**PROJECT TITLE:** Accurate Bedside Clinical Assessment of Hypertensive and 'Symptomatic' Hypotensive Patient's Intravascular Volume Status with Hand-Carried Ultrasound Devices in Hemodialysis Clinic

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**SUMMARY:**

The number of people diagnosed and living with Kidney Failure requiring dialysis in Canada has tripled in the last two decades. In center hemodialysis is a thrice-weekly treatment that attempts to remove fluid and toxins rapidly and in a short time. One of the major difficulties is determining how much fluid to remove from a patient in a given treatment as the bedside physical exam is often inaccurate. Therefore the aim of this study is to assess volume status in chronic dialysis patients by measuring the IVC diameter employing a Hand-Carried Ultrasound. Patients with Kidney Failure were recruited to the study and each was scanned three times on three different dialysis sessions. Measurements of the Inferior Vena Cava were taken pre, mid, and post dialysis sessions. Measurements of the Inferior Vena Cava were compared to clinical surrogates of volume, which include, blood pressure, symptoms, and ultrafiltration removed. The student learnt ultrasound techniques to scan for the Inferior Vena Cava, as well, he learnt basic research and statistical skills in order to assess the reliability and feasibility of using a Hand-Carried Ultrasound in clinical practice.

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## Introduction

The number of people diagnosed and living with Kidney Failure requiring dialysis in Canada has tripled in the last two decades (1). Despite recent trends in more frequent in-center and home based prescriptions, the vast majority of patients remain on thrice-weekly, facility based hemodialysis. Fluid, electrolytes, and an array of uremic toxins accumulate between these treatments days and often, patients cannot restore normal physiology because of the intermittent nature of the sessions. Due in part to these factors, patients with Kidney Failure suffer significant degradation in health-related quality of life and annual mortality rates reaching 15-20% in most studies (2-5). However, by minimizing the intermittent nature of the treatments and intensifying dialysis prescriptions, improved outcomes can result likely due to better volume control (6). It is possible that not all patients benefit from intensified dialysis prescriptions, which require increased time on treatment for patients, and increased cost for payers. Accurate volume assessments may help guide the optimal use of intensified dialysis prescriptions, especially for resource intense facility based hemodialysis treatments.

### Volume Assessment

Dry weight, is the target weight that a clinician hopes the patient can be at after a dialysis treatment (7). This parameter is important because over or under estimation could lead to chronic hypervolemia or worse, acute hypovolemia. Chronic hypervolemia leads to hypertension, with resultant left ventricular hypertrophy, cardiomyopathies and mortality (8-11). Aggressively adjusting volume to try to prevent hypervolemia, however, leads to even worse outcomes (12-14). On the other hand, acute hypovolemia and subsequent hypotension is the most common complication on hemodialysis leading to dizziness, cramping, GI upset, dialysis access clotting, palpitation, tinnitus and in extreme situations, loss of consciousness, seizures and even death. An accurate, real time assessment of Intravascular Volume Status (IVS) could aid in establishing a true dry weight and avoiding the complications of hypo- or hypervolemia (15-19).

Presently, there are a variety of ways in assessing a patient's dry weight. Clinical methods are quick and easy to perform, but the accuracy and reliability have much to be desired and one method alone cannot determine a patient's dry weight (7). Non-clinical methods can provide a more objective assessment of dry weight, but are limited from a practical and resource standpoint (20). Table 1 summarizes the clinical and non-clinical methods employed. For the IVC, however, some of these disadvantages can be circumvented.

### Hand-Carried Ultrasound

A Hand-Carried Ultrasound (HCU) costs significantly less than the traditional ultrasound and can offer easy, reproducible, quantifiable, portable and non-invasive measurements of the Inferior Vena Cava. More specifically, the IVC diameter (IVCdi) and the IVC collapsibility index (IVCci), which studies have shown to have significant correlation to the right atrial pressure (19,21) and Intravascular Volume Status (IVS) (12). An accurate measurement of IVS is critical in patient care as it allows for a more precise estimation of the dry weight, which in turn, lets the patients achieve euvolemic status after every dialysis session. Adjusting the dry weight to the range of euvolemia suggested by the IVCdi and IVCci significantly decreases cardiac morbidities such as left ventricular mass and left atrial size and also increases the patient's quality of life by reducing adverse intradialytic events (10,15). By analyzing measurements taken from hypertensive, hypotensive, and normotensive patients, the relationship between IVC, IVS, and blood pressure may become more distinct.

## Objectives

The primary objective of this study is to determine if IVC diameter and collapsibility index, measured with a HCU, correlates with traditional assessment of volume status in patients undergoing hemodialysis.

As a secondary objective, we sought to determine whether dynamic intradialytic IVC diameter measurements correlate with the amount of volume removed and the systolic blood pressure on dialysis (16,22).

## Materials and Methods

### Patient Population

Prevalent hemodialysis patients were recruited from Seven Oaks General Hospital dialysis program in Winnipeg, Canada. Inclusion criteria for patients participating in the study were: 1) Receiving chronic dialysis for at least three months 2) No documented tricuspid regurgitation or heart failure, and 3) Adequate IVC visualization by HCU. Patients were recruited according to a priori blood pressure strata of hypertensive, hypotensive and normotensive. Hypertensive was defined as systolic blood pressures greater or equal to 140 mmHg throughout their treatment. Hypotensive patients had symptoms of hypotension (cramping, dizziness, GI upset, palpitations), and a systolic blood pressure of 100 mmHg and under at some point during their treatments. Normotensive was if systolic blood pressures ranged between 100 mmHg and 140 mmHg throughout their six previous treatment sessions. The following demographics and dialysis characteristics were collected by chart abstraction: age, sex, race, dialysis prescription, dialysis vintage, and dialysis access (see Table 2). Comorbidity data collected included: presence of documented cardiovascular disease (including CHF), diabetes, hypertension, and malignancy. Health Research Ethics Board from the University of Manitoba reviewed and granted approval for this study.

**HCU**

The Hand-Carried Ultrasound used in this study is a pocket-sized device produced by GE (Figure 1). It weighs 390 grams with broad-bandwidth phase array probe ranging from 1.7 to 3.8 MHz [GE]. It provides black and white two-dimensional and color Doppler in real time. The depth can be adjusted up to 24cm and video recorded. The retail price for this device is under $10,000.

A medical student with no previous experience or exposure to echocardiography performed the scans. He received a mixture of didactical and practical training over a one-week period. The measurements of patient's IVC were made at the sub-xiphoid position with the patient lying supine. Videos of the IVC were then recorded on a quick inspiration or "sniff" and expiration and the measurement of the diameter were done within 0.5 to 3 cm proximal to the junction of the ostium of the right atrium (Figure 2a) [ASE]. The collapsibility index was determined by measuring the IVC at its smallest point ("sniff"/quick inspiration) and determining if the diameter is greater or lesser than 50% of the maximum IVC diameter. Measurements of IVC indices, IVCdi and IVCci, were made by HCU before dialysis, mid way through dialysis, and after dialysis. Similarly, blood pressure and symptom recordings were made at the same durations as part of routine practice. Each patient were scanned on three different dialysis sessions separated by at least a week and on the same day of the week to minimize the effect of differential fluid gains on longer "breaks" from dialysis. The IVC diameters over the three sessions were reported as means. Patients were separated into individual scans when we sought for relationship between IVC diameters and clinical measures of volume status. In addition, in a smaller subset of patients, the IVC was taken two hours after HD to allow interstitial fluids to shift into equilibrium. The selection for these patients was strictly based on patient availability.

**Statistical Analysis**

Continuous variables of interest were summarized as means with standard deviations. Differences in baseline characteristics were determined by two-tailed t-test for continuous variables and chi-square for dichotomous variables. Univariate regression and logistic analysis were performed for IVC diameter and clinical variables indicating volume status. All statistical tests were considered significant if $p < 0.05$.

**<u>Results</u>**

**Patient Population**

For the study, 43 patients were consented (Table 3). From that number, 7 people withdrew consent, 3 were not scanned due to scheduling conflicts or switching to a different dialysis modality, and 4 were taken out due to a poorly visualized IVC (Figure

2b). Patient demographics and comorbidity information can be seen in Table 2. The average age of patients is 63 with 65.5% of the participants being male. The average patient had been on dialysis for almost 5 years with the main cause of kidney failure being diabetes. Cardiovascular disease, diabetes, and hypertension were highly prevalent in this patient population.

**IVC Diameter and Collapsibility Index**

The IVC diameter for pre-dialysis (Table 4) is 1.65±0.40 cm, mid dialysis is 1.29±0.33 cm, and post is 1.39±0.32 cm. The IVC diameter appeared to be at its smallest point in the middle of the dialysis session (Figure 3) as opposed to the end. Student's Paired T-test was performed and statistically significant ($p<0.05$) changes in IVC diameter occur between pre and post dialysis session, pre and mid, and as well, mid and post. Moreover, for the 5 patients that came back for an additional scan two hours after their dialysis session ended, the rebounding trend of the IVC diameter toward pre-dialysis levels continued. The collapsibility index did not appear to exhibit any trend from pre to mid and post dialysis.

**Volume Status**

The $r^2$ value between the change in IVC diameter and change in systolic blood pressure is 0.00262. Post IVC diameter seems to associate with post-dialytic hypotensive symptoms. The $r^2$ value between change in IVC diameter and ultrafiltration is 0.02468. Univariate analysis of IVC diameter and clinical indicators of fluid status can be seen in Table 5. IVC collapsibility had a poor association with all clinical measurements of volume status.

## <u>Discussion</u>

We found that the IVC diameter changes throughout the treatment. However, there does not appear to be any significant association between IVC diameter and blood pressure, ultrafiltration amount, or symptoms (Figure 4a and 4b, Table 5). Therefore, dynamic IVC diameter monitoring does not add value to current methods of assessing volume status. Blood pressure and symptoms were compared to IVC diameter because they are clinical means of assessing volume status in patients (7,20). Systolic blood pressures and UF removed were examined due to evidence from previous studies that they have a strong predictive value of long-term comorbidities for patients on hemodialysis (8,9,14,23). It should be noted that blood pressure is one of the most important measures that we currently use to assess volume status. It is associated with mortality and morbidity, however, it is not perfect for every patient group. In some patients, consistently high blood pressure does not equal fluid overload. In other patients, hypervolemia can persist despite low blood pressures. In spite of the lack of correlation between the IVC diameter and blood pressure, it is possible that IVC diameter can still offer valuable information and be an addition assessment to volume status. In previous studies, it has shown that when using the IVC diameter to adjust for dry weight, patients experienced decreased number of adverse clinical events leading to increased quality of life (15-19). It is possible that very much like all other clinical and non-clinical methods, IVC diameter simply gives limited amount of information regarding volume status. IVC collapsibility had a poor association with all clinical measurements of volume status.

A study done by Brennan et al. (2006) also involved the measurement of the Intravascular Volume Status by HCU in hemodialysis clinic. Similar to our study, they also used inexperienced operators. They concluded that using the HCU to adjust for euvolemia serves to decrease adverse intradialytic events. Our study is unique in several ways. Firstly, they scanned 89 consecutive patients without excluding patients that may have cardiac conditions, such as tricuspid regurgitation and congestive heart failure, that bias the diameter of the IVC. It would cause otherwise normal or euvolemic IVC diameters to expand into the range of hypervolemia. Secondly, our study didn't assume that IVC diameter and collapsibility index was already validated in the hemodialysis population against current predictors of poor outcomes (BP, total UF, symptoms), but rather we attempted to find out whether it is. Thirdly, in the Brennan study, patients were scanned anywhere from immediately after treatment to half an hour post treatment. The IVC diameter can change quite significantly in that period of time, and consequently the determination of the patients' volume status, based off of the IVC diameters, can as well.

We found that there were significant, but not unexpected, changes between the IVC diameters before and after treatment (Figure 3). However, we did not expect to find that the IVC diameters to be at its smallest size in the middle of treatment. Despite fluid being removed throughout the entire session, the IVC diameter does not seem to reflect this fluid loss exactly. There could be a couple of processes that we can attribute to this finding. It is possible that the interstitial fluids are equilibrating and compensating with the fluids lost in the intravascular space due to dialysis. We found that with the five patients that were brought back two hours after their dialysis session ended, their IVC diameters continued to increase, enclosing on sizes that were similar to pre-dialysis. It could also be possible that the rate of which the fluids are taken off of patient varies. Two of our patients had more fluid taken off closer to the beginning of treatment. Most, however, maintain a steady rate throughout dialysis.

When we compared symptoms to changes in IVC diameters, we observed a correlation between post-dialysis IVC diameter and post-dialysis symptoms (Table 5). We did not, however, see differences in change in IVC diameter and post-dialysis symptoms. This suggests that when the IVC diameter is at a certain size, it could predict hypovolemic symptoms such as dizziness, cramps, nausea, and vomiting.

Lastly, of the 33 patients that were scanned, only 4 patients had to be discontinued due to poor IVC image quality. Our 88% success rate in reliably visualizing the IVC is near equal to the 89% that was posted in a similar study (16). Still, it is lower than the 94-95% found in other IVC studies (24,25). However, the other studies used experienced sonographers and did not have to use the HCU, which despite its considerable advantage in portability and cost, is not as powerful as a traditional ultrasound machine.

## Limitations

Our results should be interpreted with several caveats in mind. Firstly, with regards to the HCU, we were limited by its ability to provide quality imaging past the depth of 20cm. In obese and morbidly obese patients, this is a significant problem. There are times where their IVCs can be visualized, but the HCU does not have the power to do so.

We also need to take into consideration of the size of our patient population. Although we were able to find changes in the IVC diameters throughout the treatment session, we were not able to find an association between IVC diameters and clinical volume assessment. However, if we had a larger population size, we could have subdivided them into smaller groups (ie. Difference in pre and post blood pressure of greater or less than 20 mmHg). It is possible that the IVC diameter can still be valuable in certain groups. We chose subgroups a priori in this pilot study of hypotensive, hypertensive and normotensives to look for a signal of effect of HCU measurements in these three categories that could presumably have different volume status parameters during dialysis. We found no significant differences in any of these groups leading us to conclude that this technique may simply not be sensitive enough to detect clinically relevant intradialytic volume changes.

## Conclusion

Significant changes in Inferior Vena Cava diameter were observed throughout the entire hemodialysis treatment as fluid was removed. However, these changes do not correlate with changes in systolic blood pressure, volume removed, or symptoms associated with rapid volume removal. IVC diameter does not appear to be a reliable surrogate for clinically important Intravascular Volume Status. Accurate assessment of Inferior Vena Cava diameter using a hand carried ultrasound machine is easily learned and performed by an unskilled operator.

Future studies are needed to explore better methods of evaluating Intravascular Volume Status using larger numbers of patients.

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**Table 1:** Comparison of Clinical and Non-Clinical Assessments of Volume Status

| | Method | Advantages | Disadvantages | References |
|---|---|---|---|---|
| Clinical | Blood Pressure | - Quick, easy<br>- Noninvasive<br>- Indicates need to change dry weight<br>- Correlates well with negative outcomes | - Not useful in patients with poor cardiac function | - Advantage: (23,26)<br>- Disadvantage: (27) |
| Clinical | Edema | - Quick, easy<br>- Good indicator of excess fluid<br>- Noninvasive | - Some patients can be fluid overload without edema | - Advantage + Disadvantage: (28) |
| Clinical | Jugular Venous Pressure | - Quick, easy<br>- Useful sign of excess fluid<br>- Noninvasive | - Not useful in patients with poor cardiac function<br>- Cannot be easily visualized in patients with catheters | - Advantage: (29)<br>- Disadvantage: (30) |
| Non-Clinical | Inferior Vena Cava Diameter | - Widely available<br>- Reflect intravascular volumes status<br>- Useful in dry weight assessment | - Requires skilled operators<br>- Not useful in patients with heart failure or tricuspid regurgitation<br>- Highly variable; timing is important | - Advantage: (18,26)<br>- Disadvantage: (31) |
| Non-Clinical | Blood Volume Monitoring | - Can be used to assess dry weight<br>- Prevention of hypotension | - Only measures relative volume<br>- Other factors may affect hydration of the interstitial space<br>- High variation among patients | - Advantage: (32)<br>- Disadvantage: (33) |
| Non-Clinical | Bioelectrical Impedance Analysis | - Useful for dry weight assessment<br>- Easy to use<br>- Determines fluid status in all compartments | - Different processes at work that can confound measurements of the ICF and ECF | - Advantage: (34-36)<br>- Disadvantage: (37) |
| Non-Clinical | Extravascular Lung Water Index | - Accurate measurement of volume status | - Invasive<br>- Questionable applicability in everyday clinical practice | - Advantage and Disadvantage: (38) |

**Table 2** – Baseline Characteristics of the Study Population

| Demographics | |
|---|---|
| *n* | 29 |
| Age | 63.07 ± 16.44 |
| Male Gender | 19 (65.5%) |
| Race | Caucasian = 22<br>Aboriginal = 4<br>Other = 3 |
| Dialysis Vintage (months) | 57.25 ± 59.34 |
| Etiology of Kidney Disease | Diabetes = 16<br>Hypertension = 3<br>Glomerulonephritis = 7<br>Other (unknown etiology) = 3 |

| | |
|---|---|
| **Physical Examination** | |
| Height (cm) | 175.1 ± 7.6 |
| Weight (kg) | 77.05 ± 16.15 |
| BMI (kg/cm$^2$) | 25.13 |
| **Co-morbid Conditions** | |
| Cardiovascular Disease | 17 |
| Diabetes | 18 |
| Hypertension | 26 |
| Malignancy | 7 |
| Smoking | 7 |

**Table 3 – Patient Participation**

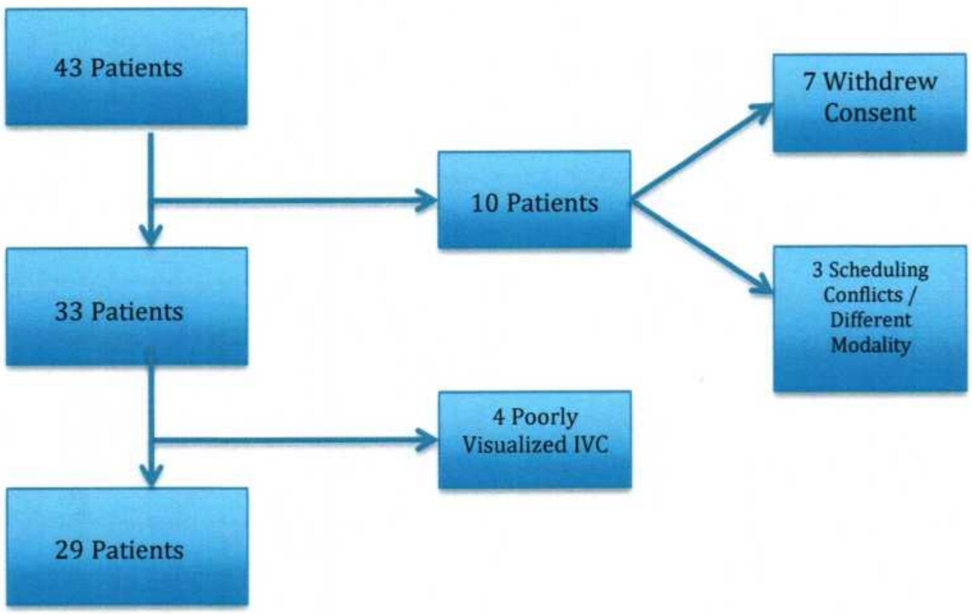



**Table 4 –** Characteristics of the Dialysis Treatments

| | **Dialysis Access** | **Catheter = 15**<br>**Fistula = 14** |
|---|---|---|
| | Number of Treatments | 82 |
| | Treatment Duration (h) | 3.95 ± 0.28 |
| **Pre-Dialysis** | Systolic Sitting Blood Pressure (mmHg) | 138 ± 26 |
| | Inferior Vena Cava Diameter (cm) | 1.65 ± 0.40 |
| **Mid-Dialysis** | Systolic Lying Blood Pressure (mmHg) | 129 ± 26 |
| | Inferior Vena Cava Diameter (cm) | 1.29±0.33 |
| **Post-Dialysis** | Systolic Sitting Blood Pressure (mmHg) | 137 ± 28 |
| | Inferior Vena Cava Diameter (cm) | 1.39 ± 0.32 |
| **Clinical Measurements** | UF (mL) | 2648.63 ± 851.33 |
| | UF Rate (mL/h) | 703.57 ± 276.97 |
| | Kt/V | 1.66 ± 0.34 |
| | Qb (mL/min) | 350.43 ± 35.43 |

**Table 5 –** Comparison of IVC Diameter and Clinical Measurements of Volume Status

| | | Blood Pressure | | | Symptoms | | Fluid Removed |
|---|---|---|---|---|---|---|---|
| | | Pre-Dialysis | Post-Dialysis | Change | Pre-Dialysis | Post-Dialysis | UF |
| IVC Diameters | Pre | 0.5908 | - | - | 0.6952 | - | 0.8501 |
| | Post | - | 0.5954 | - | - | 0.0112 | 0.3418 |
| | Change | - | - | 0.6481 | - | 0.3083 | 0.1587 |

**Figure 1**

**Figure 2a and 2b**

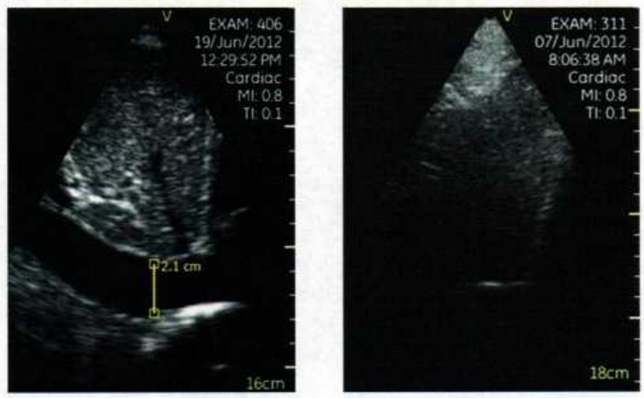



**Figure 3 –** Mean Inferior Vena Cava Diameters of 29 Patients Throughout Treatment

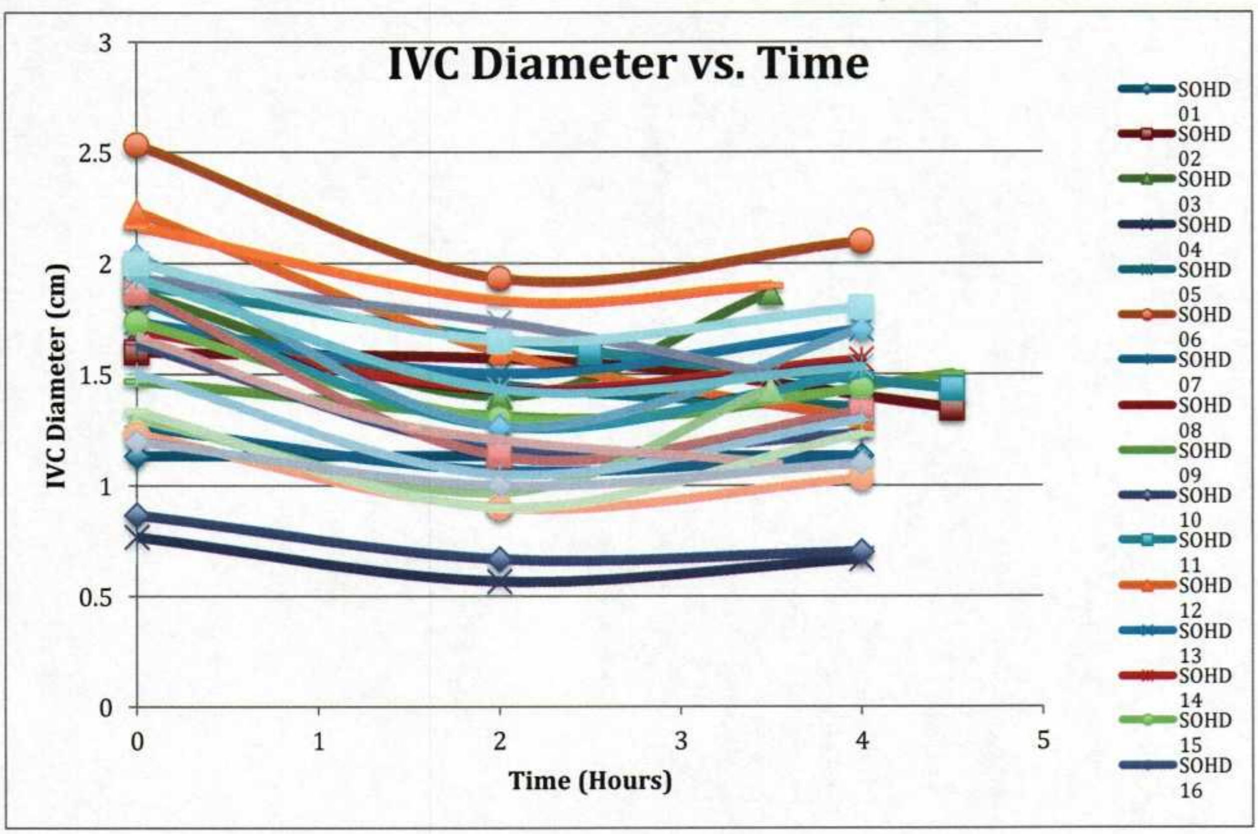
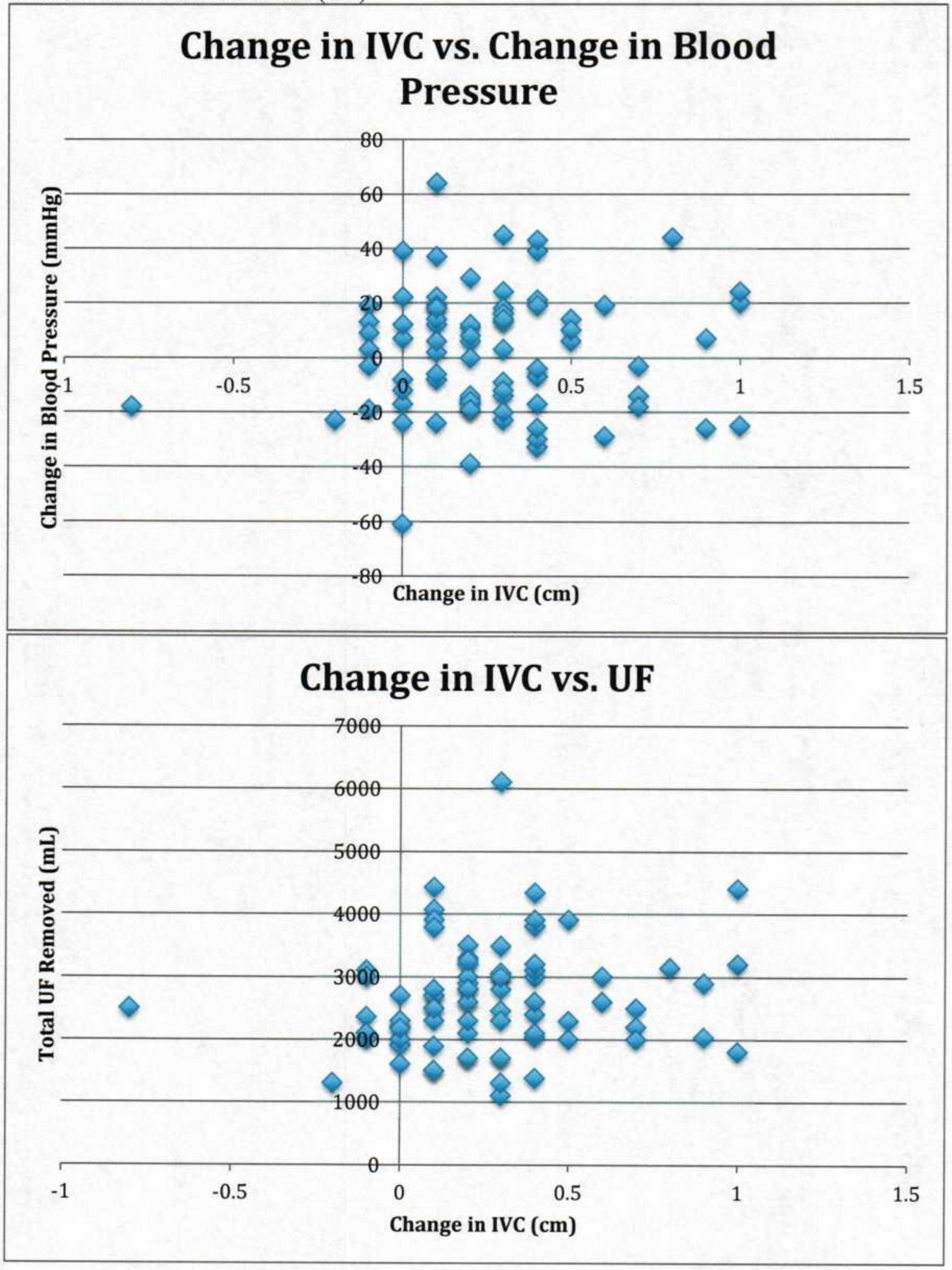


**Figure 4a and 4b –** Comparison of Change in IVC Diameter with Changes in Blood Pressure and Fluid Removed (UF)



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