephrology nurses. This study utilized a grounded theory methodology and symbolic interaction. Nephrology nurses, in particular HD nurses, are known for their autonomy.

Nurses' autonomy in dialysis units stem from the highly specified nursing tasks that untrained and novice nurses, physicians and ancillary staff are unable to perform. In order for a nurse to be considered safe and competent, an average of at least 12-18 months training is needed (Bonner and Walker, 2004). Expert nephrology nurses were defined as nurses with more than 5 years hemodialysis experience and novice nurses were defined as nurses with less than 5 years experience. Although Nephrologists and advanced practice practitioners are competent in managing HD patients, many lack the knowledge and technical ability to perform the actual treatment and its associated functions.

The study found that only the expert nephrology nurses were more likely to make patient care decisions that would normally involve a provider's order and did so by moving intermittently and purposefully for the benefit of particular patients. Expert nurses, in this study, altered medications that were used to treat symptoms of renal failure such as electrolyte imbalances, anemia, and hypertension. The nurse's actions consisted mainly of reducing or stopping a drug and adjusting fluid removal during HD. The study highlighted the fact that nephrology nurses tend to act in the immediate interest of patient by stabilizing a potentially dangerous situation. Educating the staff regarding what

benefits the patient in the long run will influence current treatment decisions and outcomes (Bonner and Walker, 2004) by setting protocols that will allow all nurses to practice within their scope.

Summary

The goal of this literature review was to assess the current literature and guidelines as related to assessment of ECV status in uncontrolled HTN in HD patients. The purpose of this literature review is to support the assessment of ECV status through clinical parameters and physical assessment and where available BVM. The findings of a project directed at determining whether there is improved patient outcomes when clinical parameters and physical exam is used compared to clinical parameters, physical exam, and BVM may lead to the purchase and use of the BVM in settings where it is currently not available.

The NKF-KDOQI guidelines state the HD prescription should be individualized to help the patient achieve euvolemic and normotensive states utilizing fluid and sodium control (National Kidney Foundation's Executive Summary, 2006). The need to provide clinicians with improved assessment skills and protocols in the area of ECV assessment are imperative to improve patient outcomes, and decrease morbidity and mortality associated with CVD. DW assessment and determination is well within the scope of practice of HD nurses. Attempts to improve ECV volume status assessment will increase patient's quality of life as well as decreasing costs associated with medications and hospitalizations.

CHAPTER 3: METHODOLOGY

A retrospective, descriptive, cross-sectional design was employed in the chart review process. The identified population consisted of patients of a freestanding hemodialysis unit in the Southern-Eastern United States with the diagnosis of ESRD and HTN with secondary causes of HTN excluded. A data collection instrument was used to obtain needed data. The descriptive design was chosen because it allowed the researcher to observe, chronicle, archive facets of HTN and ECV assessment and management in the HD patient. The patient records were available to the researcher during the operating hours of a facility that employs BVM as a fluid management tool.

The makers of the BVM, HemaMetric, state the monitor is a continuous quality improvement management tool that allows clinicians to safely and consistently dialyze patients to their ideal DW, resulting in improved measurable patient outcomes such as decreased fluid related hospitalizations, decreased pre-dialysis HTN, and decreased number of antihypertensive medications.

The use of descriptive research in this study provided insight into the validity of the BVM maker's claims as well as making observations based on trends among the hypertensive HD patients whose records were reviewed. Descriptive research allows the researcher to explore exposed relationships among the variables even in the presence of large amounts of collected data. An identified advantage of appropriating descriptive research is that the what, when, where, and why of the research question is answered. Disadvantages of the descriptive research method are that the information gathered may be ubiquitous and risk for potential research bias is possible.

Sampling

The size of the study's sample was determined by a power analysis. The analysis determined the review of 50 charts should yield enough data to answer the research question. However, there were only 42 client records that met inclusion criteria. Not having enough patients from which to collect data as recommended by the power analysis was identified as limitation. The 42 charts that did meet the inclusion criteria were used for data extrapolation and analysis.

Project Design

Demographic variables (age, gender, and race) were collected from the facility's electronic records. Descriptive variables such as the patient's primary cause of ESRD and co-morbidities were obtained from the patient's 2728 form in addition to recent hospital and provider documentation. Other descriptive variables such as dates of BVM use, prescribed anti-hypertensive medications, blood pressures, pre and post dialysis weights, albumin, hemoglobin, and sodium levels were obtained from electronic records including the facility laboratory's website. Data on these variables measured before and after BVM intervention was collected.

The identified variables were selected because they were expected to reveal relationships that may assist in assessment and management of ECV status in the hypertensive HD patient. The operational definition of HTN in HD patients was based on the NKF-KDOQI guidelines (2006) of pre-dialysis BP readings of 140/90 mm/hg and greater and post-dialysis readings of 130/80 mm/hg and greater.

The data collection tool summarized information pertaining to the demographic and descriptive variables listed above. The collected data was evaluated at nominal and

ratio levels. Nominal levels were used in the measurement of primary and co-morbid diagnosis, anti-hypertensive medications, and demographic variables. Ratio levels were used in reporting age, intradialytic weights, blood pressures, albumin, hemoglobin, and sodium levels.

Subjects/Setting

The data was collected from the records of patients receiving treatment in the hemodialysis unit. The data gathering and reviewing process took place during the facility's operating hours. Patient charts and documents were not removed from the facility. A report was created to include variables needed for data analysis and was used to populate the data collection tool. The inclusion criteria for the study's subjects included:

1. ESRD patients with at least 6 months of hemodialysis treatment history
2. History of hemodialysis at the current outpatient hemodialysis unit for 3 months
3. May be on the kidney transplant list
4. Documented diagnosis of hypertension on admission to dialysis unit or recent diagnosis within the prior 6 months
5. History of antihypertensive therapy (current or discontinued) within the prior 3 months
6. Permanent patient of medical director or physicians who round on monthly basis.

Exclusion criteria included:

1. ESRD patient less than 18 years of age
2. Less than 3 months on hemodialysis

3. No admitting diagnosis of hypertension or recent diagnosis within 6 months prior to study initiation
4. Individuals prescribed anti-hypertensive therapy for secondary causes such as rate control

Human Subjects

Because this project was a chart review, no tests, procedures, or direct patient contact was conducted, so there was no potential for harm to human subjects. The university's internal review board granted permission (IRB; see Appendix C) to proceed with the study after review of the study, methods employed and procedures to protect the patient and their information. .

Instruments

The purpose of the data collection tool (see Appendix B) was to analyze patient data before and after the use of BVM in order to answer the research question, which stated that the use of BVM along with the assessment of clinical parameters decreases blood pressure by normalizing the ECV. The tool used codes to allow for statistical analysis of data extracted and was piloted with sample of data of the studied variables. An identification number, instead of the patient's name or other identifying data, was assigned to the patient and the list kept only by the researcher in a secure location. . If confidentiality was breeched, a plan was in place to stop the breech, if possible, and notify the facility's management, patients, and other vested personnel. The Health Insurance Portability and Accountability Act (HIPPA) provides for the privacy of

personal health information. HIPPA criteria will be maintained via the study's confidentiality protocol as mentioned above.

CHAPTER 4: RESULTS

The purpose of this chapter is to present the findings of the Comparative Analysis of Assessment of Excess Extracellular Volume in Hypertensive Hemodialysis Patients. This comparative retrospective analysis is based on data from 42 patient files meeting the inclusion and exclusion criteria outlined in Chapter 3.

Sample

Figure 1 illustrates the gender distribution of the sample of this study. Of the 42 participants, 60% were male and 40% were female. Figure 2 illustrates the national average gender distribution in dialysis patients per the USRDS annual report (NIDDKD, 2008). This sample had more females than the reported national average. The mean age of the participant was 58.6 years with a standard deviation of 16. Figure 3 illustrates the sample by race. Of the 42 participants, 45% were Caucasian, 43% were Hispanics/Latinos, 7% were of African descent, and 5% were Asian. Figure 4 illustrates race of dialysis patients by national average.

Primary Cause of End Stage Renal Disease

Table 1 describes the primary cause of end stage renal disease (ESRD) for the sample ($N = 42$). This data was obtained from the patient's End Stage Renal Disease Medical Evidence Report (2728 form). Diabetes Mellitus was listed as the primary cause of ESRD in 48% of the participants followed by hypertension/large vessel disease in 33% of the participants. The sample had a higher incidence of hypertension compared to the

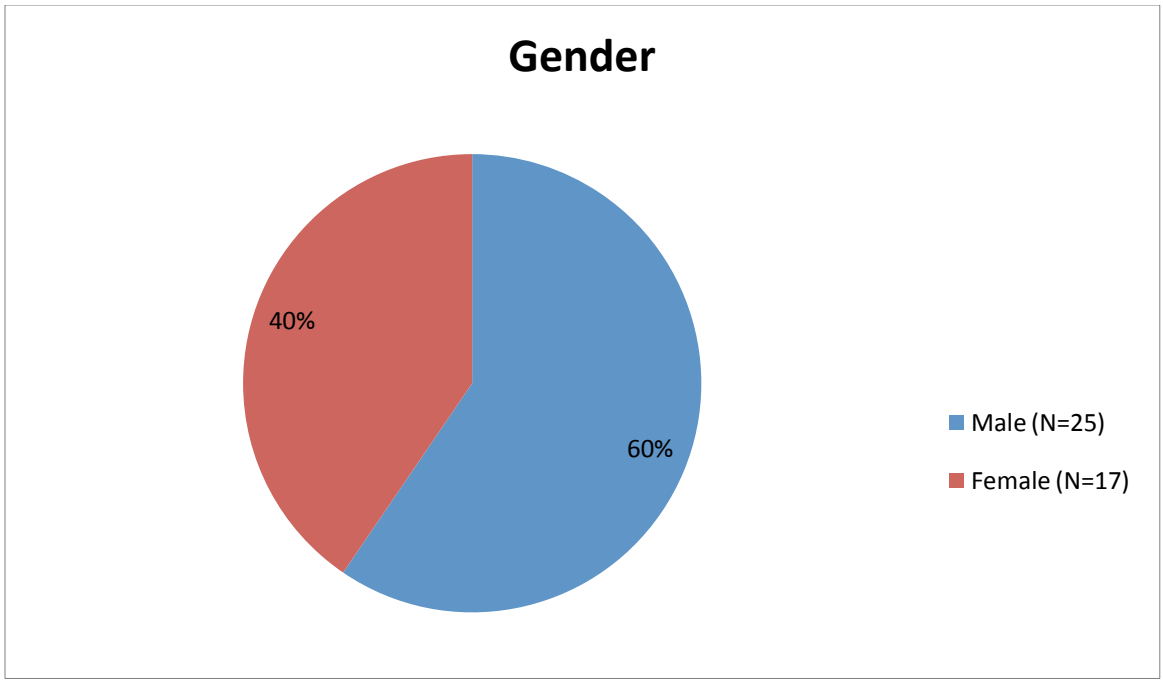
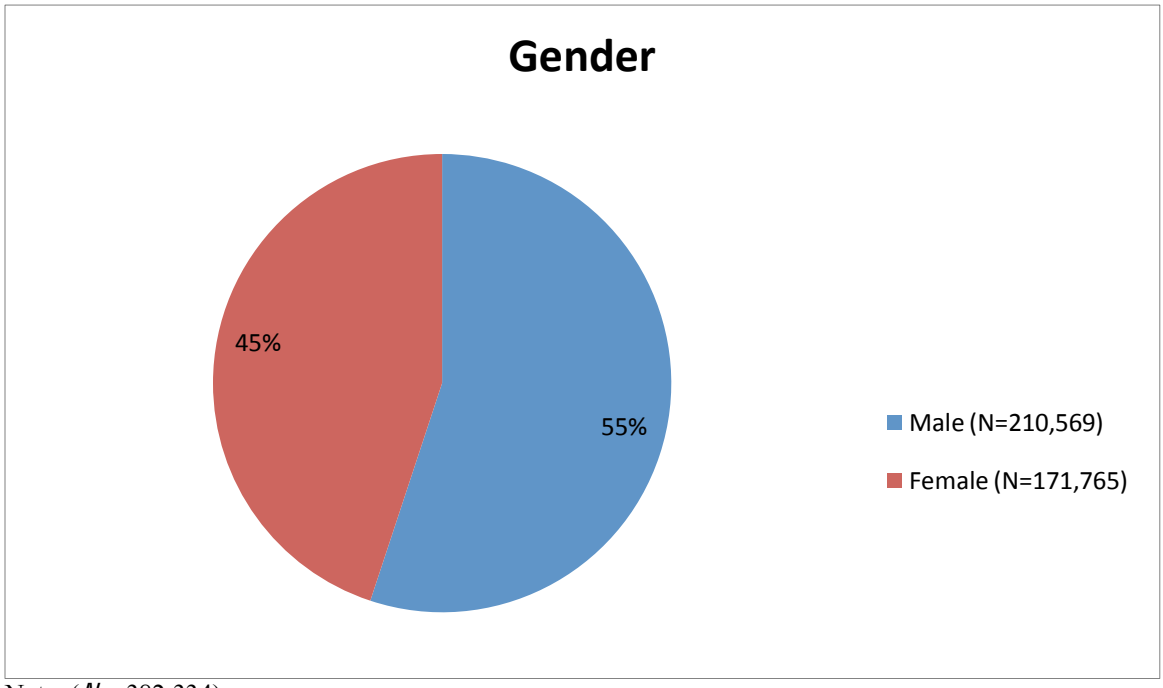


Figure 1. Gender of dialysis patients (study participants).



Note. (N = 382,334).

Figure 2. Gender of dialysis patients (national average).

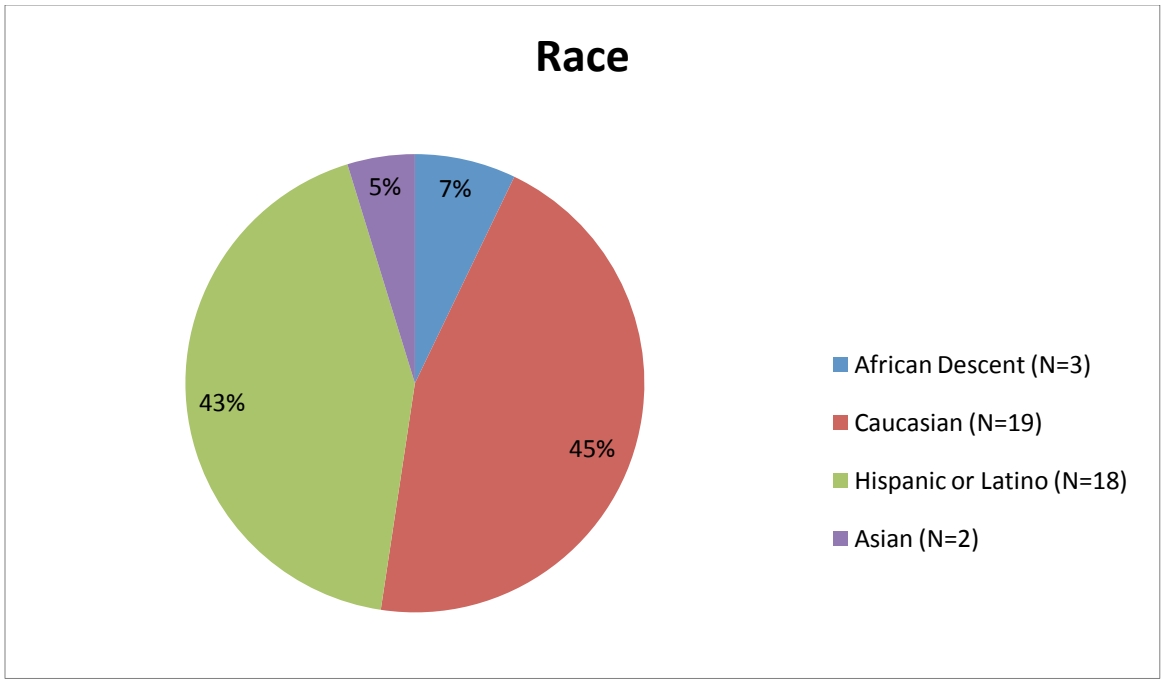
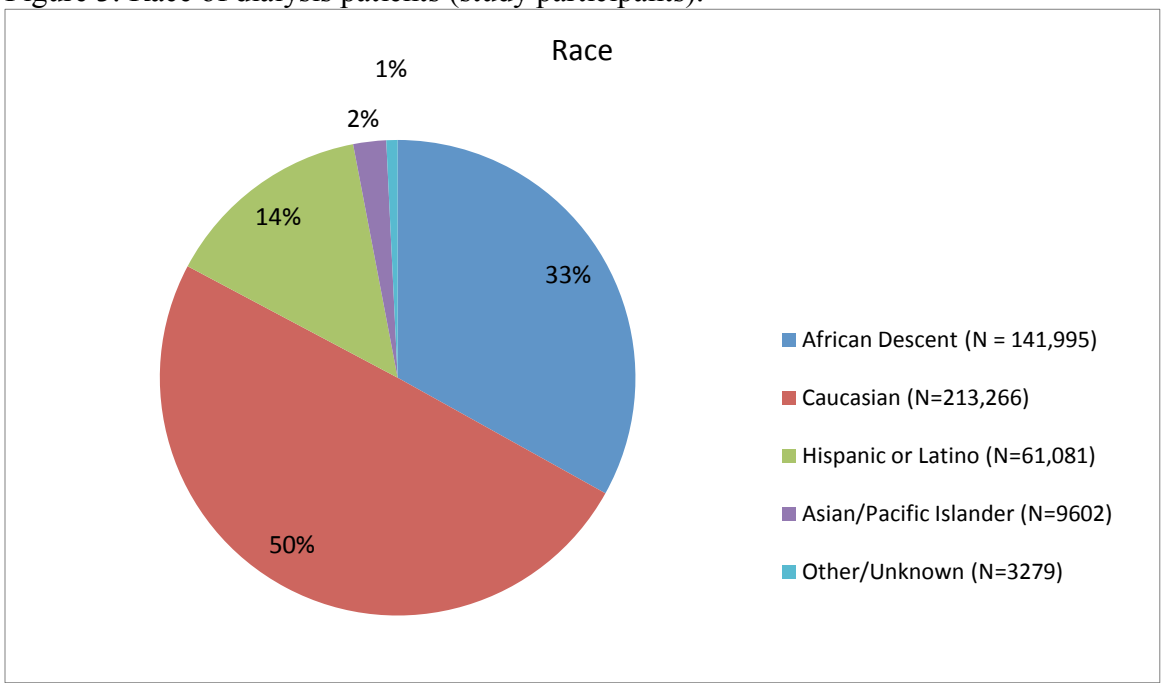


Figure 3. Race of dialysis patients (study participants).



National Institute of Diabetes and Digestive and Kidney Diseases. (2010). United States Renal Data System. 2010 Annual Report. Atlas of Chronic Kidney Disease and End Stage Renal Disease in the United States. Retrieved from http://www.usrds .org/atlas.htm

Figure 4. Race of dialysis patients (national data).

National average (thirty-three percent compared to twenty-eight percent). Glomerulonephritis was listed as the primary cause in 7% of the participants and interstitial nephritis/ pyelonephritis and neoplasms/tumors were each the cause of ESRD in 5% of participants. Secondary Glomerulonephritis was responsible for 2% of ESRD in study participants. Table 2 describes the primary cause of ESRD per data obtained from the USRDS (NIDDKD, 2008).

Table 1.

Primary Cause of End Stage Renal Disease (Study Participants)

Primary Cause	*N*	%
Diabetes Mellitus	20	47.6
Hypertension/Large Vessel Disease	14	33
Glomerulonephritis	3	7.1
Interstitial Nephritis/Pyelonephritis	2	4.8
Neoplasm/Tumors	2	4.8
Secondary Glomerulonephritis	1	2.4

Table 2.

Primary Cause of End Stage Renal Disease (national data)

Primary Cause	*N*	%
Diabetes Mellitus	167,292	42.8
Glomerulonephritis/ Secondary Glomerulonephritis	39,693	10.8
Hypertension/Large Vessel Disease	107,670	28.2
Other Known	35,015	9.2
Unknown	13,676	3.6
Interstitial Nephritis/Pyelonephritis	7,329	1.9
Missing Cause	1,352	0.4
Neoplasms/Tumors	NA	NA

Note. N = 382344.

Co-Morbidities

Table 3 depicts the co-morbidities of the participants in the study ($N = 42$) obtained from the End Stage Renal Disease Medical Evidence Report. Co-morbidities are diseases or disorders that coexist with a primary disease but also stand alone as a specific disease. Diabetes Mellitus was the most frequent co-morbidity and was present in 48% of the participants. Cardiovascular disease was present in 45% of the participants. Twenty-one percent had chronic obstructive pulmonary disease and. nineteen percent of participants had peripheral vascular disease. Amputations were documented in 17% of the participants, Cerebral vascular disease was reported in 10% of the sample. Malignancy/neoplasm and tobacco abuse were each diagnosed in 5% of the participants and 2% had documentation of hepatic disease.

Table 3.

Co-Morbidities of Study Participants

Co-Morbidities	*N*	%
Diabetes Mellitus	20	48
Cardiovascular Disease	19	45
Cerebral Vascular Accident	4	10
Chronic Obstructive Pulmonary Disease	9	21
Peripheral Vascular Disease	8	19
Amputation	7	17
Malignancy/Neoplasm	2	5
Tobacco Abuse	2	5
Hepatic Disease	1	2

Antihypertensive Medications

Table 4 lists the different classes of antihypertensive medication prescribed to the participants. Fifty-four percent of the participants were prescribed beta-blockers and 37%

received Dihydropyridine calcium channel blockers. Angiotensin converting enzyme inhibitors were prescribed for 31%, of the participants. 24% received central agonists. Twelve percent of participants took both angiotensin receptor blockers and diuretics. Benzothiazepine calcium channel blockers were taken by 2% of the participants.

Table 4.

Participant's Antihypertensive Medications

Antihypertensive Class	N	%
Angiotensin Converting Enzyme-Inhibitors	13	31
Angiotensin Receptor Blockers	5	12
Beta Blockers	22	52
Calcium Channel Blockers (Benzothiazepines)	1	2
Calcium Channel Blockers (Dihydropyridines)	15	36
Central Agonists	10	24
Diuretics	5	12

Research Question

Analysis of this data was done to accept or reject the question "Are HD patients who dialyze in a freestanding HD unit where BVM technology is used as an adjunctive tool along with assessment of clinical parameters more likely to be normotensive (BP < 140/90 pre-dialysis. 130/80 post-dialysis) secondary to achieving and maintaining an adequate dry weight?" In order to answer this question, statistical analyses were run using SPSS statistical software. Descriptive statistics were run to obtain the minimum, maximum, and mean of each variable and then paired samples test was completed on paired variables. If the *p value* is less than or equal the mean correlation coefficient (*p value less than or equal to .05*), the question was answered as yes. If the p value is

greater than the mean correlation coefficient (*p value greater than .05*), the question was answered as no.

To further explore the effect of the use of BVM on this client group, other physiologic variables that are known to impact blood pressure were also examined. Thus, tin addition to examination of pre and post BVM pre-dialysis systolic blood pressure, pre-dialysis diastolic blood pressure, post-dialysis systolic blood pressure and post-dialysis diastolic blood pressure, serum albumin, hemoglobin, and serum sodium were also examined to evaluate if their reported values were be closer to or at the nationally set goals with the use of the BVM to aid in the assistance of proper dry weight assessment and attainment.

The paired sample t-test is a statistical test which tests the means of two samples that are correlated. Paired sample t-test is used in before after studies, or when the samples are the matched pairs. Pair samples statistics was run to assess variables pre and post BVM use. Table 5 illustrates the variable, the mean, the matched pair's mean and the significance value.

Table 5.

Descriptive Statistics for Pre- and Post-BVM Use

Pre BVM	Mean	Post BVM	Mean	Matched Pair's Mean	Sig. (2-tailed)
Pre-dialysis systolic blood pressure	159.83	Pre-dialysis systolic blood pressure	149.19	10.64	.000
Pre-dialysis diastolic blood pressure	78.6	Pre-dialysis diastolic blood pressure	74.74	3.87	.055
Post-dialysis systolic blood pressure	130.21	Post-dialysis systolic blood pressure	129.07	1.14	.692

Post dialysis diastolic blood pressure	65.71	Post dialysis diastolic blood pressure	65.5	.214	.899
Interdialytic weight gain	3.3	Interdialytic weight gain	3.2	.035	.586
Serum Albumin	3.698	Serum Albumin	3.705	-.007	.637
Hemoglobin	12	Hemoglobin	11.98	.057	.641
Serum Sodium	138.14	Serum Sodium	137.67	.476	.023

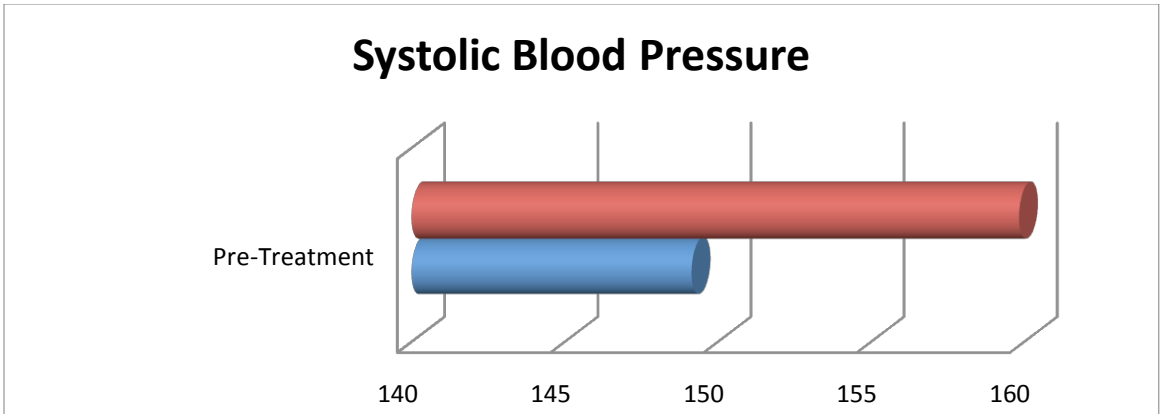
Figure 5 illustrates pre-treatment systolic blood pressure, pre and post BVM. The significance value (p-value) was found to be .000. A paired samples *t* test revealed a statistically reliable difference between the mean number pre BVM pre treatment systolic blood pressure and the post BVM pre treatment systolic blood pressure. Figure 6 illustrates pre-treatment diastolic blood pressure, pre and post BVM. The significance value (p-value) was found to be .055. A paired samples *t* test failed to reveal a statistically reliable difference between the mean number pre BVM pre treatment diastolic blood pressure and the post BVM pre treatment diastolic blood pressure. Figure 7 illustrates post-treatment systolic blood pressure, pre and post BVM. The significance value (p-value) was found to be .692. A paired samples *t* test failed to reveal a statistically significant difference between the mean number pre BVM post treatment systolic blood pressure and the post BVM pre treatment systolic blood pressure.

Figure 8 illustrates post-treatment diastolic blood pressure, pre and post BVM. The significance value (p-value) was found to be .899. A paired samples *t* test failed to reveal a statistically reliable difference between the mean number pre BVM post treatment diastolic blood pressure and the post BVM post treatment diastolic blood pressure.

Figure 9 illustrates post-treatment systolic blood pressure, pre and post BVM. The significance value was found to be .899. A paired samples t test failed to reveal a

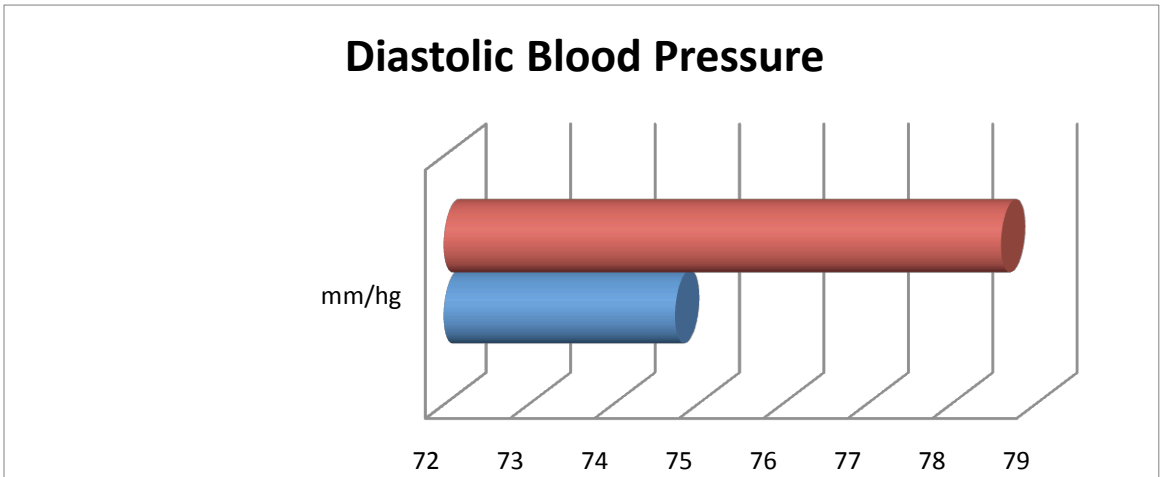
statistically reliable difference between the mean number pre BVM post treatment diastolic blood pressure and the post BVM post treatment diastolic blood pressure.. Figure 10 illustrates interdialytic weight gain pre and post BVM. The significance value was found to be .586. A paired samples t test failed to reveal a statistically reliable difference between the mean numbers pre and post BVM interdialytic weight gain.

Figure 11 illustrates serum Albumin pre and post BVM. The significance value (p-value) was found to be .637. A paired samples t test failed to reveal a statistically reliable difference between the mean numbers pre and post BVM serum Albumin. Figure 12 illustrates the Hemoglobin pre and post BVM. The significance value was found to be .641. A paired samples t test failed to reveal a statistically reliable difference between the mean numbers pre and post BVM hemoglobin. Figure 13 illustrates serum Sodium, pre and post BVM. The significance value was found to be .023. A paired samples *t* test revealed a statistically reliable difference between the mean number pre and post BVM serum sodium levels.



	Pre-Treatment
Pre BVM: Pre-Treatment Systolic Blood Pressure	159.83
Post BVM: Pre-Treatment Systolic Blood Pressure	149.14

Figure 5. Pre-treatment systolic blood pressure: pre- and post-BVM.



	mm/hg
Pre BVM Pre Treatment DBP	78.6
Post BVM Pre Treatment DBP	74.74

Figure 6. Diastolic blood pressure pre- and post-BVM

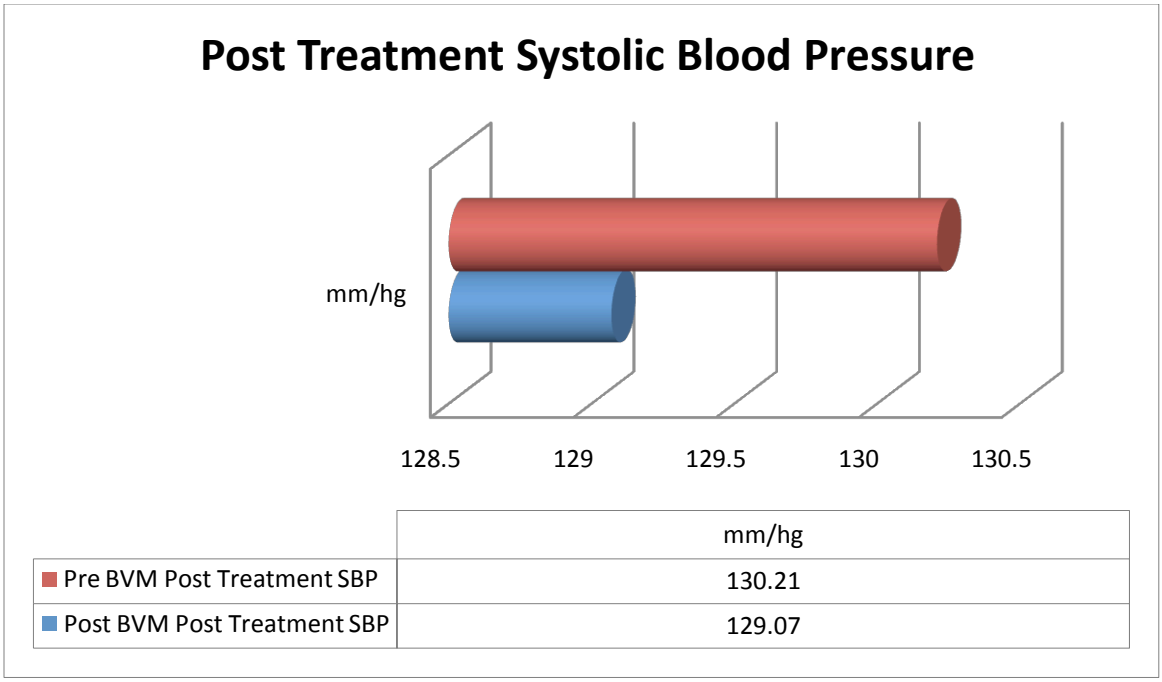


Figure 7. Post-treatment systolic blood pressure.

Post Treatment Systolic Blood Pressure
mm/hg
128.5
129
129.5
130
130.5
mm/hg
Pre BVM Post Treatment SBP
130.21
Post BVM Post Treatment SBP
129.07

Figure 8. Post-treatment systolic blood pressure: Pre- and post-BVM.

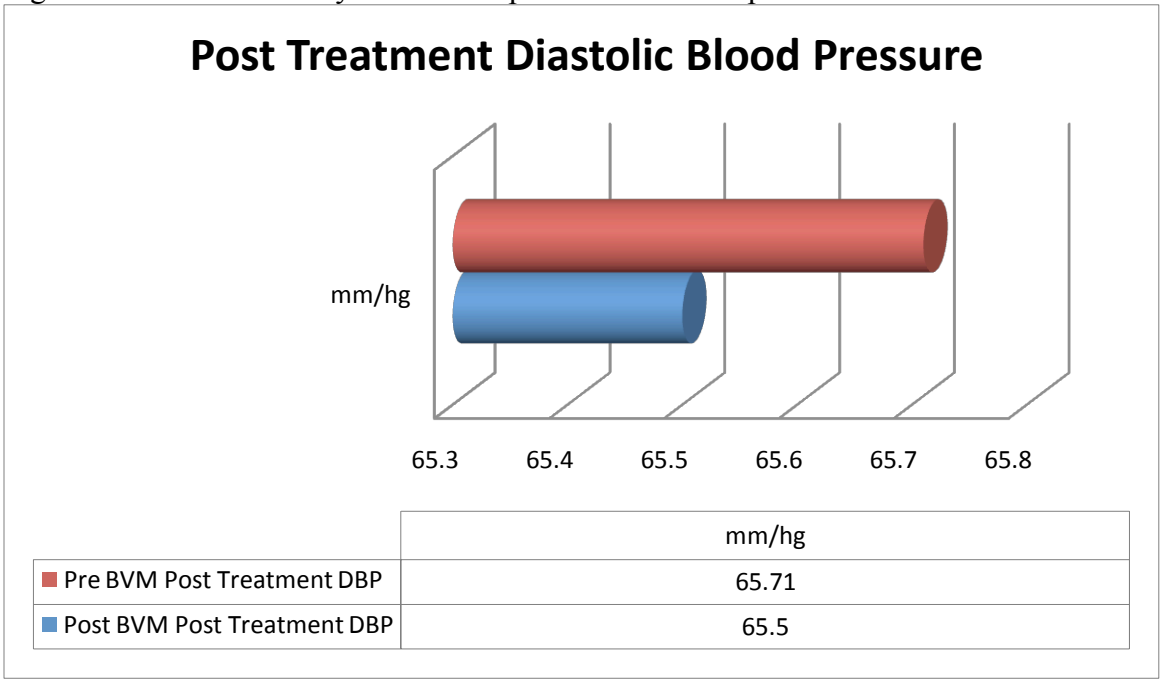


Figure 9. Post-treatment diastolic blood pressure: Pre- and post-BVM.

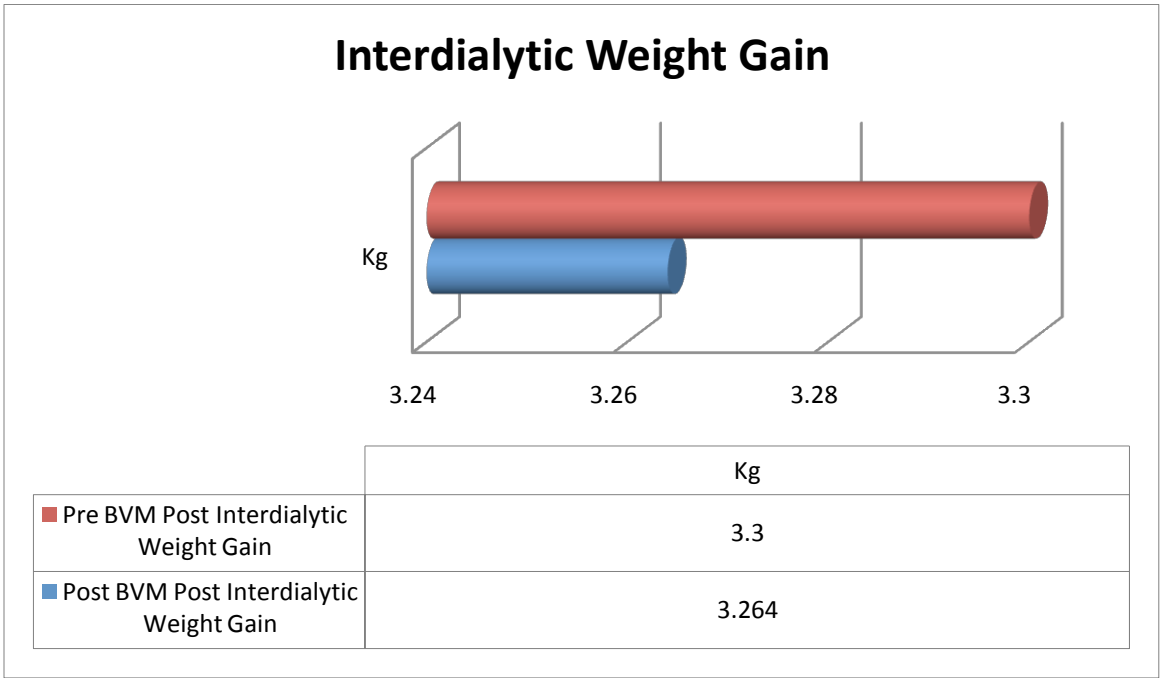
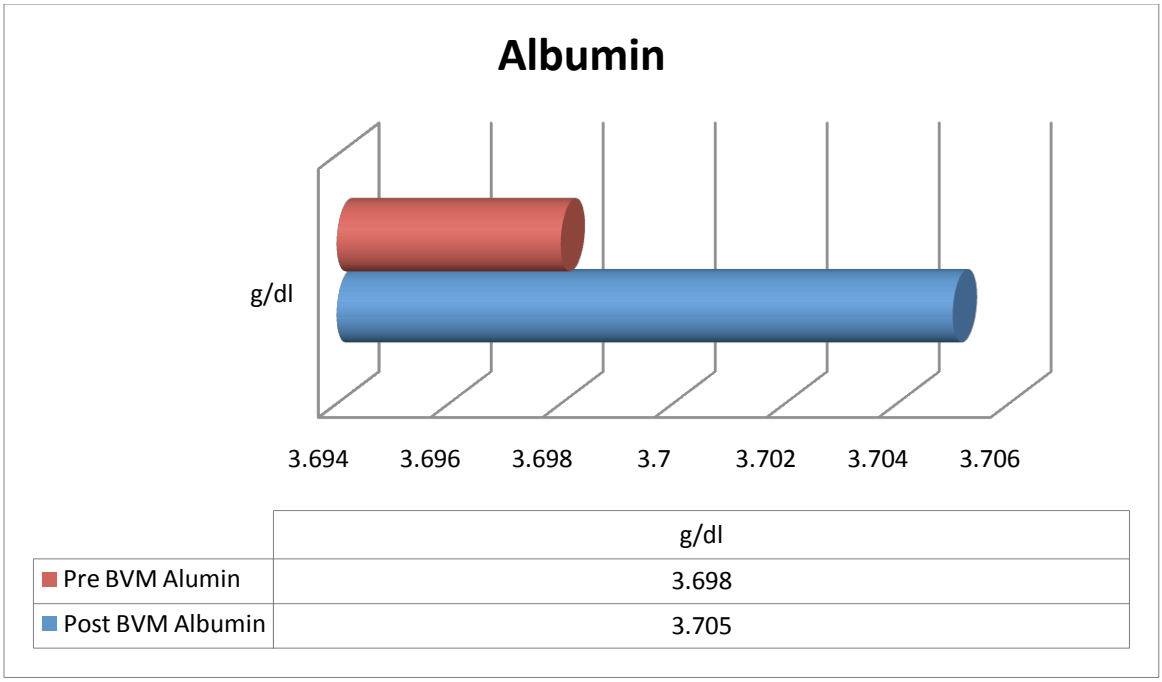
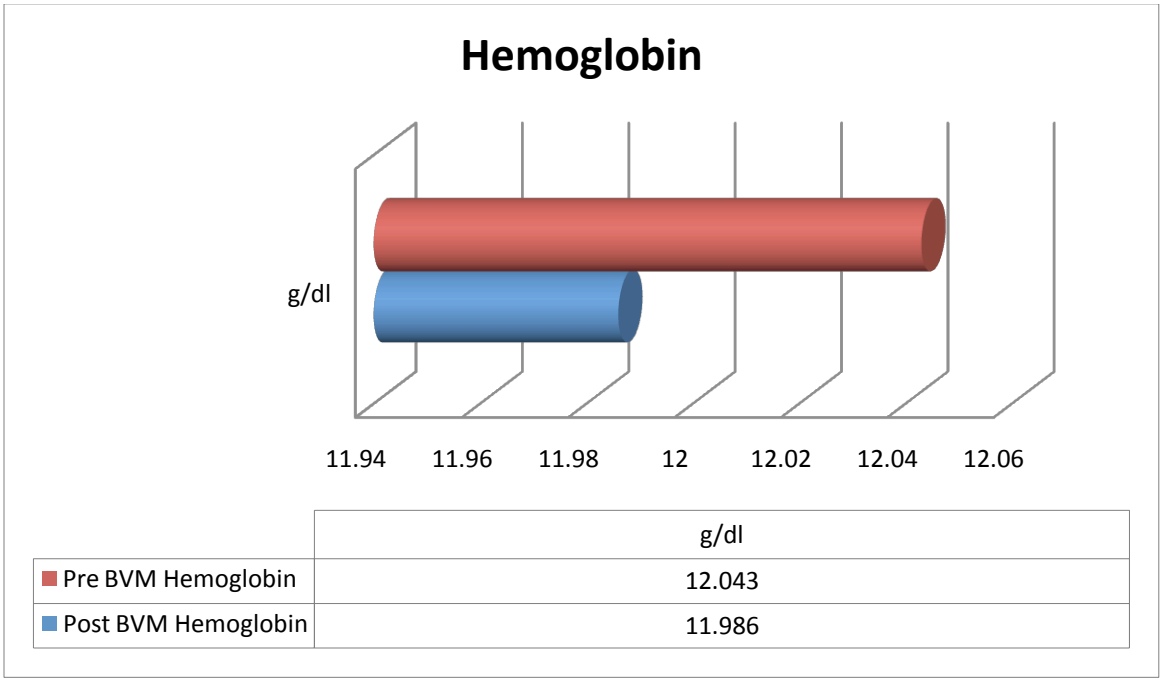


Figure 10. Interdialytic weight gain: Pre- and post-BVM.



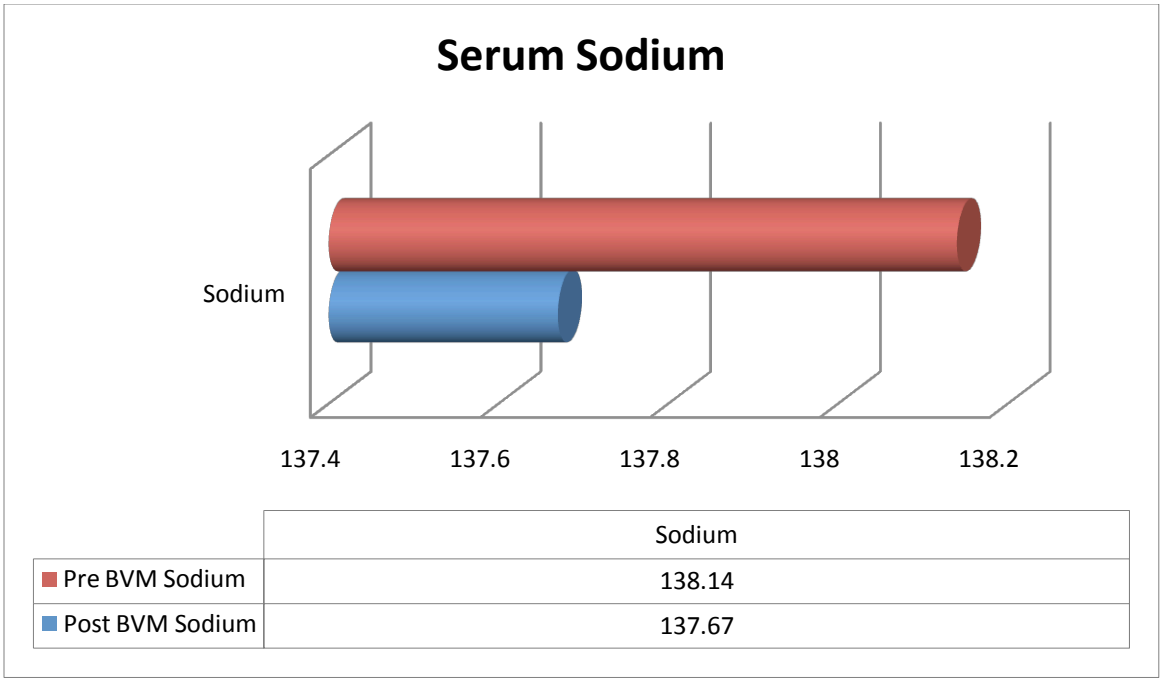
	g/dl
Pre BVM Alumin	3.698
Post BVM Albumin	3.705

Figure 11. Serum albumin: Pre- and post-BVM.



	g/dl
Pre BVM Hemoglobin	12.043
Post BVM Hemoglobin	11.986

Figure 12. Hemoglobin: Pre- and post-BVM.



	Sodium
Pre BVM Sodium	138.14
Post BVM Sodium	137.67

Figure 13. Serum sodium: Pre- and post-BVM.

CHAPTER 5: DISCUSSION

The purpose of this comparative retrospective chart review was to assess the possible correlation between control of hypertension in hemodialysis patients when fluid management technology is used in conjunction with the assessment of clinical parameters to manage DW. The effective management of hypertension in this population is highly dependent on optimal fluid removal in manner that does not illicit intra, inter or post dialytic complications such as nausea, vomiting, cramps in extremities, and fluid resuscitation to treat hypotension (San Miguel, 2010). The problem of how best to assess fluid status in ESRD patients has long plagued hemodialysis healthcare providers charged with maintaining the balance among hypovolemia, euvolemia, and hypervolemia. Hemodialysis nurses are responsible for carrying out the nephrologist and advanced practitioner's prescription for the dialysis treatment including the prescribed dry weight. This is especially true for nephrology nurses since they are involved in the patient's treatment and may contribute either positively or negatively to the patient's outcome.

Achieving optimal dry weight (DW) is often difficult in the outpatient hemodialysis unit because of the lack of credible criteria to determine if the DW has been achieved or whether a particular assessment is superior to another in assessing DW. A prospective study of 150 HD patients found reduction in the DW has a positive effect on blood pressure but had a negative impact on intravascular volume depletion to the point of necessitating fluid resuscitation and clotting of the vascular access (Agarwal et al., 2009).

Another variable that further confounds the management of DW is the patient. HD patients are aware of the need to restrict their fluid intake, particularly those with

little to none residual renal function. San Miguel (2010) stated that the sensation of thirst is often results in behavioral activities such as drinking whereas the onset of drinking results from motivational and cognitive processed that elicit the behavior. Fisher (2004) observed that fluid restriction among HD patients creates an uncomfortable state of ambivalence regarding drinking and Fisher conceptualized a model regarding fluid intake in this population. The conceptualized model assumes there is tension between the need to restrict fluid intake and the desire to drink and it is this focus on fluid restriction and an increased sensation of thirst (Fisher, 2004). The accumulation of these sensations triggers a sense of powerlessness and poor self-efficacy.

The direct relation between increased extracellular volume and hypertension led to the formulation of the research question. The question stated: "Do hypertensive patients who dialyze in dialysis unit where BVM technology is used along with the assessment of clinical parameters more likely to be normotensive as defined by a pre dialysis blood pressure of less than 140/90 and post dialysis blood pressure less than 130/80"? The following sections describe the study's findings, limitations, conclusions, implications to nursing, future research recommendations, and summary.

The data collection tool was tested and retested for usability through a pilot study. The findings from the pilot study were then applied to the tool and another pilot study was completed. At the conclusion of the pilot study, the tool was found to usable to extrapolate data needed for analysis.

Demographics

The retrospective chart review was completed on 42 charts that met the inclusion criteria. The demographics of the sample were representative of dialysis units in the

United States and the sample was compared to the most recently retrieved data from the United States Renal Data Systems (2010). Of the 42-hemodialysis patients 40.5% were female and 59.5% compared to the national average of 44% females and 56% males.

The four races identified in the sample included: African descent, (includes African Americans and Afro- Caribbean), Caucasian, Hispanic/Latino, and Asian. The sample yielded 7.1% of African descent compared to the national average of 37.1%. Caucasians comprised 45.2% compared to the national average of 55.8%. Hispanic/Latinos made up 42.9% of the sample compared to the national average of 16%. Lastly, 4.8% of the sample was Asian, which matched the national average. The sample yielded a large percentage of Hispanic/Latino patients compared to the national average (42.9% vs.16%) and conversely small percentage of African descent compared also to the national average (7.1% vs.37.1%).

The data was obtained from a geographic location where the population was 59.5% Caucasian, 16.1% African descent, 21.5% Hispanic/Latino and with an Asian population of less than 1%. The disproportionate percentage of African descent and Hispanic/Latinos within the sample is seen as a factor which may have affected the outcome of the study's results especially in regards to the higher than national average of diabetes mellitus seen in the Hispanic population.

Primary Cause of End Stage Renal Disease

The primary causes of end stage renal disease (ESRD) identified in the records of patient reviewed for this study were diabetes mellitus, Glomerulonephritis, secondary glomerulonephritis, interstitial nephritis/pyelonephritis, hypertension/large vessel disease, and neoplasm/tumors. Diabetes mellitus was the primary cause of ESRD in 47.6% of the

sample compared to the national average of 43.8%. Hypertension/large vessel disease was listed as the primary cause of ESRD in 33% of the sample compared to the national average of 28.3%. Glomerulonephritis was listed in 7.1% compared to the national average of 10.4%. 2.4% of the sample listed Secondary Glomerulonephritis listed as the primary cause of ESRD that was equal to the national average. Interstitial nephritis/pyelonephritis was responsible for 4.8% of the cases as the primary cause of ESRD in the sample compared to the national average of 3.2%. Lastly neoplasms/Tumors were responsible for 4.8% of the causes compared to 2.4% national average. Diabetes mellitus and hypertension/large vessel diseases were noted to be more prevalent in the studied population, which may be secondary to the large Hispanic/Latino population in the sample.

Co-Morbidities

Co-morbidities identified in this study included amputation, chronic obstructive pulmonary disease (COPD), cerebral vascular accident (CVA), cardiovascular disease (CVD), diabetes mellitus (DM), malignancy/neoplasm, hepatic disease, depression and tobacco abuse. The co-morbidities were taken from the list provided on the 2728 form. COPD, CVD, DM, and PVD had the highest occurrences of co-morbidities within the study sample. Hypertension was not counted in co-morbidities, as it was an inclusion criterion for the study.

Antihypertensive Medication

The data revealed that 31% of the sample were prescribed ACE-I, 11.9% were prescribed ARB. Calcium channel blockers (CCB) (all classes) are the most widely

prescribed class of drugs for dialysis patients (NKF Clinical Practice Guidelines, 2006). 38.1% of the patients were prescribed CCB. CCB appears to be more effective when the plasma volume is expanded and since hypertension in this population is a result of extracellular volume expansion this class of medications has an advantage of reducing hypertension hemodialysis patients.

Blood Pressure Management

The comparative analysis of excess extracellular volume in hypertensive hemodialysis (HD) patients sought to answer the question which asked "Are hypertensive hemodialysis patients who dialyze in a freestanding dialysis unit, with blood volume monitoring (BVM) technology available, more likely to be normotensive or closer to normotension as defined by a pre dialysis blood pressure of less than 140/90 and post dialysis blood pressure less than 130/80"? The paired samples T-test was run on the collected data to assess the changes or lack thereof, to correctly answer the research question within the paired data.

The four paired samples included: Pre-BVM: pre-dialysis SBP compared to post-BVM: SBP, Pre-BVM: Pre-dialysis DBP compared to post-BVM: Pre-BVM post-dialysis SBP to post-BVM: post-dialysis SBP, and Pre-BVM: post-dialysis DBP. The records reviewed in this retrospective chart review demonstrated that the pre BVM pre dialysis systolic blood pressure (SBP) had a mean of 160 mm/hg compared to a post BVM pre dialysis SBP of 149 mm/hg. This result was found to be statistically significant with a significance value (2-tailed) of .000 ($p \leq 0.05$) so the answer to the research question "Are hypertensive hemodialysis patients who dialyze in a freestanding dialysis unit, with BVM) technology available and utilized, more likely to be normotensive as

defined by a pre dialysis blood pressure of less than 140/90 and post dialysis blood pressure less than 130/80?" is yes in relation to pre dialysis systolic blood pressure.

This statistically significant finding supports the correlation between reduction in the HD patient's extracellular volume and improved blood pressure control. The reduction of pre-dialysis SBP was significant because Agarwal (2006) made the observation that most patients on hemodialysis have systolic hypertension that may or may not coexist with diastolic hypertension. Pre dialysis systolic blood pressure is superior to post dialysis blood pressure as a screening tool for detecting hypertension in dialysis patients (Charra, 2007).

The pre BVM post dialysis SBP mean was 130 mm/hg and the post BVM post dialysis mean was 129 mm/hg. There was no statistical significance noted (.692). The answer to the research question *"*Are hypertensive hemodialysis patients who dialyze in a freestanding dialysis unit, with BVM) technology available and used, more likely to be normotensive as defined by a pre dialysis blood pressure of less than 140/90 and post dialysis blood pressure less than 130/80?" is no in relation to systolic blood pressure before and after BVM use.

However, it is important to note that both values met guidelines of a post dialysis SBP of less than or equal to 130 mm/hg. This finding leads one to speculate that the availability and use of the BVM technology may be a reason why this goal is attained.

The pre BVM pre dialysis diastolic blood pressure was found to have a mean of 79 mm/hg compared to the post BVM pre dialysis DBP mean of 75 mm/hg. Again, this value was not statically significant (.055). The answer to the research question *"*Are hypertensive hemodialysis patients who dialyze in a freestanding dialysis unit, with

BVM) technology available and used, more likely to be normotensive as defined by a pre dialysis blood pressure of less than 140/90 and post dialysis blood pressure less than 130/80?" is, again, no in relation diastolic blood pressure before and after BVM use. However, again, this may have clinical significance because national guidelines/recommendations were met for systolic and diastolic readings.

The pre BVM post dialysis DBP presented with a mean of 67 mm/hg compared to post BVM post dialysis DBP of 66 mm/hg that is once again not statistically significant (.899). The answer to the research question *"*Are hypertensive hemodialysis patients who dialyze in a freestanding dialysis unit, with BVM) technology available and used, more likely to be normotensive as defined by a pre dialysis blood pressure of less than 140/90 and post dialysis blood pressure less than 130/80?" is no in relation to pre and post dialysis diastolic blood pressure. However, it is important to note that the diastolic values at both points met guidelines and it is important to remember many patients have systolic hypertension without diastolic hypertension.

Other Observations

While not related to the specific research question, the following summarizes observations based on data collected in association with this study.

Interdialytic Weight Gain

The mean pre BVM interdialytic weight gain (IDWG) average was 3.3kg compared to the mean of 3.3kg post BVM intervention. The findings were not statically significant ($p \leq 0.05$). NKF-KDOQI (2006) state the average IDWG should be less than or equal to 3kg. Kalantar-Zadeh et al. (2009) found in long-term hemodialysis patients, a higher IDWG is associated with poor survival and increased cardiovascular death. Most

importantly they found the patients with the lowest interdialytic fluid retention had the greatest risk of survival observed across the subgroups of hemodialysis patients.

Can the use of the BVM technology used in conjunction with the assessment of clinical parameters help patients control their intradialytic weight gain? When a patient is eulvolemic there may be an increase in energy that leads to an overall sense of wellbeing, which may mitigate improved adherence with dietary fluid restriction. The BVM may be effective in attaining the correct dry weight by showing a visualization of the patient's current fluid status and allowing active patient participation in their care. Lindberg (2008) made the observation that pragmatic and effective ways of helping patients with fluid management are lacking and the results o of intervention studies in this area have in general been disappointing. Baraz (2010) conducted a randomized clinical trial that provided educational video two times a week for two weeks. The video emphasized ESRD dietary management, identification of appropriate provisions, fluid restrictions, and consequences of fluid overload. The outcome was fluid overload was reduced. This study validated the importance of education and patient involvement to impact outcomes.

Albumin

The pre BVM mean for serum Albumin was 3.7 g/dl and the post BVM serum Albumin mean was also 3.7. This finding was not statistically significant because of a p value ≥ 0.5 ($p = .637$). San Miguel (2010) stated that assessment of Albumin is pivotal, in combination of other clinical parameters, when assessing dry weight (DW). Particular attention should be paid to patients with a low Albumin (<3.4 g/dl) because these patients are likely to show signs of not tolerating fluid removal with HD such as hypotension and cramps despite the presence of excess extracellular volume (2010).

Sodium

The pre BVM mean for sodium was 138 and the post BVM mean was 137. The finding was found to be statistically significant with a p value of .023. With the removal of ECV to achieve the prescribed dry weight there is a decrease in the serum sodium as the ECV normalizes (2007). Sodium is often the forgotten element in managing a patient's ECV and dry weight but assessment to serum sodium levels may assist in ECV and dry weight management by monitoring fluctuations in reported values. During the dialysis process often the sodium is increased to alleviate intradialytic symptoms such as hypotension and cramping. The hemodialysis machine has the ability to deliver between 135-145mEq/L of sodium during a dialysis treatment (2007).

Agarwal (2006) used the example of a patient who weighs 72kg. The total body water is estimated at 43L. If the pre dialysis sodium concentration is 135mEq/L and the patient is dialyzed against 145mEq/L, a total of 430mEq of sodium will be delivered to the patient during the treatment during a typical of 210-240 minutes. This is equal to 3kg of interdialytic weight gain and this type of weight gain is directly responsible for increased thirst and, interdialytic hypotension (Agarwal, 2006). In order to end this cycle interdialytic sodium delivery should be based on individual patient needs. The take away message is reinforcing the importance of the sodium-restricted diet in dialysis patients as another method to effectively control intradialytic fluid weight gain and hypertension.

Researchers found that adherence to a 2 gm sodium diet would decrease interdialytic weight gain by controlling thirst and limiting weight gain may alleviate the large variations in BP and possibly prevent intradialytic hypotensive symptoms (Agarwal, 2006). Agarwal (2006) states a patient who follows a 2 gm sodium diet would

most likely have an interdialytic weight gain of 1.25kg over 48 hours and 1.9kg in 72 hours. Sodium restriction is beneficial because it may assist in limiting large interdialytic weight gains and mitigates the large swings in blood pressures that may decrease incidences of intradialytic hypotensive symptoms (Agarwal, 2006).

Hemoglobin

The pre and post BVM hemoglobin (Hgb) mean was 12 mg/dl with a p value of .641, which was not statistically significant. However the Hgb values did meet national guidelines and recommendations from the NFK-KDOQI guidelines that target Hgb ranges between 10-12 g/dl for dialysis patients. The BVM utilizes the patient's real time Hgb to estimate the patient's extracellular status given Hgb variability changes in the patient's fluid levels (Hlebovy, 2003).

Limitations

Limitations were identified in this study. All of the records reviewed were from patients at one freestanding outpatient hemodialysis unit chosen by a convenience sampling method. The sample size was small (N=42) and did not meet the number (50) mandated by the power analysis.

The dialysis unit's population of 45.2% Caucasian, 42.9% Hispanic/Latino, and 7.1% African descent was not representative of the national average. This is seen as a limitation if results are to be applied nationally. The large Hispanic group may have been responsible for the larger percentage of diabetes mellitus and hypertension. The small percentage of African descent patients may have limited the power of the BVM intervention as various studies have found a higher prevalence of volume dependent hypertension among those of African descent (Kalantar-Zadeh et al.2009 & Baraz, 2010).

Another limitation was the inability to collect patient's pre and post BVM glucose readings because the unit monitors Hemoglobin A1C levels four times a year in known diabetic patients only. There were also no current serum glucose levels. Elevated serum glucose levels may be a cause of excess ECV due to increased serum osmolarity.

The limited use of the BVM in the facility used was also identified as a limitation. Optimally, the BVM should be used every 2-4 weeks on all patients to continue ongoing ECV management. It was also not possible to document the level of education of staff on the use of the BVM or the degree to which individual nurses used this data when making decisions during any one-dialysis event. The staff must be retrained and checked off on the proper use and interpretation of data obtained from the BVM in order to effectively use this technology to assess and manage ECV. Finally, research bias was a limitation. The bias of this author is that the primary etiology hypertension in most hemodialysis patients is resultant of excess ECV and diligent attention must be paid to this detail. These limitations have been acknowledged.

Conclusion

The findings of this study suggest the use of the use BVM is effective in the management of hypertension in hemodialysis patients with excess ECV. There were statically significant positive changes in post BVM pre dialysis systolic pressures, which were closer to the national guidelines goal of 140 mm/hg. A statically significant change was also found in pre vs. post BVM serum sodium. The data also revealed that the mean pre and post BVM diastolic blood pressure, sodium, and hemoglobin were all within the goals of national guidelines. This finding lends support of the belief that the use of BVM

technology may assist with normalization of blood pressure and more effective management of excess ECV.

Implications for Nursing

The effectiveness of the use of the BVM to manage hypertensive hemodialysis patients is evident in this comparative descriptive study. Nephrologists and Advanced practitioners (Nurse practitioners [NP] and physician assistants [PA] will prescribe the dialysis prescription and consultation but the day-to-day management, including the safe execution of evidence based treatment, responsibility falls on the nurse. This study should help improve this process as these providers combine physical assessment parameters and BVM technology to formulate the protocol for specific patients.

This also has implications for nurses actually supervising the dialysis event and making bedside decisions (often without the ARNP or physician provider present) as to when and how to end a session. Lindberg (2008) found that one in five HD patients were being dialyzed to an inadequate DW. A possible explanation may be lack of knowledge of the nursing staff about how to use the BVM data to make decisions about how to best achieve DW. In addition nurses may need education about how to use this data without fear of causing the patient undue discomfort because of removal of fluid either in a manner, which is too rapid possibly resulting in nausea, vomiting, or leg cramps.

An expert dialysis nurse knows how the variables of intradialytic weight gain and rate of fluid removal (ultrafitration rate) are key quality indicators for qualitynephrology nursing care. They know how to (and actually do) assess these factors on a regular basis. This retrospective study did not look at individual clinical assessment parameters used by the nursing staff (such as edema, or adventitious lung sounds) and it is important to note

nursing support is critical to assisting patients in developing proficiency in certain skills and tasks.

Due to the increasing prevalence of chronic kidney disease (CKD) and ESRD in the United States and excess ECV management is imperative to decrease patient morbidity and mortality. The belief that fluid overload is a normal condition in most HD patients is a paradigm that must be discarded in favor of a new paradigm that emphasizes cardiovascular disease is the leading cause of mortality with over hydration as a major contributing factor (Linberg, 2008). The nephrology nurse and the nephrology Advanced Practitioner have regular and frequent interactions with the HD patient and hence have an opportunity to educate the patient about fluid, sodium, and hypertension management (2008). It is the hope of this researcher that the findings will be used to imporve protocols to manage ECV in the HD patient.

Advanced practice nurses in nephrology, in particular those with a doctorate in nursing practice (DNP), will be able to take the information from this study and improve routine evaluation of patients' ECV status and possibly adjustment of the dry weight through the use of protocols. Lindberg (2008) observed that advanced practice nurses often provide expert care, which results in optimized patient self-management. DNP may take the reigns of to educate advanced practice nurses, nephrology nurses, and ancillary staff on the signs and symptoms of ECV excess. Effective ECV management is achieved ongoing assessment with the goal of getting the patient as close to normotension as possible while decreasing the patient's pill burden by discontinuing antihypertensive medications as warranted.

Dialysis staff must be trained that if the patient begins to experience hypotension, cramps, and/or nausea and/or vomiting to notify the nursing staff or the advanced practitioner nurse to make adjustments to the rate of fluid removal, medications, and /or dry weight. All those involved in the care of the dialysis patient must be involved must empower the patient by providing ongoing education regarding ECV and blood pressure management along with information regarding sodium and fluid restrictions.

Suggestions for Future Research

Future research is recommended for excess ECV management in hypertensive HD patients with the hope of decreasing morbidity and mortality associated with cardiovascular disease. The same study may be duplicated in units with a population closer to the national average to better assess the use of the use of BVM technology in hypertensive hemodialysis patients in which secondary causes have been excluded. The BVM is expensive so there are limited quantities available in select HD units but a protocol in which BVM is used weekly may seek to decrease hospitalizations and morbidity and mortality rates. Research that would continue to reinforce the role of excess ECV in dialysis patients is needed to decrease morbidity and mortality in this vulnerable population. A much larger prospective study in which the glucose levels are measured in correlation with hypertension and increased ECV (either by hemoglobin A1C or serum glucose) may capture variables not captured in this study.

The NKF-KDOQI guidelines (2006) state drugs that inhibit the renin-angiotensin system (RAS), such as angiotensin converting enzyme inhibitors (ACE-I) or angiotensin II-receptor blockers (ARB) are preferred in the management of hypertension in dialysis patients because they cause greater regression of left ventricular hypertrophy (LVH),

reduce sympathetic nerve activity, reduce pulse wave velocity, may improve endothelial function, and may reduce oxidative stress (Agarwal, 2007). A follow up study with a larger sample may examine if the findings of the BVM along with certain antihypertensive medications to assess which single medication or combination of medications will improve make no change, or possibly worsen patient outcomes.

Summary

The reported outcomes of this project are relevant to the management of hypertensive dialysis patients with excess ECV yet there is vast room for improvement in this arena. Individuals that will benefit from the outcomes of this study include physicians, advanced practice practitioners, nephrology nurses and ancillary staff who were unaware of the importance of excess ECV in the management of HTN in dialysis patients. Familiarity with the pathophysiology of HTN in this population will lead to decrease pill burden, decreased hospitalizations, and decreased morbidity and mortality. The outcomes revealed descriptive information about the management of ECV in hypertensive HD patients. Extrapolated information included the statistically significant reduction in pre dialysis systolic blood pressure and post BVM serum sodium. These findings may be used as the foundation for future works of research in dialysis patients and all those with issues of excess ECV such as those with heart and liver failure.

APPENDIX A: 2728 FORM

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0046

END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT
MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS

1. Name *(Last, First, Middle Initial)*

2. Health Insurance Claim Number

3. Social Security Number

4. Full Address *(Include City, State, and Zip)*

5. Phone Number
( )

6. Date of Birth
_____/_____/_____
MM DD YYYY

7. Sex
☐ Male ☐ Female

8. Ethnicity
☐ Hispanic: Mexican ☐ Hispanic: Other ☐ Non-Hispanic

9. Race *(Check **one** box only)*
☐ White
☐ Black
☐ American Indian/Alaskan Native
☐ Asian
☐ Pacific Islander
☐ Mid-East/Arabian
☐ Indian sub-Continent
☐ Other, specify _____
☐ Unknown

10. Medical Coverage *(Check **all** that apply)*
a. ☐ Medicaid
b. ☐ DVA
c. ☐ Medicare
d. ☐ Employer Group Health Insurance
e. ☐ Other Medical Insurance
f. ☐ None

11. Is Patient Applying for ESRD Medicare Coverage? *(if **YES**, enter address of Social Security office)*
☐ Yes ☐ No

CITY STATE ZIP

12. Primary Cause of Renal Failure *(Use code from back of form)*

13. Height
INCHES OR CENTIMETERS

14. Dry Weight
POUNDS OR KILOGRAMS

15. Employment Status *(6 mos. prior and current status)*

Prior	Current	
☐	☐	Unemployed
☐	☐	Employed Full Time
☐	☐	Employed Part Time
☐	☐	Homemaker
☐	☐	Retired due to Age/Preference
☐	☐	Retired (Disability)
☐	☐	Medical Leave of Absence
☐	☐	Student

16. Co-Morbid Conditions *(Check **ALL** that apply currently or during last 10 years)* *See instructions

a. ☐ Congestive heart failure
b. ☐ Ischemic heart disease, CAD*
c. ☐ Myocardial infarction
d. ☐ Cardiac arrest
e. ☐ Cardiac dysrhythmia
f. ☐ Pericarditis
g. ☐ Cerebrovascular disease, CVA, TIA*
h. ☐ Peripheral vascular disease*
i. ☐ History of hypertension
j. ☐ Diabetes (primary or contributing)
k. ☐ Diabetes, currently on insulin
l. ☐ Chronic obstructive pulmonary disease
m. ☐ Tobacco use (current smoker)
n. ☐ Malignant neoplasm, Cancer
o. ☐ Alcohol dependence
p. ☐ Drug dependence*
q. ☐ HIV positive status ☐ Can't Disclose
r. ☐ AIDS ☐ Can't Disclose
s. ☐ Inability to ambulate
t. ☐ Inability to transfer

17. Was pre-dialysis/transplant EPO administered?
☐ Yes ☐ No

18. Laboratory Values Prior to First Dialysis Treatment or Transplant *See Instructions.

LABORATORY TEST	VALUE	DATE	LABORATORY TEST	VALUE	DATE
a. Hematocrit (%)			e. Serum Creatinine (mg/dl)		
b. Hemoglobin (g/dl)*			f. Creatinine Clearance (ml/min)*		
c. Serum Albumin (g/dl)			g. BUN (mg/dl)*		
d. Serum Albumin Lower Limit (g/dl)			h. Urea Clearance (ml/min)*		

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

19. Name of Provider

20. Medicare Provider Number

21. Primary Dialysis Setting
☐ Hospital Inpatient ☐ Dialysis Facility/Center ☐ Home

22. Primary Type of Dialysis
☐ Hemodialysis ☐ IPD ☐ CAPD ☐ CCPD ☐ Other

23. Date Regular Dialysis Began
_____/_____/_____
MM DD YY

24. Date Patient Started Chronic Dialysis at Current Facility
_____/_____/_____
MM DD YY

25. Date Dialysis Stopped
_____/_____/_____
MM DD YY

26. Date of Death
_____/_____/_____
MM DD YY

CMS-2728-U3 (6-97)

C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

27. Date of Transplant _____/_____/_____ MM DD YY	28. Name of Transplant Hospital	29. Medicare Provider Number for Item 28

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

30. Enter Date _____/_____/_____ MM DD YY	31. Name of Preparation Hospital	32. Medicare Provider Number for Item 31

33. Current Status of Transplant

☐ Functioning ☐ Non-Functioning

34. If Nonfunctioning, Date of Return To Regular Dialysis _____/_____/_____ MM DD YY	35. Current Dialysis Treatment Site ☐ Hospital Inpatient ☐ Dialysis Facility/Center ☐ Home

D. COMPLETE FOR ALL ESRD SELF-DIALYSIS TRAINING PATIENTS (MEDICARE APPLICANTS ONLY)

36. Name of Training Provider	37. Medicare Provider Number of Training Provider
38. Date Training Began _____/_____/_____ MM DD YY	39. Type of Training ☐ Hemodialysis ☐ IPD ☐ CAPD ☐ CCPD
40. This Patient is Expected to Complete *(or has completed)* Training and Will Self-dialyze on a Regular Basis. ☐ Yes ☐ No	41. Date When Patient Completed, or is Expected to Complete, Training _____/_____/_____ MM DD YY

I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

42. Printed Name and Signature of Physician Personally Familiar with the Patient's Training	43. UPIN of Physician in Item 42

E. PHYSICIAN IDENTIFICATION

44. Attending Physician *(Print)*	45. Physician's Phone No. ( )	46. UPIN of Physician in Item 44

PHYSICIAN ATTESTATION

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

47. Attending Physician's Signature of Attestation *(Same as Item 44)*	48. Date _____/_____/_____ MM DD YY

49. Remarks

F. OBTAIN SIGNATURE FROM PATIENT

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

50. Signature of Patient *(Signature by Mark Must Be Witnessed.)*	51. Date _____/_____/_____ MM DD YY

G. PRIVACY ACT STATEMENT

The collection of this information is authorized by section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Privacy Act Issuance, 1991 Compilation, Vol. 1, pages 436–437, December 31, 1991, or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for a research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the *Federal Register* notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

H. FOR ESRD NETWORK USE ONLY IN CASES REFERRED TO ESRD MEDICAL REVIEW BOARD

52. Network Confirmed as ESRD ☐ Yes ☐ No	53. Authorized Signature	54. Date _____/_____/_____ MM DD YY	55. Network Number

CMS-2728-U3 (6-97)

LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Item 12. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code plus the letter code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary.

ICD-9	LTR	NARRATIVE
DIABETES		
25000	A	Type II, adult-onset type or unspecified type diabetes
25001	A	Type I, juvenile type, ketosis prone diabetes
GLOMERULONEPHRITIS		
5829	A	Glomerulonephritis (GN) (histologically not examined)
5821	A	Focal glomerulosclerosis, focal sclerosing GN
5831	A	Membranous nephropathy
5832	A	Membranoproliferative GN type 1, diffuse MPGN
5832	C	Dense deposit disease, MPGN type 2
58381	B	IgA nephropathy, Berger's disease (proven by immunofluorescence)
58381	C	IgM nephropathy (proven by immunofluorescence)
5804	B	Rapidly progressive GN
5834	C	Goodpasture's Syndrome
5800	C	Post infectious GN, SBE
5820	A	Other proliferative GN
SECONDARY GN/VASCULITIS		
7100	E	Lupus erythematosus, (SLE nephritis)
2870	A	Henoch-Schonlein syndrome
7101	B	Scleroderma
2831	A	Hemolytic uremic syndrome
4460	C	Polyarteritis
4464	B	Wegener's granulomatosis
5839	C	Nephropathy due to heroin abuse and related drugs
4462	A	Vasculitis and its derivatives
5839	B	Secondary GN, other
INTERSTITIAL NEPHRITIS/PYELONEPHRITIS		
9659	A	Analgesic abuse
5830	B	Radiation nephritis
9849	A	Lead nephropathy
5909	A	Nephropathy caused by other agents
27410	A	Gouty nephropathy
5920	C	Nephrolithiasis
5996	A	Acquired obstructive uropathy
5900	A	Chronic pyelonephritis, reflux nephropathy
58389	B	Chronic interstitial nephritis
58089	A	Acute interstitial nephritis
5929	B	Urolithiasis
2754	A	Nephrocalcinosis
HYPERTENSION/LARGE VESSEL DISEASE		
4039	D	Renal disease due to hypertension (no primary renal disease)
4401	A	Renal artery stenosis
59381	B	Renal artery occlusion
59381	E	Cholesterol emboli, renal emboli
CYSTIC/HEREDITARY/CONGENITAL DISEASES		
75313	A	Polycystic kidneys, adult type (dominant)
75314	A	Polycystic, infantile (recessive)
75316	A	Medullary cystic disease, including nephronophthisis
7595	A	Tuberous sclerosis
7598	A	Hereditary nephritis, Alport's syndrome
2700	A	Cystinosis
2718	B	Primary oxalosis
2727	A	Fabry's disease
7533	A	Congenital nephrotic syndrome
5839	D	Drash syndrome, mesangial sclerosis
7532	A	Congenital obstructive uropathy
7530	B	Renal hypoplasia, dysplasia, oligonephronia
7567	A	Prune belly syndrome
7598	B	Hereditary/familial nephropathy
NEOPLASMS/TUMORS		
1890	B	Renal tumor (malignant)
1899	A	Urinary tract tumor (malignant)
2230	A	Renal tumor (benign)
2239	A	Urinary tract tumor (benign)
2395	A	Renal tumor (unspecified)
2395	B	Urinary tract tumor (unspecified)
20280	A	Lymphoma of kidneys
2030	A	Multiple myeloma
2030	B	Light chain nephropathy
2773	A	Amyloidosis
99680	A	Complication post bone marrow or other transplant
MISCELLANEOUS CONDITIONS		
28260	A	Sickle cell disease/anemia
28269	A	Sickle cell trait and other sickle cell (HbS/Hb other)
64620	A	Post partum renal failure
0429	A	AIDS nephropathy
8660	A	Traumatic or surgical loss of kidney(s)
5724	A	Hepatorenal syndrome
5836	A	Tubular necrosis (no recovery)
59389	A	Other renal disorders
7999	A	Etiology uncertain

INSTRUCTIONS FOR COMPLETION OF END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

For whom should this form be completed:

This form **SHOULD NOT** be completed for those patients who are in acute renal failure. Acute renal failure is a condition in which kidney function can be expected to recover after a short period of dialysis; i.e., several weeks or months.

This form **MUST BE** completed within 45 days for **ALL** patients beginning any of the following:

A. For all patients who initially receive a kidney transplant instead of a course of dialysis.
B. All patients for whom a regular course of dialysis has been prescribed by a physician because they have reached that stage of renal impairment that a kidney transplant or regular course of dialysis is necessary to maintain life. The first date of a regular course of dialysis is the date this prescription is implemented whether as an inpatient of a hospital, an outpatient in a dialysis center or facility, or a home patient. This form should be completed for all patients in this category even if the patient dies within this time period.
C. For beneficiaries who have already been entitled to ESRD Medicare benefits and those benefits were terminated because their coverage stopped 3 years post transplant but now are again applying for Medicare ESRD benefits because they returned to dialysis or received another kidney transplant.
D. For beneficiaries who stopped dialysis for more than 12 months, have had their Medicare ESRD benefits terminated and now returned to dialysis or received a kidney transplant. These patients will be reapplying for Medicare benefits.

All Items except as follows: To be completed by the attending physician, head nurse, or social worker involved in this patient's treatment of renal disease.
Items 12, 16, 47-48: To be completed by the attending physician.
Item 42: To be signed by the attending physician or the physician familiar with the patient's self-care dialysis training.
Items 50 and 51: To be signed and dated by the patient.

1. Enter the patient's legal name (Last, first, middle initial). Name should appear exactly the same as it appears on patient's Social Security or Medicare card.
2. If the patient is covered by Medicare, enter his/her Health Insurance Claim Number as it appears on his/her Medicare card. This number can be verified from his/her Medicare card.
3. Enter the patient's own Social Security number. This number can be verified from his/her Social Security card.
4. Enter the patient's mailing address (number and street or post office box number, city, State, and ZIP code).
5. Enter the patient's home area code and telephone number.
6. Enter patient's date of birth (2-digit Month, Day, and 4-digit Year). Example 07/25/1950.
7. Check the appropriate block to identify sex.
8. Check the appropriate block to identify ethnicity. Definitions of the basic ethnicity categories for Federal statistics are as follows:

   Hispanic: Mexican—A person of Mexican culture or origin, regardless of race.

   Hispanic: Other—A person of Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.

   Non-Hispanic—A person of culture or origin not described above, regardless of race.
9. Check **one** appropriate block to identify race. Definitions of the basic racial categories for Federal statistics are as follows:

   White—A person having origins in any of the original white peoples of Europe.

   Black—A person having origins in any of the black racial groups of Africa.

   American Indian/Alaskan Native—A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

   Asian—A person having origins in any of the original peoples of the Far East and Southeast Asia. Examples of this area include China, Japan and Korea.

   Pacific Islander—A person having origins in any of the peoples of the Pacific Islands. Examples of this area include the Philippine Islands, Samoa and Hawaiian Islands.

   Mid-East/Arabian—A person having origins in any of the peoples of the Middle East and Northern Africa. Examples of this area include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, and Kuwait.

   Indian Sub-Continent—A person having origins in any of the peoples of the Indian Sub-continent. Examples of this area include India and Pakistan.

   Other, specify—A person not having origins in any of the above categories. Write race(s) in space provided.

   Unknown—Check this block if race is unknown.
10. Check **all** the blocks that apply to this patient's current medical insurance status.

    Medicare—Patient is currently entitled to Federal Medicare benefits.

    Medicaid—Patient is currently receiving State Medicaid benefits.

DISTRIBUTION OF COPIES:

- Forward the first part (blue) of this form to the Social Security office servicing the claim.
- Forward the second (green) of this form to the ESRD Network Coordinating Council.
- Retain the last part (white) in the patient's medical records file.

CMS-2728-U3 (6-97)

DVA—Patient is receiving medical care from a Department of Veterans Affairs facility.

Employer Group Health Insurance—Patient receives medical benefits through an employer group health plan that covers employees, former employees, or the families of employees or former employees.

Other Medical Insurance—Patient is receiving medical benefits under a health insurance plan that is not Medicare, Medicaid, Department of Veterans Affairs, nor an employer group health insurance plan. Examples of other medical insurance are Railroad Retirement and CHAMPUS beneficiaries.

None—Patient has no medical insurance plan.

11. Check the appropriate yes or no block to indicate if patient is applying for ESRD Medicare. Note: Even though a person may already be entitled to general Medicare coverage, he should re-apply for ESRD Medicare coverage. If answer is yes, enter the address of the local Social Security office (street address, city, State and zip code) where patient will be applying for benefits.
12. **To be completed by the attending physician.** Enter the ICD-9-CM plus letter code from back of form to indicate the primary cause of end stage renal disease. These are the only acceptable causes of end stage renal disease.
13. Enter the patient's most recent recorded height in inches **OR** centimeters at time form is being completed. If entering height in centimeters, round to the nearest centimeter. Estimate or use last known height for those unable to be measured. (Example of inches - 62. DO NOT PUT 5'2") NOTE: For amputee patients, enter height prior to amputation.
14. Enter the patient's most recent recorded dry weight in pounds **OR** kilograms at time form is being completed. If entering weight in kilograms, round to the nearest kilogram.

NOTE: For amputee patients, enter actual dry weight.

15. Check the first box to indicate employment status 6 months prior to renal failure and the second box to indicate current employment status. **Check only one box for each time period**. If patient is under 6 years of age, leave blank.
16. **To be completed by the attending physician.** Check all co-morbid conditions that apply.

    ***Ischemic heart disease** includes prior coronary artery bypass (CABG), angioplasty and diagnoses of coronary artery disease (CAD)/coronary heart disease.

    ***Cerebrovascular Disease** includes history of stroke/ cerebrovascular accident (CVA) and transient ischemic attack (TIA).

    ***Peripheral Vascular Disease** includes absent foot pulses, prior typical claudication, amputations for vascular disease, gangrene and aortic aneurysm.

    ***Drug dependence** means dependent on illicit drugs.
17. If EPO (erythropoietin) was administered to this patient prior to dialysis treatments or kidney transplant, check "Yes." If EPO was not administered to this patient prior to dialysis treatments or kidney transplant, check "No."

NOTE: For those patients re-entering the Medicare program after benefits were terminated, Items 18a thru 18h should contain initial laboratory values within 45 days of the most recent ESRD episode.

18.a. Enter the hematocrit value (%) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. If hematocrit value is not available, complete 18.b. hemoglobin.

18.b. Enter the hemoglobin value (g/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. Enter value if hematocrit is not available.

18.c. Enter the serum albumin value (g/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant.

18.d. Enter the lower limit of the normal range for serum albumin (g/dl) from the laboratory which performed the serum albumin test entered in 18.c.

18.e. Enter the serum creatinine value (mg/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. **THIS FIELD MUST BE COMPLETED.**

NOTE: Except for diabetic and transplant patients, it has been determined by a consensus panel that the value of this field should be greater than or equal to 8.0 for a patient to receive renal replacement therapy without further justification. If this value is less than 8.0 AND creatinine clearance is equal to or greater than 10.0 this case will be subject to ESRD Network Medical Review Board Review. In these cases, please annotate in Remarks (Item 49) additional medical evidence to support renal replacement therapy. If there is not enough room in the remarks section, you may attach an additional sheet of paper.

18.f. If value of 18.e., serum creatinine, is < 8.0 mg/dl, enter creatinine clearance value (ml/min) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. If these data are not available, creatinine clearance will be computed, therefore Items 13 and 14 must be completed.

18.g. If value of 18.e., serum creatinine, is < 8.0 mg/dl, enter BUN value (mg/dl) and date test was taken. This value and date must be within 45 days prior to the first dialysis treatment or transplant.

18.h. If value of 18.e., serum creatinine, is < 8.0 mg/dl and 18.f., creatinine clearance, is > 10.0, enter the urea clearance value (ml/min) and date test was taken. This value and date must be 45 days prior to the first dialysis treatment or transplant.

19. Enter the name of the dialysis provider where patient is currently receiving care and who is completing this form for patient.
20. Enter the 6-digit Medicare identification code of the dialysis facility in item 19.
21. If a person is receiving a regular course of dialysis treatment, check the appropriate **anticipated long term treatment setting** at the time this form is being completed. If a patient is a resident of and receives their dialysis in an intermediate care facility or nursing home, check home.
22. If the patient is, or was, on regular dialysis, **check the anticipated long term primary type of dialysis**: Hemodialysis, IPD (Intermittent Peritoneal Dialysis), CAPD (Continuous Ambulatory Peritoneal Dialysis), CCPD (Continuous Cycle Peritoneal Dialysis), or Other. **Check only one block**. NOTE: Other has been placed on this form to be used only if a new method of dialysis is developed prior to the renewal of this form by Office of Management and Budget.
23. Enter the date (month, day, year) that a "regular course of dialysis" began. The beginning of the course of dialysis is counted from the beginning of regularly scheduled dialysis necessary for the treatment of end stage renal disease (ESRD) regardless of the dialysis setting. The date of the first dialysis treatment after the physician has determined that this patient has ESRD and has written a prescription for a "regular course of dialysis" is the "Date Regular Dialysis Began" regardless of whether this prescription was implemented in a hospital inpatient, outpatient, or home setting and regardless of any acute treatments received prior to the implementation of the prescription.

NOTE: For these purposes, end stage renal disease means irreversible damage to a person's kidneys so severely affecting his/her ability to remove or adjust blood wastes that in order to maintain life he or she must have either a course of dialysis or a kidney transplant to maintain life.

If re-entering the Medicare program, enter beginning date of the current ESRD episode. Note in Remarks, Item 49, that patient is restarting dialysis.

24. Enter date patient started chronic dialysis at current provider of dialysis services. In cases where patient transferred to current dialysis provider, this date will be after the date in Item 23.
25. If a patient began a regular course of dialysis, then stopped dialysis therapy, enter the last dialysis treatment date. Examples of when this field should be completed are: (1) dialysis stopped due to transplant; (2) patient died during Medicare 3-month qualifying period (also complete item 26); (3) patient withdrew from treatment.
26. If the patient has died, enter the date of death. If date of death is completed, please also complete CMS-2746 ESRD Death Notification and attach to ESRD Network copy of CMS-2728.
27. Enter the date(s) of the patient's kidney transplant(s). If re-entering the Medicare program, enter current transplant date.
28. Enter the name of the hospital where the patient received a kidney transplant on the date in Item 27.
29. Enter the 6-digit Medicare identification code of the hospital in Item 28 where the patient received a kidney transplant on the date entered in Item 27.
30. Enter date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation. This includes hospitalization for transplant workup in order to place the patient on a transplant waiting list.
31. Enter the name of the hospital where patient was admitted as an inpatient in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation.
32. Enter the 6-digit Medicare identification number for hospital in Item 31.
33. Check the appropriate functioning or nonfunctioning block.
34. If transplant is nonfunctioning, enter date patient returned to a regular course of dialysis. If patient did not stop dialysis post transplant, enter transplant date.
35. If applicable, check where patient is receiving dialysis treatment following transplant rejection. A nursing home or skilled nursing facility is considered as home setting.

Self-dialysis Training Patients (Medicare Applicants Only)

Normally, Medicare entitlement begins with the third month after the month a patient begins a regular course of dialysis treatment. This 3-month qualifying period may be waived if a patient begins a self-dialysis training program in a Medicare approved training facility and is expected to self-dialyze after the completion of the training program. Please complete items 36–43 if the patient has entered into a self-dialysis training program. Items 36–43 must be completed if the patient is applying for a Medicare waiver of the 3-month qualifying period for dialysis benefits based on participation in a self-care dialysis training program.

36. Enter the name of the provider furnishing self-care dialysis training.
37. Enter the 6-digit Medicare identification number for the training provider in Item 36.
38. Enter the date self-dialysis training began. (While it is expected that this date will be after the date patient started a regular course of dialysis, it should not be more than 30 days prior to the start of a regular course of dialysis.)
39. Check the appropriate block which describes the type of self-care dialysis training the patient began.
40. Check the appropriate block as to whether or not the physician certifies that the patient is expected to complete the training successfully and self-dialyze on a regular basis.
41. Enter date patient completed or is expected to complete self-dialysis training.
42. Enter printed name and signature of the attending physician or the physician familiar with the patient's self-care dialysis training.
43. Unique Physician Identification Number (UPIN) of physician in Item 42. (See Item 46 for explanation of UPIN.)
44. Enter the name of the physician who is supervising the patient's renal treatment at the time this form is completed.
45. Enter the area code and telephone number of the physician who is supervising the patient's renal treatment at the time this form is completed.
46. Enter the physician's UPIN assigned by CMS.

    A system of physician identifiers is mandated by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985. It requires a unique identifier for each physician who provides services for which Medicare payment is made. An identifier is assigned to each physician regardless of his or her practice configuration. The UPIN is established in a national Registry of Medicare Physician Identification and Eligibility Records (MPIER). Transamerica Occidental Life Insurance Company is the Registry Carrier that establishes and maintains the national registry of physicians receiving Part B Medicare payment. Its address is: UPIN Registry, Transamerica Occidental Life, P.O. Box 2575, Los Angeles, CA 90051-0575.
47. To be signed by the physician supervising the patient's kidney treatment. Signature of physician identified in Item 44. A stamped signature is unacceptable.
48. Enter date physician signed this form.
49. This remarks section may be used for any necessary comments by either the physician, patient, ESRD Network or Social Security field office.
50. The patient's signature authorizing the release of information to the Department of Health and Human Services must be secured here. If the patient is unable to sign the form, it should be signed by a relative, a person assuming responsibility for the patient or by a survivor.
51. The date patient signed form.

NOTICE

This form is to be completed for all End Stage Renal Disease patients beginning April 1, 1995, regardless of when the patient started dialysis or received a kidney transplant. Versions of the HCFA-2728 dated prior to April 1995 will not be accepted by the Social Security Administration or the ESRD Network Coordinating Councils.

CMS-2728-U3 (6-97)

APPENDIX B: DATA COLLECTION TOOL

DIABETES

Type II, adult-onset type or unspecified type diabetes

Type I, juvenile type, ketosis prone diabetes

CYSTIC/HEREDITARY/CONGENITAL DISEASES

Polycystic kidneys, adult type (dominant)

Polycystic, infantile (recessive)

Medullary cystic disease, including nephronophthisis

Tuberous sclerosis

Hereditary nephritis, Alport's syndrome

Cystinosis

Primary oxalosis

Fabry's disease

Congenital nephrotic syndrome

Drash syndrome, mesangial sclerosis

Congenital obstructive uropathy

Renal hypoplasia, dysplasia, oligonephronia

Prune belly syndrome

Hereditary/familial nephropathy

GLOMERULONEPHRITIS

Glomerulonephritis (GN)

(histologically not examined)

Focal glomerulosclerosis, focal sclerosing GN

Membranous nephropathy

Membranoproliferative GN type 1, diffuse MPGN

Dense deposit disease, MPGN type 2

IgA nephropathy, Berger's disease

(Proven by immunofluorescence)

IgM nephropathy (proven by immunofluorescence)

Rapidly progressive GN

Goodpasture's Syndrome

Post infectious GN, SBE

Other proliferative GN

SECONDARY GN/VASCULITIS

Lupus erythematosus, (SLE nephritis)

Henoch-Schonlein syndrome

Scleroderma

Hemolytic uremic syndrome

Polyarteritis

Wegener's granulomatosis

Nephropathy due to heroin abuse and related drugs

Vasculitis and its derivatives

Secondary GN, other

HYPERTENSION/LARGE VESSEL DISEASE

Renal disease due to hypertension (no primary renal disease)

Renal artery stenosis

Renal artery occlusion

Cholesterol emboli, renal emboli

INTERSTITIAL NEPHRITIS/PYELONEPHRITIS

Analgesic abuse

Radiation nephritis

Lead nephropathy

Nephropathy caused by other agents

Gouty nephropathy

Light chain nephropathy

Amyloidosis

NEOPLASMS/TUMORS

Renal tumor (malignant)

Urinary tract tumor (malignant)

Renal tumor (benign)

Urinary tract tumor (benign)

Renal tumor (unspecified)

Urinary tract tumor (unspecified)

Lymphoma of kidneys

Multiple myeloma

Complication post bone marrow or other transplant

MISCELLANEOUS CONDITIONS

Sickle cell disease/anemia

Sickle cell trait and other sickle cell (HbS/Hb other)

Post partum renal failure

AIDS nephropathy

Traumatic or surgical loss of kidney(s)

Hepatorenal syndrome

Tubular necrosis (no recovery)

Other renal disorders

Etiology uncertain

Co-Morbid Conditions (Current or during last 10 years)

Congestive heart failure

Ischemic heart disease, CAD

Myocardial infarction

Cardiac arrest

Cardiac dysrhythmia

Pericarditis

Cerebrovascular disease, CVA, TIA

Peripheral vascular disease

History of hypertension

Diabetes (primary or contributing)

Diabetes, currently on insulin

Chronic obstructive pulmonary disease

Tobacco use (current smoker)

Malignant neoplasm, Cancer

Alcohol dependence

Drug dependence

HIV positive status

AIDS

Amputation

Inability to ambulate

Inability to transfer

APPENDIX C: UNIVERSITY OF CENTRAL FLORIDA INSTITUTIONAL REVIEW BOARD APPROVAL

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Amma Serwaah-Bonsu**

Date: **October 18, 2010**

Dear Researcher:

On 10/18/2010, the IRB approved the following human participant research until 10/17/2011 inclusive:

Type of Review:	Submission Correction for UCF Initial Review Submission Form
Project Title:	Assessing Extracellular Volume Excess in Hypertensive Hemodialysis Patients
Investigator:	Amma Serwaah-Bonsu
IRB Number:	SBE-10-07150
Funding Agency:	
Grant Title:	
Research ID:	N/A

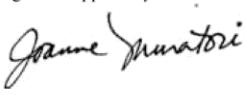
The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

If continuing review approval is not granted before the expiration date of 10/17/2011, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Joseph Bielitzki, DVM, UCF IRB Chair, this letter is signed by:

Signature applied by Joanne Muratori on 10/18/2010 10:57:37 AM EDT



IRB Coordinator

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