2018

Ultrasound measurements on the inferior vena cava by renal nursing staff for assessment and management of intravascular volume status in haemodialysis patients

Ulrich Steinwandel

Edith Cowan University

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Ultrasound measurements on the inferior vena cava by renal nursing staff for assessment and management of intravascular volume status in haemodialysis patients

This thesis is presented for the degree of

Doctor of Philosophy

Ulrich Steinwandel

Edith Cowan University
School of Nursing and Midwifery
2018
Abstract

**Title:** Ultrasound measurements on the inferior vena cava (IVC-US) by renal nursing staff for assessment and management of intravascular volume status in haemodialysis patients.

**Aims:** The primary aim of this thesis was to provide evidence that renal nurses could safely and efficiently perform IVC-US on haemodialysis patients to obtain objective assessment of intravascular volume status and potentially reduce adverse events and morbidity.

The secondary aims for this study were: (1) conduct a systematic literature review to identify evidence if renal nurses have previously used this method for intravascular volume assessment; (2) teach a renal nurse through a staged educational programme, guided by a medically trained ultrasonographer, a sonologist, to gain competency in ultrasound image acquisition and interpretation of the scans; (3) measure the prevalence of any form of intradialytic hypotension in a satellite haemodialysis clinic over a three-month period and (4) attain concurrent IVC-US and bioimpedance spectroscopy measurements on 30 patients during their haemodialysis treatment and to compare these findings with their intravascular volume status using the traditional clinical nursing assessment method.

**Materials and Methods:** To achieve this primary aim, this thesis was separated into multiple phases. First, a systematic literature review of medical and nursing databases was performed to summarise the use of IVC-US in haemodialysis patients by renal nurses. The second phase involved a retrospective data analysis, where the prevalence rate of nurse-documented fluid related intradialytic hypotensive events was measured and a Generalised Estimating Equation (GEE) model was used to predict the likelihood of any form of intradialytic hypotension or postdialytic overhydration. In the next phase a four-step educational programme was developed in collaboration with an expert sonologist, guiding the renal nurse through the process of skill acquisition and accurate fluid assessment based on nurse-performed IVC-US scans. Following this phase, and after receiving theoretical training and performing 100 proctored scans, the renal nurse then performed 60 IVC-US scans independently, which were subsequently assessed by two sonologists, resulting in a cross-sectional interrater study, confirming competency. The final phase of the thesis consisted of a simulative pilot study, where 30 haemodialysis patients were assessed during three intradialytic moments of a single session on their intravascular volume status with IVC-US.

**Results:** The systematic literature review revealed that there is a paucity of knowledge regarding renal nurses and IVC-US. The 3-month data analysis has shown that intradialytic hypotension (IDH) was still the most common adverse intradialytic event with 13.1% of all treatments affected. The renal nurse mastered the educational programme and was deemed competent by the experts. Finally, the simulative pilot study revealed that if IVC-US had been performed and indicated intravascular hypovolemia, patients had a 14-fold chance to experience subsequent IDH events. An algorithm using IVC-US combined with bioimpedance spectroscopy (BIS) and mean arterial pressure (MAP) revealed a sensitivity of 95% and a specificity of 100% for the prevention of IDH.
Conclusions: This thesis demonstrates the obvious need for more objective and reliable fluid assessment methods in the haemodialysis population to improve clinical outcomes. Most importantly, it has been shown that renal nurses can master the skill to perform IVC-US and that IVC-US is a useful and reliable method of fluid assessment. Performing IVC-US is a transferrable skill and has potential to be preventative for intradialytic hypotension if added to the clinical fluid assessment routine by renal nurses. It has potential to change clinical practice and policy in future, but further research studies are needed to provide evidence for this.

Keywords: haemodialysis, renal nurses, intradialytic hypotension, ultrasound inferior vena cava, nursing competency, interrater reliability, intravascular volume status, point of care ultrasound, symptomatic hypotension, asymptomatic hypotension, overhydration, fluid overload, satellite dialysis, clinical skills, fluid assessment, hydration status, nurse education, nursing skills, prevention
Chapter 5
  Assessing nursing competency in volume assessment using IVC-US
    5.1 Introduction

Chapter 6
  6. Correlation and predictive value of IVC-US with BIS when observing for intravascular volume
    6.1 Introduction

Chapter 7
  7. Discussion
    7.1 Introduction
    7.2 Overview of major findings
    7.2.1 IVC-US as a tool for renal nurses
    7.2.2 The prevalence rate of intradialytic hypotension (IDH)
    7.2.3 The educational programme for renal nurses to perform IVC-US and to attain competency
    7.2.4 Assessing nursing competency in volume assessment using IVC-US
    7.2.5 Predictive value of IVC-US and BIS when observing for intravascular volume
    7.2.6 Summary of major findings
    7.3 Limitations
    7.4 Recommendations for policy, practice and research

Chapter 8
  8. Conclusion

References

Appendices
  Copyright declaration for systematic literature review article (Journal of Renal Care) 2017
  Copyright declaration for interrater study article (Hemodialysis International) 2017
  Copyright declaration for Prevalence article (Journal of Clinical Nursing) 2018
  Renal Society of Australasia Communiqué 2017
  The Raine Medical Research Foundation Annual Report 2015
  The Raine Medical Research Foundation Annual Report 2016
  The Raine Medical Research Foundation Annual Report 2017
  Certificate of attendance – Renal Society of Australasia – WA Branch Meeting Perth 2017
  Renal Society of Australasia WA Branch Symposium Program 2017
  Certificate of attendance - Renal Society of Australasia – Annual Conference Sydney 2017
  Renal Society of Australasia – Annual conference Sydney 2017 – Abstract submission
  Renal Society of Australasia - Annual conference program Sydney 2017
  Fremantle Hospital Medical Research Foundation Annual report 2013/2014
  STROBE checklist for cross-sectional studies
  STROBE checklist for observational studies
List of Tables

Table 1-1 IVCCI cut-offs according to the ‘Guidelines for the Echocardiographic Assessment of the Right Heart in Adults’ ........................................................................................................................................... 18

Table 1-2 Indexed vena cava diameter corrected for body surface area (VCDi) cutoffs according to ‘Echography of the Inferior Vena Cava is a Simple and Reliable Tool for Estimation of ‘Dry weight’ in Haemodialysis Patients’ (Cheriex, Leunissen, Janssen, 1989) ........................................................................................................................................ 18
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Annual Reports


Statement of Originality of Authorship

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(Ulrich Clemens Steinwandel)
Pages ix – xiv, Statement of Originality of Authorship, are not included in this version of the thesis.
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-IDH</td>
<td>Asymptomatic intradialytic hypotension</td>
</tr>
<tr>
<td>BIS</td>
<td>Bioimpedance spectroscopy</td>
</tr>
<tr>
<td>BCM</td>
<td>Body Composition Monitor</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>BP</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>BSA</td>
<td>Body surface area</td>
</tr>
<tr>
<td>BVM</td>
<td>Blood Volume Monitor</td>
</tr>
<tr>
<td>EFV</td>
<td>Extracellular fluid volume</td>
</tr>
<tr>
<td>ESRD</td>
<td>End-stage renal disease</td>
</tr>
<tr>
<td>FMC</td>
<td>Fresenius Medical Care</td>
</tr>
<tr>
<td>GEE</td>
<td>Generalised Estimating Equation</td>
</tr>
<tr>
<td>HD</td>
<td>Haemodialysis</td>
</tr>
<tr>
<td>HDF</td>
<td>Haemodiafiltration</td>
</tr>
<tr>
<td>IDH</td>
<td>Intradialytic hypotension</td>
</tr>
<tr>
<td>IDWG</td>
<td>Interdialytic weight gain</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>IVC</td>
<td>Inferior vena cava</td>
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<tr>
<td>IVCd</td>
<td>Inferior vena cava diameter</td>
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<tr>
<td>IVCd_{min}</td>
<td>Indexed minimum inferior vena cava diameter</td>
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<tr>
<td>IVCd_{max}</td>
<td>Indexed maximum inferior vena cava diameter</td>
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<tr>
<td>IVC_{min}</td>
<td>Minimum inferior vena cava diameter</td>
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<tr>
<td>IVC_{max}</td>
<td>Maximum inferior vena cava diameter</td>
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<tr>
<td>IVCCI</td>
<td>Inferior vena cava collapsibility index</td>
</tr>
<tr>
<td>IVC-US</td>
<td>Ultrasound of the inferior vena cava</td>
</tr>
<tr>
<td>IBW</td>
<td>Ideal Body Weight</td>
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<tr>
<td>KDOQI</td>
<td>Kidney Disease Outcome Quality Initiative</td>
</tr>
<tr>
<td>LA</td>
<td>Long axis</td>
</tr>
<tr>
<td>LUS</td>
<td>Lung ultrasound</td>
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<tr>
<td>LVH</td>
<td>Left ventricular hypertrophy</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>--------------</td>
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<tr>
<td>MAP</td>
<td>Mean arterial pressure</td>
</tr>
<tr>
<td>MFBIA</td>
<td>Multifrequency bioelectrical impedance analysis</td>
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<tr>
<td>NKF</td>
<td>National Kidney Foundation</td>
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<tr>
<td>NQF</td>
<td>National Quality Forum</td>
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<tr>
<td>OH</td>
<td>Overhydration</td>
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<tr>
<td>POCUS</td>
<td>Point-of-care ultrasonography</td>
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<tr>
<td>QIP</td>
<td>Quality Incentive Program</td>
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<tr>
<td>RBV</td>
<td>Relative blood volume</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<tr>
<td>RRT</td>
<td>Renal Replacement Therapy</td>
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<tr>
<td>SA</td>
<td>Short axis</td>
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<tr>
<td>SBP</td>
<td>Systolic blood pressure</td>
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<td>S-IDH</td>
<td>Symptomatic intradialytic hypotension</td>
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<tr>
<td>TDMS</td>
<td>Therapy Data Management System</td>
</tr>
<tr>
<td>UF</td>
<td>Ultrafiltration</td>
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<tr>
<td>UFR</td>
<td>Ultrafiltration rate</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>US</td>
<td>Ultrasound</td>
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<tr>
<td>VCDi</td>
<td>Indexed vena cava diameter</td>
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<td>WA</td>
<td>Western Australia</td>
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Introduction

Haemodialysis and intradialytic hypotension (IDH)

This first chapter describes some of the daily challenges renal nurses in Western Australia (WA) face when they perform the technical procedure of haemodialysis (HD) on patients under their care. Satellite HD clinics in WA are nurse-led, which means there are generally no doctors present when treatments are performed. This implies that renal nurses have the sole responsibility for the assessment of the patient for safe performance of treatments and they have to prevent patients from unnecessary harm or adverse events. The nursing care they deliver is determined by their standards of practice according to the definitions outlined by the Nursing and Midwifery Board of Australia (Cashin et al., 2017).

In 2012 there were 11,446 chronic dialysis patients in Australia (Briggs, Hurst, McDonald, & Clayton, 2013). The majority (61%) of these receive HD treatment three times per week for up to five hours per session in a satellite dialysis clinic as outpatients across all states and territories of Australia (Briggs et al., 2013). HD is a medical treatment which aims to remove excess fluid and metabolic waste products in patients with end stage renal disease (ESRD), which is equivalent to stage five chronic kidney disease (CKD) (Mahon, Jenkins, & Burnapp, 2013). CKD is a clinical condition, characterised by a gradual loss of kidney function over time predominantly caused by hypertension and diabetes mellitus (Thomas, 2013). Patients with CKD usually start with ongoing HD treatment once their kidney function declines below a glomerular filtration rate (GFR) of < 7-9 mL/min/1.73 m² in combination with worsening of clinical symptoms (Thomas, 2013). Symptoms include fluid retention, fatigue and weakness caused by an increase in metabolic substances which are normally excreted in the urine (Mahon et al., 2013). Furthermore, HD aims for a physiological balance of electrolytes and blood pH in addition to normalisation of the blood pressure (Thomas, 2013).

Prior to a regular HD session and for assessment of the clinical condition of a patient, a renal nurse performs a brief visual observation for any signs of fluid overload such as oedema (swollen ankles or legs), shortness of breath or elevated jugular vein pressure (Mahon et al., 2013, p. 384), and the patient is weighed. It is assumed that this gain of bodyweight since the last treatment represents the accumulated fluid that would have been normally excreted by the kidneys. Then, the renal nurse calculates and decides on an individual fluid removal (ultrafiltration (UF) goal in ml) for the present treatment. This decision is mainly based on the bodyweight gain.
of the patient since the last treatment, the current blood pressure and the clinical condition. This UF goal will then be entered into the HD machine and the patient will be connected via two cannulae and an extracorporeal blood circuit onto the machine. The HD machine then gradually removes the pre-set volume of fluid from the patient’s blood by negative (hydrostatic) pressure in the dialyser, an artificial blood filter which removes fluid and metabolic substances. Over 4 to 5 hours it is expected that the patient achieves the calculated fluid volume removal upon cessation of the session without clinical complications and is able to leave the satellite dialysis clinic in a stable physical condition (Mahon et al., 2013). Renal nurses, as part of the assessment also need to establish a new, or review an established ideal body weight (IBW) regularly for each patient as the major guideline for the UF goal for each dialysis session (Kinton, 2005). IBW is defined as the “lowest tolerated post dialysis weight at which there are minimal signs or symptoms of hypovolemia or hypervolemia” (Sinha & Agarwal, 2009).

In all WA satellite dialysis units, there are no doctors available on-site during treatment hours, which means nurses are responsible for making critical decisions regarding the amount of fluid to be removed, a crucial determinant of a patient’s well-being and morbidity. Fluid removal during HD is essential for maintaining the overall condition of patients with ESRD. Sometimes HD patients experience adverse events during dialysis, often due to intradialytic hypotension (IDH) (Burton, 2009, p. 48).

The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) is an American institution which provides yearly updates on evidence-based clinical practice guidelines for all stages of CKD and related complications. These guidelines are internationally recognised to improve the quality of life of many patients with CKD. The NKF KDOQI guidelines define IDH as: “A decrease in systolic blood pressure ≥ 20 mmHg or a decrease in mean arterial pressure by 10 mmHg associated with symptoms that include: abdominal discomfort, yawning, sighing, nausea, vomiting, muscle cramps, restlessness, dizziness or fainting and anxiety. These clinical events indicate the need for nursing interventions.” (National Kidney Foundation Inc., 2005)

This symptomatic IDH (S-IDH) is normally caused by an UF goal which has been chosen too high or has been achieved too fast and it can be managed by adjusting the UF goal on the dialysis machine and administering IV saline (Hayes & Hothi, 2011). IDH can also occur without any clinical symptoms as asymptomatic IDH (A-IDH) and has been defined as a systolic blood pressure (SBP) lower than 100mmHg without symptoms (Chesterton,
Selby, Burton, & McIntyre, 2009). The Hemodialysis (HEMO) study with 1426 participants revealed that IDH occurred in a median of 12.5% of dialysis sessions and required nursing interventions including administration of intravenous administered saline and a reduced ultrafiltration rate (Sherman & Kapoian, 2011). These authors support reducing the frequency of IDH as it can cause cardiac stunning, leading ultimately to irreversible heart damage. Moreover, it increases the risk for vascular access thrombosis (VAT), which is critical for HD patients as their arteriovenous fistula (AVF) is their primary option for connecting to the HD machine (Mahon et al., 2013; Sherman & Kapoian, 2011). The AVF is a surgically created vascular access, an artificial shortcut between an artery and a vein and is the vascular access of choice for HD. An AVF is necessary to perform maintenance HD, as during each session large blood volumes, typically around 90 litres per session, need to be circulated through the HD machine to achieve adequate dialysis (Ganie, Lone, Dar, Lone, & Wani, 2013). Although the native AVF is regarded as the vascular access of first choice and is predominantly used in Australia, central venous catheters (CVC) are also often placed in patients requiring dialysis and they appear not to be adversely affected from VAT (following an episode of IDH) due to their technical characteristics when compared to AVF (Roberts, Polkinghorne, McDonald, & Ierino, 2011).

One potential impact of conventional HD is recurrent systemic circulatory stress on multiple organ systems such as the heart, brain, gut and the kidneys (McIntyre, 2010). This is important as not all patients with ESRD on HD have completely lost their kidney function, and some patients are left with a reasonable fluid excretion function (Davenport, 2016). Adverse events during treatment such as IDH have a negative impact on residual kidney function and could have irreversible consequences on the long-term quality of life of patients (McIntyre, 2010). Yet, renal nurses who witness the occurrence of IDH daily have only a few objective parameters available to determine a patient’s fluid status, such as blood pressure and body weight. They must assume that the patient’s blood pressure status throughout the course of HD reflects the current intravascular fluid status, due to the lack of any other non-invasive objective parameters.

Brennan et al. (2006) demonstrated that the ultrasound (US) assessment of the inferior vena cava (IVC) can be useful for evaluating the volume-status of a patient. Their study also revealed that medical residents with minimal echocardiographic training could adequately measure the IVC with a portable ultrasound device. When compared to previous studies their achievement of obtaining high-quality pictures was only slightly lower (89%) than those of experienced sonographers (94%). Importantly, they also demonstrated that almost
50% of their patients were volume depleted at the start of their dialysis session. They concluded that an IVC-US was an achievable option for swiftly assessing the intravascular fluid status in a renal outpatient clinic setting.

Renal nurses are crucial to monitoring and improving fluid assessment of their patients as they see their patients for extended periods at least three times per week, which is much more often than renal consultants (Chamney, 2007; San Miguel, 2010). Evidence shows medical residents achieved good ultrasound skills with minimal training, so it is postulated that renal nurses would also be able to learn this skill and use it to potentially enhance fluid assessment in HD patients. As such, this project sets out to assess whether trained renal nurses can safely and efficiently perform IVC-US measurements on HD patients to objectively assess their fluid status, ideally better defining the intended UF goal for the dialysis session and thus reducing the risk of IDH.

**Aims of this thesis**

To provide evidence that renal nurses could safely and efficiently perform ultrasound on the inferior vena cava (IVC-US) on HD patients to obtain an objective assessment of intravascular volume status and potentially reduce adverse events and morbidity.

**Research questions**

Considering the issues described above in determining the objective measurement of the intravascular volume status of HD patients during their treatment, the following research questions have been articulated for this thesis:

**Primary question**

Can a renal nurse safely and efficiently perform IVC-US on HD patients and obtain an objective assessment of their fluid status, and could these findings potentially lead to improved health outcomes for patients?
Secondary questions

- What is the prevalence rate of intradialytic hypotension episodes in a nurse-led satellite HD clinic in Western Australia (WA)?
- Is the traditional predialytic clinical fluid assessment performed by renal nurses efficient and/or sufficient to prevent adverse events of intradialytic hypotension?
- Is there any evidence that highlights renal nurses have previously performed IVC-US to determine intravascular volume status in HD patients?
- What is the design and structure of an educational programme for renal nurses to successfully acquire the skills for IVC-US?
- Can a renal nurse learn the skill of IVC-US as taught by a sonologist and gain competency to perform IVC-US and objectively assess the intravascular volume status of a HD patient?
- Does the intravascular volume status in HD patients measured by IVC-US correlate with other validated techniques such as bioimpedance spectroscopy (BIS)?
- Could renal nurse-initiated IVC-US reduce the incidence of IDH and lead to better patient outcomes?

Research objectives

At the end of this thesis the candidate will have achieved the following research objectives:

1. performed a structured systematic literature review to find relevant peer-reviewed articles in regard to the use of IVC-US by renal nurses for intravascular volume assessment
2. measured the prevalence of S-IDH, A-IDH and post-dialysis overhydration in a satellite HD clinic over a three-month period
3. developed and instructed a renal nurse through a staged educational programme guided by a sonologist to gain competency in ultrasound image acquisition and interpretation of the scans
4. obtained simultaneously BIS and IVC-US scans on 30 patients over the course of a single treatment session and compare the findings on intravascular volume status with the traditional clinical assessment method
5. hypothesised on the usefulness of IVC-US in preventing adverse events during HD
Significance

The significance of this thesis is that it is the first to explore the use of IVC-US in renal nurse clinical practice. IVC-US has been shown to reliably visualise intravascular volume status at any intradialytic time, providing the observer with essential information to reconsider initial decisions. This could potentially be preventative for S-IDH and A-IDH episodes, which represent the most common adverse events during HD. This thesis also provides detailed insight into the prevalence rate of both forms of IDH in a typical Western Australian satellite dialysis clinic. During this research, an educational programme evolved, consisting of four consecutive stages, which demonstrated the feasibility and success of such a programme in the transferability of skills. Results from this research gives the renal clinical community potential evidence to explore novel avenues when intending to perform more accurate fluid assessments on patients. This thesis has provided essential information to inform clinical practice, which can be considered when policymakers critically review existing policies and procedures.

Scope

The scope of this thesis was limited to adult HD patients on maintenance HD in two satellite HD clinics in the wider Perth Metropolitan area. The patient cohorts in both clinics were deemed indicative of the general HD population in Western Australia (WA). Satellite HD clinics provided detailed nursing progress notes recorded in an electronic database, allowing for extensive data analysis, and the Body Composition Monitor (BCM), a fluid assessment tool used in conjunction with IVC-US for the intervention, and explained in more detail later in this thesis.

Structure of this thesis

This thesis consists of eight chapters. The introductory chapter describes the adverse event of intradialytic hypotension and its diversity in clinical symptoms. It also includes possible causes of intradialytic hypotension, known prevalence rates and links to morbidity and mortality. It further comprises an overview of current fluid assessment tools, aims of this thesis, research questions, and the significance of this study.

Chapter 1 provides an introduction to the topic ‘Intradialytic hypotension’, giving an overview on the definition, prevalence rates and existing preventative methods.
Chapter 2 presents the findings from the systematic literature review regarding the use of IVC-US by nurses in general and in the context of fluid assessment in HD patients. It focuses on research objective 1.

Chapter 3 describes results of a study on the prevalence rate of IDH in a West Australian satellite HD clinic and links to research objective 2.

Chapter 4 describes an educational ultrasound programme, comprising four stages through which competency in performing IVC-US for a renal nurse can be achieved. This chapter relates to research objective 3.

Chapter 5 describes the results of a study on the comparison of a renal nurse’s fluid assessments obtained from IVC-US compared to two sonologists, and also focuses on research objective 3.

Chapter 6 presents the findings from a study on the comparison of 2 additional fluid assessment methods with the traditional clinical fluid assessment method, relating to research objective 4.

Chapter 7 summarises and discusses all findings gained from the studies included in this thesis. Additionally, suggestions are made for future research studies. This chapter relates particularly to research objective 5.

Chapter 8 provides the conclusions of this thesis.
Chapter 1
Intradialytic hypotension – Definition, prevalence rates and preventative methods

1.1 General Introduction

This chapter begins with a description of how a predialytic fluid assessment is typically performed by renal nurses, allowing a renal nurse to determine an UF goal specific for the patient. This is followed by the definition of IDH, including the range of clinical symptoms of IDH, currently known prevalence rates and patient characteristics. Potential causes and the clinical interventions when IDH occur are described, as well as clinical outcomes such as morbidity and mortality. Finally, commonly used intradialytic fluid assessment methods are summarised to specify the range of different approaches and techniques.

1.2 Predialytic fluid assessment

Patients with end-stage renal disease (ESRD) require ongoing renal replacement therapy (RRT) for the remainder of their life or until kidney transplantation occurs. The vast majority of these patients in Western Australia receive maintenance HD three times per week, typically with a minimum of four hours each session (Briggs et al., 2013). Most of these routine sessions occur in outpatient satellite HD clinics, close to the patient’s home and are run by specialised renal nurses but without direct medical supervision (Davenport, 2006). One of the major goals of HD is the removal of excess fluid from extracellular space, as well as removing metabolic waste products and other goals such as balancing of electrolytes and pH levels (Chamney, 2007; San Miguel, 2010).

Removal of excess fluid during HD is achieved through ultrafiltration (UF) during HD for oligo- and anuric patients (Chou & Kalantar-Zadeh, 2017). Extracellular fluid volume (EFV) from the extracellular space is mainly the source of net UF during HD (Jeong, Lim, Choi, & Oh, 2016) or haemodiafiltration (HDF) (Tapolayai et al., 2014) regardless of a patient’s hydration status. HDF is another form of blood purification along with a component of UF and has been shown to have an improved solute clearance over HD, especially for middle molecules (Locatelli et al., 2010). Although HDF has shown to be superior over HD with regards to solute clearance, and may be used as a novel treatment option in some satellite HD clinics in WA, none of the patients in this study received HDF as it was not the routine standard of care at the clinics of this study.
Traditionally, all renal clinicians, doctors and nurses aim to accurately assess haemodialysis patients on excess fluid to achieve safe treatment goals of fluid removal. Assessing extracellular fluid and determining the treatment regimen to achieve euvolemia has been described as one of the biggest challenges for nephrologists (Ishibe & Peixoto, 2004). Fluid assessment is one of several major responsibilities of renal nurses when caring for patients with ESRD (Chamney, 2007). This is of particular importance to provide a safe and uneventful treatment, as renal nurses initiate every treatment session. Generally nurses predominantly perform a predialytic fluid assessment and local policy will dictate if nurses or doctors may decide on subsequent goals of fluid removal (Mahon et al., 2013). This means that it is highly likely that renal nurses carry substantial responsibility in the ongoing care and management of patients when observing individual patients for fluid and weight trends. Currently, renal nurses predominantly use their clinical skills alone to assess patients with ESRD on their level of excess fluid prior to each HD session. This mandatory predialytic fluid assessment remains a challenge, as the renal nurse has only few objective parameters on hand to validate the clinical decision for an individual UF. Parameters consist mostly of clinical observations of body weight and blood pressure measurements before, during and after HD sessions (Chamney, 2007; Meredith, Pugh, Sutherland, Tarassenko, & Birks, 2015) and are considered representative of the current cornerstones when assessing fluid status. Knowing that renal nursing care has a considerable impact on patient outcomes (Ludvigsen, Hermansen, & Lindberg, 2015), it is essential that these parameters also take into account an individual’s general weight trend, including their ideal body weight (IBW) or dry weight (Lindberg, Bäckström-Andersson, Lindström, & Lindberg, 2013). This is usually defined as the lowest tolerated post-dialytic weight at which there are no or minimal clinical signs or symptoms of hyper- or hypovolemia (Sinha, Light, & Agarwal, 2010). Additional nursing observations for pre- or intradialytic symptoms like shortness of breath, peripheral oedema and elevated jugular venous pressure (Mahon et al., 2013) are deemed to be helpful when assessing for fluid status (Chou & Kalantar-Zadeh, 2017). Additionally, patients need to be observed for other signs of fluid overload such as inspiratory crepitation, low oxygen saturation and/or the need for oxygen saturation as these may indicate the onset of pulmonary oedema (Levy, 2009). These few pre-session parameters typically guide a renal nurse in their decision-making to determine an individual UF goal (Bradshaw & Bennett, 2015). It is likely that this UF goal is ultimately decisive for the occurrence (or, preferably, non-occurrence) of intradialytic hypotensive episodes (Canaud & Lertdumrongluk, 2012; Stefansson et al., 2014).
Therefore, it has been suggested that more objective and quantitative measurements are needed, and that reliable methods to predict target endpoints for euvoolemia need to be found (Wizemann, 2009) and tested (Chou & Kalantar-Zadeh, 2017). Ludvigsen et al. (2015) have also concluded that intradialytic observational nursing care during ultrafiltration could be improved. These authors found that some patients were exposed to excessive UF volumes and too-rapid fluid removal leading to adverse events such as IDH. This was particularly observed in younger dialysis patients and patients with low body weight. Applied critical thinking and adherence to recommended maximum UF volume thresholds per hour (Flythe & Brunelli, 2011; Ludvigsen et al., 2015) by nurses could prevent long term side effects of HD.

1.3 Definition of IDH and clinical symptoms

According to the National Kidney Foundation (NKF) Kidney Diseases Outcomes Quality initiative (KDOQI) guidelines, S-IDH has been defined as a SBP drop of 20 mmHg or more or a decrease in mean arterial pressure (MAP) by 10 mmHg, combined with symptoms like muscle cramps, fatigue nausea and vomiting, restlessness, dizziness and loss of consciousness and anxiety (National Kidney Foundation Inc., 2005). Although this definition is the most commonly used, there exists a number of other definitions of IDH which typically combine a drop in SBP with other nursing interventions such as intravenous saline bolus administration and/or pausing of UF (Flythe, Xue, Lynch, Curhan, & Brunelli, 2015). Other IDH definitions only focus on intradialytic SBP evaluation, with a precondition of a SBP drop of 20-40 mmHg or nadir SBP of 90-100 mmHg (Dheenan & Henrich, 2001; Flythe et al., 2015). Further, the combination of an SBP fall with SBP nadir of less than 110 mmHg has also been commonly accepted as a valid IDH definition (Flythe et al., 2015; Imai et al., 2006). A-IDH has been defined as SBP lower than 100 mmHg exclusive of any clinical symptoms (Chesterton et al., 2009). Bradshaw, Bennett, Hutchinson, Ockerby, and Kerr (2017) have described A-IDH as a decrease in MAP of 30 mmHg or more in comparison to predialytic MAP, or a MAP below 70 mmHg, also without any clinical signs. Interestingly, another study by Zumrutdal (2013) described the symptom of transient vocal hoarseness at the end of HD sessions as most likely to be caused from volume depletion and dialysis-induced hypotension. This has also been described by Unver et al. (2015), suggesting that their approach of objective voice analysis could even be used to determine IBW. Other clinical symptoms like excessive sweating and change in skin tone have also been reported during an IDH event (Meredith et al., 2015).
However, the present thesis used the definition for IDH based on NKF KDOQI guidelines, as this is predominantly used throughout most present publications.

### 1.4 Reported prevalence rates of IDH

IDH has been described as the most common adverse event during HD and a broad range of prevalence rates of IDH are reported in various studies throughout the literature, ranging from 5 to 93% (Awan, Shafi, Ahmed, & Aasim, 2011; Kron et al., 2017; Rocha, Sousa, Teles, Coelho, & Xavier, 2015; Schiller, Arramreddy, & Hussein, 2015). Some studies also report a high variability within patients (0-100%) (Rocha et al., 2015) but most authors report a prevalence rate of 20 to 30% of all treatments (Rocha et al., 2015; Schiller et al., 2015). Typically, IDH events occur more frequently in the elderly, female and diabetic patients with higher Body Mass Index (BMI), higher UF goals and predialytic hypotension (Schiller et al., 2015). Patients with larger interdialytic weight gains (IDWG) are also more often affected (Awan et al., 2011), while it is traditionally assumed that weight gain between sessions is usually being equivalent to fluid gain (Lindberg & Ludvigsen, 2012) (1g ≈ 1ml). This is also confirmed in a study by Schulz et al. (2007), where fewer episodes of IDH in patients with IDWG < 1.5 kg/2 days were described. Importantly, an IDWG < 1 kg/2 days was described as being advantageous for survival with the lowest risk of death (Chou & Kalantar-Zadeh, 2017).

### 1.5 Potential causes and treatment of IDH events

Prior to a regular HD session, a renal nurse calculates an individual fluid removal in millilitres (UF goal) for the present treatment. This is based mainly on the bodyweight gain of the patient since the last treatment, the current blood pressure and the clinical condition observed by the nurse. This UF goal calculation is based on the assumption that this increase of bodyweight represents excess fluid which would have been normally excreted by the kidneys. This calculated UF goal will then be entered into the HD machine and the patient will be connected via two cannulae and an extracorporeal blood circuit onto the machine. The HD machine subsequently gradually removes the pre-set volume of fluid from the patient’s blood during treatment by negative (hydrostatic) pressure in the dialyser, an artificial blood filter, which removes fluid and metabolic substances. Over 4 to 5 hours it is expected that the patient achieves the calculated fluid volume removal upon cessation of the session without clinical complications and is able to leave the satellite dialysis clinic in a stable physical condition (Mahon et al., 2013). Rapid elimination of osmotic active substances, mainly urea and
sodium, in combination with delayed re-filling from the intracellular space along with intravascular volume depletion caused by UF may predispose patients to develop IDH (Mc Causland, Brunelli, & Waikar, 2013). This model is supported by the fact that intravenous administration of hypertonic glucose or hypertonic saline improved intradialytic blood pressure decline and correlated symptoms (Canzanello et al., 1991). Multiple authors have described the same mechanism, in that IDH is a direct consequence of an imbalance between passive plasma re-filling and excessive intravascular fluid removal (Agar, 2016; Bossola et al., 2013; Davenport, 2006). Sherman (2002) supports this theory in that IDH is rare when no UF is performed during a HD session.

Another important factor during the development of an IDH event is the UF rate (UFR). The UFR is expressed as the amount of UF per hour (in ml/hr) occurring for an individual during HD. High UFR’s (> 10 ml/kg/hour) have shown to be correlated with IDH, morbidity and mortality (Flythe & Brunelli, 2011; Hussein, Arramreddy, Sun, Reiterman, & Schiller, 2017). Agar (2016) proposed that an extended treatment time would allow for additional time to remove excess fluid safely, especially in patients with large IDWG. He also emphasised the importance of an individual UFR ≤ 10 ml/kg/hour and a maximum UFR of 13 ml/kg/hour to reduce risk. However, it is not unlikely that other multiple factors contribute to the formation of an IDH event. Intradialytic food intake, especially during increased treatment times, incorrect IBW, patient characteristics, dialysate composition and temperature, and autonomic nerve dysfunction may play an additional role (Roberts, Anne Kenny, & Brierley, 2003; Sherman & Kapiroian, 2011). Other contributing risk factors for IDH such as cardiac dysfunction, hypoalbuminemia, underestimated IBW and antihypertensive medication have also been identified (Berger & Takala, 2016; Chao, Huang, & Yen, 2015; Charra, 2007; San Miguel, 2010).

S-IDH and A-IDH can also be caused by an UF goal being set too high as well as being achieved too fast, and it can be managed by adjusting the UF goal on the dialysis machine and administering IV saline (Hayes & Hothi, 2011). Current conventional therapy of an acute IDH event comprises of pausing UF or decreasing the UF rate, reducing the blood flow rate, positioning the patient in Trendelenburg position and, in severe cases, even a premature cessation of the treatment (Bayya, Rubinger, Linton, & Svir, 2011; Stefansson et al., 2014).
1.6 Clinical outcomes of IDH events

When occurring repeatedly, IDH episodes during HD have harmful effects on multiple organ systems and are considered to cause morbidity and increased mortality for patients with chronic kidney disease (Henderson, 2012). There is sufficient evidence to conclude that both S-IDH and A-IDH qualify as an ischaemic insult to organs (Bradshaw & Bennett, 2015; Daugirdas, 2015; Davenport, 2015). IDH adversely affects a variety of vital end organs including the brain, gastrointestinal tract and the heart, causing a decline in residual kidney function as well as cardiac stunning and ischemic brain injury (Huang, Filler, Lindsay, & McIntyre, 2015; McIntyre & Goldsmith, 2015). IDH has been linked to vascular access thrombosis (VAT) (Chang et al., 2011), insufficient dialysis dose with reduced metabolic clearance due to repeated prematurely cessation of HD sessions (Jepson, 2009) and has a negative effect on the quality of life of these patients (Ghaffar & Easom, 2015). Eldehni and McIntyre (2012) have described ischemic brain injuries which were likely due to recurrent circulatory stress from multiple IDH episodes, subsequently causing cognitive impairment with major consequences not only for the patient’s quality of life, but also for their survival. Similarly, the effects of IDH events on the cardiovascular system have been described, resulting in arrhythmias, myocardial ischemia, infarction, stroke and cardiovascular death (Flythe, Kimmel, & Brunelli, 2011; Movilli et al., 2007). IDH has been identified as an independent risk factor for two-year mortality in HD patients (Shoji, Tsubakihara, Fujii, & Imai, 2004). Left ventricular hypertrophy has been described in nearly three-fourths of chronic dialysis patients and cardiac structural changes have already occurred during early renal function impairment, so the condition may only worsen after dialysis is initiated (Chao et al., 2015).

1.7 Intradialytic fluid assessment methods

Traditionally, intradialytic blood pressure (BP) measurements combined with patient observations on fluid-related signs and symptoms (as described in the NKF-KDOQI guidelines) are the most usual intradialytic fluid assessment method routinely applied worldwide by renal nurses (Germain et al., 2017). Assimon and Flythe (2015) have stated that BP measurements are a fundamental part of monitoring patient safety during HD and have critical clinical and prognostic significance. As intradialytic BP fluctuations with IDH are common and renal nurses are responsible for preventing harm to their patients through preventative measures, it has been recommended that BP measurements in 15-minute intervals are superior over longer time intervals to prevent intradialytic complications (Horkan, 2013). A study by Roberts et al. (2003) underscored how important post-
dialytic blood pressure measurements were to prevent patients from postural hypotension and subsequent episodes of falls, especially in the elderly patient. A survey by Bradshaw, Ockerby, and Bennett (2015) amongst Australian and New Zealand nurses revealed that they considered the systolic blood pressure as the most important indicator for a deteriorating HD patient. These authors also suggested that because of the nature of longstanding care for HD patients and knowing their specific BP threshold, renal nurses might be more aware of an individual patient’s circumstances and could potentially predict when they become hypotensive. Bradshaw et al. (2017) have further emphasized the importance of measuring and monitoring the MAP, as it could serve as an early indicator for A-IDH. These authors suggested that using the lowest tolerable threshold of 70 mmHg or a fall in MAP of 30 mmHg compared to predialytic MAP could be used to predict an imminent episode of IDH. Subsequent pausing of UF could be used to avoid the occurrence of IDH and also allow for continuation of the treatment (Bradshaw et al., 2017). What is clear is that BP measurements for assessing fluid status in HD patients certainly have their limitations.

Further, Van Buren and Inrig (2017) have described a group of HD patients where intradialytic BP increased despite ultrafiltration taking place. These authors have described an unexpected chronic phenomenon, intradialytic hypertension, which occurs in almost every HD patient occasionally and may occur recurrently. They also identified this underreported subgroup of patients for an exceedingly high risk of morbidity and mortality. A study by Wabel et al. (2008) revealed that in almost a quarter of their HD patients there was no correlation between hypertension and hypervolemia. Similarly, Khan, Sarriff, Adnan, Khan, and Mallhi (2017) found 22% of their study population was hypertensive but euvoletic, while 12% were normotensive but fluid overloaded. These facts underscore the fact that renal nurses should not rely solely on BP measurements as an indicator for fluid status.

Blood volume monitoring (BVM) is another method that can be used by renal nurses to observe a patient’s intradialytic progress in fluid removal (Damiasiewicz & Polkinghorne, 2011). BVM devices use light to constantly measure intradialytic haematocrit and haemoglobin values, displaying an overall trend for the circulating relative blood volume (RBV). They are supposed to indicate a specific threshold when UFR exceeds passive plasma-refilling (Damiasiewicz & Polkinghorne, 2011) and indicating an imminent episode of IDH. While some studies advocate the use of BVM devices to prevent patients from IDH (Saxena, Sharma, Gupta, & John, 2015), others see its use in a critical light and suggest that its use must be combined with the nurses’ critical
thinking skills to be effective (Micklos, 2013). Ibrahim and Taweel (2007) claim that assessing intradialytic changes in plasma for estimation of hydration status is not useful. Although BVM may be used frequently in HD units elsewhere, it is a piece of equipment which does not exist in the clinical areas where this research took place, and therefore is beyond the scope of this thesis.

Another method to approximate fluid status is bioimpedance spectroscopy (BIS). This technique measures conductivity in body tissue in response to a small bioelectrical current (Earthman, Traughber, Dobratz, & Howell, 2007). While this current is conducted well by water and tissues containing electrolytes (e.g. muscles and blood), there is poor conduction by fat, bone and air-filled areas and has the potential to cause inaccurate readings. The Body Composition Monitor (BCM, Fresenius Medical Care, Bad Homburg, Germany) uses multifrequency bioelectrical impedance analysis (MFBIA) to detect fluid overload and to determine the patient’s overall fluid status (Machek, Jirka, Moissl, Chamney, & Wabel, 2010; Wizemann, 2009). It has limitations and should not be used in patients with implanted pacemakers, defibrillators or cochlear implants (Wabel et al., 2008). Further, although indicating EFV, it cannot discriminate between extravascular and intravascular volume, whereas in HD the critical value for the definition of an UF goal aiming for a stable treatment without IDH events is the intravascular fluid status (Jaeger & Mehta, 1999). Based on this, Davenport (2013) claimed that exact intravascular volume assessment in HD patients remains vital to prevent patients from both IDH and from hypervolemia. However, Davenport (2013) also warned that using this tool to reduce IBW aggressively while not knowing the intravascular fluid status could potentially cause a prematurely loss of residual urine output function, a disaster for a patient with ESRD. Although BIS was available in one of the dialysis units during this project, this device was not regularly used as part of a nursing routine for fluid assessment. A national survey amongst dialysis clinics in the United Kingdom (UK) in 2016 revealed that only 27% of the dialysis clinics were using BIS and only 38% felt that fluid management was adequate (Dasgupta, Farrington, Davies, Davenport, & Mitra, 2016). A vast majority (77%) of surveyed dialysis clinics felt there was a need for better evidence in fluid assessment and 91% would participate in a study addressing this issue (Dasgupta et al., 2016). These survey results underscore the urgency and importance of the substantive problem for improved accuracy of fluid assessments in haemodialysis patients.

In contrast to BIS, Simoni, Vitturi, and Dugo (2016) have stated that the IVC most accurately reflects the intravascular part of body fluid volume. Usually, the systemic circulation of a healthy adult holds 84% of the
total blood volume and 64% of this is pooled in the venous system (Hall, Guyton, & Ebook, 2011). Although it might vary with different states of venoconstriction and dilatation, it indicates the importance of the venous blood system for the assessment of intravascular volume status. Veins serve as a blood reservoir for blood circulation, and the inferior vena cava represents the largest venous vessel in the human body (Hall et al., 2011). Therefore, clinicians have considered the measurement of the IVC for intravascular volume assessment in patients, assuming that either a collapsed or distended state could be reflective of venous filling (Chen, Kim, & Santucci, 2007). Lyon, Blaivas, and Brannam (2005) have demonstrated that IVC-US is a reliable indicator for blood loss, even for small volumes (e.g. 450ml), and they suggested it could be helpful when assessing potential volume depleted patients. Further, IVC-US has been demonstrated to be a useful method to evaluate the volume-status of a HD patient (Brennan et al., 2006). The IVC diameter (IVCd) is indicative of the circulating blood volume during and after HD and ultrasound could provide non-invasive real-time information about blood volume which correlates with central venous pressure (CVP) (Tetsuka, Ando, Ono, & Asano, 1995; Wallace, Allison, & Stone, 2010). Therefore, IVC-US could hold important prognostic value as CVP is prominently reduced during the first hour of HD (Thalhammer et al., 2015). A study by Brennan et al. (2006) revealed not only that IVC-US could be performed by clinicians with minimal echocardiographic proficiency, but it also demonstrated that almost 50% of their patients were already volume depleted at treatment start and concluded that IVC-US is an achievable option to assess the intravascular volume status in a satellite dialysis clinic. The IVCd changes dynamically during the respiratory cycle, therefore an ultrasound measurement of the IVC needs to be obtained during inspiration reflecting the IVC minimum diameter (IVCmin), while a second measurement needs to be acquired at maximum expiration reflecting the IVC maximum diameter (IVCmax). From these two measurements, an IVC collapsibility index (IVCCI) can be calculated \( [(IVC_{\text{max}} - IVC_{\text{min}}) / IVC_{\text{max}} \times 100] \) which correlates with CVP (Thanakitcharu, Charoenwut, & Siriwitwatanakul, 2013). IVCCI calculations based on US are simple and non-invasive and could be used to monitor intravascular volume status during slow continuous ultrafiltration and hence optimise fluid removal rates (Guiotto et al., 2010). Another measure relevant to intravascular fluid is the indexed vena cava diameter (VCDi). This is calculated by dividing IVCmax (in mm) by the body surface area in m² (Cheriex, Leunissen, Janssen, Mooy, & Van Hooff, 1989). These two derived measurements provide a good point approximation of the intravascular volume status. The current ‘Guidelines for the Echocardiographic Assessment of the Right Heart in Adults’ (Rudski et al., 2010) propose that a diameter < 2.1 cm and IVCCI > 50% indicates hypovolemia correlating with venous pressure.
IVCCI cut-offs for hypovolemia, euvoolemia and hypervolemia are shown in Table 1 and VCDi cut-offs are displayed in Table 2. Care needs to be taken when assessing VCDi as in patients with tricuspid regurgitation caused by pulmonary hypertension or biventricular heart failure a dilated IVC may be observed, which could be misinterpreted as hypervolemia (Yepes-Hurtado, Omar, Monzer, Alalawi, & Nugent, 2016). On the other hand, distal IVC thrombosis can lead to a narrower IVC and could potentially be misinterpreted as hypovolemia (Häusler, Hübner, Delhaas, & Mühler, 2001).

**Table 1.** IVCCI cut-offs according to the ‘Guidelines for the Echocardiographic Assessment of the Right Heart in Adults’

<table>
<thead>
<tr>
<th>Volume status</th>
<th>IVCCI Collapsibility Index (%) = 100 (max - min diameter) / max diameter</th>
<th>Maximum IVC diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypovolemia</td>
<td>&gt; 50%</td>
<td>&lt; 2.1 cm</td>
</tr>
<tr>
<td>Euvolemia</td>
<td>&gt; 50%</td>
<td>&gt; 2.1 cm</td>
</tr>
<tr>
<td></td>
<td>&lt; 50%</td>
<td>&lt; 2.1 cm</td>
</tr>
<tr>
<td>Hypervolemia</td>
<td>&lt; 50%</td>
<td>&gt; 2.1 cm</td>
</tr>
</tbody>
</table>

**Table 2.** Indexed vena cava diameter corrected for body surface area (VCDi) cutoffs according to ‘Echography of the Inferior Vena Cava is a Simple and Reliable Tool for Estimation of ‘Dry weight’ in Haemodialysis Patients’ (Cheriex, Leunissen, Janssen, 1989)

<table>
<thead>
<tr>
<th>Volume status</th>
<th>IVCCI Collapsibility Index (%) = 100 (max - min diameter) / max diameter</th>
<th>Indexed vena cava diameter corrected for body surface area (VCDi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypovolemia</td>
<td>&gt; 75%</td>
<td>&lt; 8 mm/m2</td>
</tr>
<tr>
<td>Euvolemia</td>
<td>≥ 40 and ≤ 75%</td>
<td></td>
</tr>
<tr>
<td>Hypervolemia</td>
<td>&lt; 40%</td>
<td>&gt; 11.5 mm/m2</td>
</tr>
</tbody>
</table>

Several studies have confirmed that ultrasound-naïve clinicians can successfully be upskilled to perform and interpret IVC-US with moderate to good agreement with an expert (Brennan et al., 2006; Fields et al., 2011; Muniz Pazeli et al., 2014). Specialised nurses from various clinical areas such as emergency departments and
heart failure clinics have used IVC-US with success, achieving similar results to ultrasound experts (Dalen et al., 2015; Gustafsson, Alehagen, & Johansson, 2015). While nurses in the study from Dalen et al. (2015) had experience performing focused ultrasound of the IVC, the nurses in the report from Gustafsson et al. (2015) were ultrasound novices and, although specialised in their clinical area, were unfamiliar in the use of ultrasound. These studies demonstrated that even nurses without formal ultrasound training were able to develop a new clinical skill, which was thought to be helpful for their everyday practice and which was considered to improve patient outcomes.

Renal nurses spend significant time with patients during their regular treatments and they make important observations on adverse events during treatment time as part of their regular clinical practice. They are in an ideal situation to collect additional information to improve direct patient care and to enhance knowledge of clinical nursing. At present regular nursing care includes pre-, intra and post-dialytic patient observations and a clinical fluid assessment prior to HD to inform a critical decision on an intended UF goal. This decision is mostly based on very few objective parameters including systemic BP, predialytic weight, IBW and recorded data from previous dialysis sessions. As a consequence, the occurrence of any intradialytic adverse event, which are most commonly episodes of IDH, relates mostly to this initial decision-making process. Providing renal nurses with another dimension of clinical information through IVC-US was considered potentially helpful. Knowledge of intravascular volume status through direct visualisation with IVC-US could potentially inform the renal nurse to validate the initial decision on the UF goal or reconsider further clinical measures. Generally, there is no radiographer available in satellite HD clinics and these significant and sometimes difficult clinical decisions must be made quickly. With IVC-US being a swift, non-invasive and focused method to assess intravascular volume status, it is considered that this would deliver essential additional information to renal nurses. In light of this, finding evidence in publications and exploring whether this method had been previously used by renal nurses was an integral part of this study.

Hence, this next chapter set out to explore if renal nurses in outpatient HD clinics have previously used IVC-US and if IVC-US was used for the purpose of intravascular fluid assessment to diagnose imminent hypovolemia and avoid adverse outcomes for HD patients.
Chapter 2

2. Literature Review

2.1 Foreword

This chapter provides a published review of the literature between 1996 and 2015 and then updated literature since publication (see section 2.2). It evaluates the existing scientific literature with regard to the use of ultrasound by nurses in a broad variety of clinical specialities and in particular whether renal nurses have successfully used IVC-US for the purpose of intravascular volume assessment. Multiple studies have identified that IVC-US used by healthcare professionals is a swift and non-invasive method when assessing HD patients for intravascular volume (Brennan et al., 2006; Thanakitcharu et al., 2013). Finding scientific evidence to identify the previous use of IVC-US by renal nurses was essential prior to the start of this research project.

The PRISMA statement for reporting a systematic literature review was chosen to demonstrate rigor and to obtain objective and reliable results. Multiple medical and nursing databases were examined for relevant content to aggregate significant information with the potential to answer the primary research question. The intention of this approach was to first identify multiple research studies and scientific publications, critically analyse the quality of their content and then present the combined findings.

These findings were important for this research project, as renal nurses are responsible for ongoing clinical observation during an individual treatment session, but also for the critical decision of the UF goal prior to treatment initiation. Renal nurses in satellite HD clinics in WA have generally no medical backup available and must decide on UF goals on their own, based on their assessment of the patient and on their own knowledge, skill and experience. This decision, generally based on several clinical parameters such as assessing a patient’s general fluid status, IBW and predialytic BP readings, has significant potential to influence patient outcomes during and directly after their session. Hence, it is postulated that IVC-US could potentially deliver important additional objective information for this initial decision-making process and help the renal nurse to reconsider UF goals.

The following article has been published in the journal ‘Journal of Renal Care’, Sep 2017
Pages 21-31 are not available in this version of the thesis as it includes the article:


*An Open Access version of the article is also available at* [https://ro.ecu.edu.au/ecuworkspost2013/3268/](https://ro.ecu.edu.au/ecuworkspost2013/3268/).
2.2 Additions to the systematic literature review (from 2015 to 2017)

The quality appraisal of articles used in this preceding published article was based on the recommended methods of the PRISMA Statement (Moher, Liberati, Tetzlaff, & Altman, 2009). Minimum requirements for inclusion of published literature in the systematic literature review were peer-reviewed articles including an abstract and full-text articles with available references.

The following section describes and summarizes further details of peer-reviewed scientific publications, which describe recent findings of experts in the area of intravascular volume assessment using a variety of different approaches and methodologies.

Since publication of this systematic literature review (Steinwandel, Gibson, Rippey, Towell, & Rosman, 2017) new knowledge has emerged on the use of ultrasound and other technical methods for intravascular volume assessment. Chou, Kalantar-Zadeh, and Mathew (2017) have highlighted the importance of clinical studies to determine objective intravascular volume correlating with IDH and the need for scientific findings where interventions could be cost-effective and beneficial. Inaccurate fluid assessment by clinical staff before and during a HD session are associated with chronic fluid overload and poorer health outcomes for HD patients (Chou & Kalantar-Zadeh, 2017). These authors also stated that additional methods, like IVC-US and BIS amongst other methods, might deliver objective results for volume status, but may carry the risk of being erroneous during calibration and may vary in the operator interpretation of the findings. The crucial question still remains, how much fluid can safely be removed with HD? (Chou & Kalantar-Zadeh, 2017). Chou et al. (2017) have now suggested offering additional dialysis sessions to patients with large IDWG’s, so that more frequent or even nocturnal HD reduces the risk of myocardial stunning.

Other forms of ultrasound techniques to assess HD patients for fluid have recently been successfully used. Lung ultrasound (LUS) on HD patients revealed a strong correlation with fluid removed from patients and a so-called reduction in B-lines (Jiang, Patel, Moses, DeVita, & Michelis, 2017). B-lines are sonographic findings depicting pulmonary interstitial oedema and can be detected by LUS (Jiang et al., 2017). The reduction of detected B-lines correlated with intradialytic fluid loss in their study. Hence, LUS was described by these authors as a helpful tool to achieve a more accurate IBW, providing precise information on adequacy of fluid removal.
Although published prior to 2015, an important finding in regards to shape of the collapse of the IVC had been presented by Naruse, Sakaguchi, Nakayama, Nonoguchi, and Tomita (2007) when assessing a HD patient for fluid. These authors postulated that individual IVCd’s differed in shape and while most people had a horizontal ellipse in IVC, some others had a vertical shaped IVC. The shape of collapse of the IVC, either horizontal or vertical, needs to be taken into account and it was shown to be more accurate when calculated as an IVC flat ratio, which correlated well with fluid status.

Another essential study by Dietel, Filler, Grenda, and Wolfish (2000) had revealed a good correlation between BIS, IVCd and fluid status in paediatric HD patients. They suggested combining both methods as an adjunct for post-dialysis assessment for dry-weight.

An observational, retrospective study by Sangala, Gangaram, Atkins, Elliot, and Lewis (2017) concluded that delta SBP is useful for the prevention of IDH. Delta SBP is calculated with the following formula [(pre SBP – post SBP)/pre SBP x 100] and could be used to identify patients most at risk for IDH. According to these authors, delta SBP is expressed as a ratio and varies with hydration status. They further described that an increase in hydration status consequently reduced IDH symptoms and delta SBP and concluded that a reduction in hydration status is associated with an increased risk of IDH along with an increase of delta SBP.

Recently, the BISTRO study has been initiated to determine if the use of BIS to guide IBW decisions in novice HD patients, with a minimum of 500 ml residual urine output, will have a positive effect on patient outcomes and could preserve residual urine output (Davies et al., 2017). Results of this study could potentially lead to recommendations for using BIS on a broader scale, especially having more objective parameters on hand to guide clinical decision making. Similarly, a study by Siriopol et al. (2016) aimed to compare head-to-head BIS and LUS on their predictive value of all-cause mortality. This study found that fluid overload measured by BIS, but not LUS, improved risk prediction for death. Following this, another study by Siriopol, Siriopol, Voroneanu, and Covic (2017) has demonstrated that the combination of BIS and brain-type natriuretic peptide (BNP) in diagnosis of fluid overload led to a more comprehensive fluid evaluation and could improve patient outcomes.

A mandatory pay-for-performance ESRD Quality Incentive Program (QIP) in the United States (US), introduced in 2012, linked Medicare payments to dialysis providers performance on recommended quality methods (Flythe, Assimon, & Overman, 2017). Following this, the National Quality Forum (NQF) endorsed the UF rate
measure in 2015, intending to support balance between overzealous and too conservative fluid removal. To achieve this, the UFR needs to be limited either with the extension of treatment time or lowering of UF volumes (J. E. Flythe et al., 2017). Their study showed the significance of an extracellular fluid measure in outweighing an UF rate measure, especially as in the US, HD treatment times are markedly shorter than in the rest of the world (J. E. Flythe et al., 2017). These authors highlighted the importance of identifying and validating objective measures of volume status in the future to enable more informed approximation and prescription of IBW, thus preventing patients from harm caused by forceful fluid removal. Flythe, Assimon, and Wang (2017) have also underscored the importance of always questioning and reconsidering accepted standards, and never allowing complacency to lead to the belief that existing standards equate with best practice.

Valtuille (2017) has described IVC-US as a safe and cheap technique that can be performed at the patient’s bedside, but has also described IVC-US as an operator-dependent technology and supervised training is essential for the correct interpretation of findings (Basso et al., 2013). Valtuille (2017) suggested using BIS as a routine bedside clinical tool to help for decision-making processes of health care professionals.

A literature review by Zhang and Zhao (2017) revealed reliability and accuracy of IVC-US for volume assessment, but recommended that the interpretation of results should be by physicians with acceptable understanding of underlying physiological changes. They also described a failure rate of almost 15% for IVC visualisation due to the occurrence of increased subcutaneous fat tissue and bowel gas, limiting its use in obese patients. This may affect HD some patients, as they generally have to use oral phosphate binders which have abdominal bloating as a common side-effect (Chan et al., 2017).

With regard to technique, the best practice for mode and view of the IVC with point-of-care ultrasonography (POCUS) was assessed in a study by Finnerty et al. (2017). It was revealed that the sub-xiphoid transabdominal long axis (LA) in B-mode held the best promise in delivering reliable dimensions of IVCd and had the highest interrater reliability (IRR) compared to M-mode and transabdominal short axis (SA) or right lateral transabdominal coronal long axis. These findings corroborate the decision to use only LA and SA measurements for all IVC-US measurements in our research project.
A comparison between BIS and echocardiographic fluid assessments in HD patients by Cristina Di Gioia et al. (2017) revealed that the left atrial volume index evaluated by echocardiography correlated with BIS. Moreover, a meta-analysis by Covic et al. (2017) reviewed seven randomised controlled trials (RCTs) where BIS was used to assess IBW and fluid status compared with standard assessment methods. This meta-analysis showed that BIS-based IBW assessment had no statistical significant effect on all-cause mortality in ESRD, but indicated that BIS could improve BP control and overall overhydration. It was recommended that larger studies combining BIS with other methods like LUS could be useful for IBW assessment in ESRD patients (Covic et al., 2017).

Alexiadis et al. (2017) compared multiple fluid assessment methods, including LUS, BVM and BIS in HD patients with IVC-US, using IVCd as the baseline reference method for all other methods. LUS indicated the most promising results in predicting overhydration compared to reference values of IVCd measured by IVC-US. Therefore, these authors concluded that LUS should be considered as a useful method to assess fluid status and evaluation of IBW. Conversely to this study, Sabaghan, Hajibaratata, and Samavat (2016) used BIS as the reference method to evaluate the best echocardiographic marker of volume status in HD patients. They found that IVCd_{min} (indexed minimum inferior vena cava diameter = IVC_{min}/BSA) showed the best correlation with hydration status prior to HD, compared to other indices like IVCd or IVCd_{max} (indexed maximum inferior vena cava diameter = IVC_{max}/BSA). The Body Surface Area (BSA) is defined as the measured or calculated surface area of the human body and is usually calculated with the Du Bois formula. (BSA (in m^2) = 0.007184 x body weight^{0.425} (in kilograms) x body height^{0.725} (in centimetres). These authors have therefore recommended the use of IVCd_{min} as a good parameter for assessment of the volume status of HD patients.

2.3 Conclusion

In summary, recently emerged literature compared a variety of additional objective fluid assessment methods and parameters including BVM, BIS, BNP, LUS and IVC-US, however none of these were specifically used by renal nurses. All these methods were applied in a variety of combinations to validate their accuracy and assess correlation with clinical signs of excess fluid. These studies underscored the general need for more reliable and accurate information about volume status to ultimately reduce intradialytic and immediate post-dialytic
adverse events. Several reports described a wider use of ultrasound techniques, particularly LUS, and this relatively novel method was also compared to IVC-US to evaluate excess fluid.

Multiple features of IVC-US technique have been shown to be favourable over other methods. Alexiadis et al. (2017) highlighted several aspects where IVC-US was a technique that provided critical accurate and reliable information. They argued that IVC-US was safe because it was radiation-free, simple and comparably inexpensive. These authors outlined further that skill acquisition of the IVC-US technique should be easy and could be done at the bedside. Additionally, they highlighted a significant difference when comparing LUS with IVC-US. LUS may only be able to indicate information on overhydration, as the minimum B-Line score was 0 (no oedema). It could therefore be difficult to depict hypovolemia with LUS, which is a common adverse event in HD patients. In view of this fact, LUS was not considered appropriate for comparison in this study as the focus of this thesis is mainly concerned with IDH, an adverse event associated with hypovolemia. However, as the most commonly mentioned and validated reference method was BIS, this was chosen in this study as a comparator to IVC-US in order to demonstrate their usefulness and validity against traditional clinical assessment methods.

IDH has been described as the most common adverse event during HD, but reported prevalence may vary depending on numerous contributing factors. These may include different approaches for IDH prevention locally and globally. Additionally, there may exist a broad variety of dialysis unit-specific policies and procedures regarding clinical fluid assessment and fluid removal, including diverse fluid assessment methodologies. In view of this, it was necessary to evaluate the magnitude and scale of IDH in the project population, and to this end a retrospective observational study was performed in a local satellite HD clinic, measuring the prevalence of IDH events.
Chapter 3

The prevalence rate of Intradialytic hypotension

3.1 Introduction

This chapter aims to describe the prevalence rate of IDH in a satellite HD clinic in the wider Perth metropolitan area, in order to explore the magnitude of the problem of IDH at the local level.

Daugirdas (2015) has recommended tracking IDH events to help dialysis care providers evaluate the success of quality improvement activities, with the aim of reducing incidences of IDH. This part of the research project also aimed to identify the proportion of both S-IDH and A-IDH to demonstrate their true frequency. This phase of the study was of particular interest as A-IDH may often be underreported due to its asymptomatic nature. As described earlier, various definitions for A-IDH exist and for the purposes of this study we used the commonly accepted definition according to the National Kidney Foundation (National Kidney Foundation Inc., 2005), defined as a drop in SBP of at least 20 mmHg from baseline.

Due to a broad variety of clinical definitions for any form of IDH, there is also a broad range of prevalence rates being reported in the literature (Flythe et al., 2015). Combined prevalence rates of IDH ranging from 15 to 50% of all HD sessions are reported (Flythe et al., 2015), but generally a prevalence rate of 20 -30% has most commonly been reported (Rocha et al., 2015; Schiller et al., 2015). Individual figures at a local level may also vary widely, depending on a variety of factors. Firstly, there may be geographical differences in the way ambulatory HD was delivered. Secondly, some of the data reported may have preceded any recent preventative measures including quality improvement activities that might have been implemented at a local level. Thirdly, patient-staff ratios, nursing staff levels, the level of their individual renal-specific education, and facility-specific practices may play significant roles when comparing facilities delivering HD care and the occurrence of IDH. Although likely to be of influence, these factors were beyond the scope of this thesis and hence were not explored in the modelling described in this chapter but remain a potential focus for future research.

As IDH has been described to not only affect the quality of life of HD patients but also to be harmful to various organ systems (McIntyre & Goldsmith, 2015), this study aimed to accurately record the quantity and scale of
both IDH and OH events over an extended time period of 3 months. Reporting these figures, including the description of characteristics of individuals mostly affected by IDH, was considered to be informative and provided valuable insights in preparation for this research project. It is expected that results from this chapter may provide essential data to inform current nursing practice, and may direct clinicians to reconsider and potentially improve their current clinical approach in predialytic fluid assessment. It is postulated that this could generally involve the use of a wider array of objective fluid assessment methods, including IVC-US and/or BIS for the prevention of IDH.

The following article has been published in the journal ‘Journal of Clinical Nursing’ on the 15th February 2018.

https://doi.org/10.1111/jocn.14309
Pages 39-48 are not available in this version of the thesis as it includes the article:


An Open Access version of the article is also available at: https://ro.ecu.edu.au/ecuworkspost2013/4266/
4. **The educational programme for renal nurses to perform IVC-US**

4.1 **Introduction**

The previous chapter has indicated that IDH episodes occur frequently in local satellite dialysis clinics and that UF goals are occasionally overestimated. Previous research has demonstrated that IVC-US may be a helpful addition when assessing fluid status and that medical residents with no prior official ultrasound training were able to acquire this skill (Brennan et al., 2006). In Brennan’s 2006 study, physicians undergoing limited training were able to obtain high-quality pictures almost comparable to those of experienced sonographers. However, IVC-US measurements are user-dependent and bowel gas may affect the visibility of the IVC in some patients (Dou, Zhu, & Kotanko, 2012).

The clinical skill set of renal nurses usually does not include IVC-US for intravascular volume assessment. Historically, some renal nurses may have received theoretical and practical training in the use of ultrasound to assess arteriovenous fistulas of HD patients (Marticorena et al., 2015). Therefore, for some renal nurses they may now have a basic understanding of practical ultrasound skills. However, for renal nurses to acquire skills in the specific area of objective volume assessment in patients using IVC-US, there is need to establish and provide further education.

To achieve this, a comprehensive educational programme was designed and created in collaboration with an expert sonologist from the emergency department of a local, large tertiary hospital. A sonologist is a medical doctor who performs ultrasound scans and uses their cognitive and radiographic skills to make the diagnostic determination at the time of the bedside application of focused ultrasound (Stawicki & Bahner, 2015). The clinical experience of the sonologist was deemed to be the fundamental prerequisite for adequate guidance and clinical direction in this project, as this expert provided the required theoretical and practical support. Tailoring the educational programme to the specific needs of renal nurses, and focussing the POCUS on a specific anatomical area so that they could acquire a particular skill, was one of the major challenges during this design process.

The structured educational programme was created following the theoretical framework by Benner (1984), which describes five stages in the acquisition and development of a skill for a nurse until finally clinical
competence can be achieved. In the first stage, where the novice has no experience in situations in which they are expected to perform, the nurse lacks confidence and cannot demonstrate safe practice while continuous support is needed. In stage two, as an advanced beginner, the nurse demonstrates marginally acceptable performance and developing knowledge, while in stage three competency is achieved, through repetition and demonstrated efficiency and a task can be completed within a suitable time frame without external support. Benner (1984) then continues to describe the stage four where the nurse becomes proficient, perceiving situations as a whole and achieving finally stage five, the last stage, where a nurse becomes an expert. In this last stage an expert nurse is more guided by an intuition and has a deep understanding of the total clinical situation. This framework was deemed to be a relevant model for contemporary renal nursing practice as nursing in the acute care setting has grown increasingly complex and there is a need for highly experienced nurses who use efficiently their resources. Furthermore, nurses have presently a higher responsibility than in the past, specifically in the ambulatory haemodialysis clinic setting where no medical staff is present and have to make independently critical decisions with potentially significant consequences for patients.

The structured programme consisted of four modules (theory, observation, demonstration and assessment). The programme was delivered in a stepped approach, so that the renal nurse was able to refine the practical skills of IVC-US at an individual pace. A critical element for the success of this programme was module 3 (demonstration), during which the renal nurse had to perform 100 proctored scans, the first 30 under direct supervision by the expert, then 70 independent and self-directed scans to refine skills and image-acquiring techniques. These 100 scans, although performed independently, were recorded and reviewed post-hoc by the sonologist to ensure validity and accuracy. Despite being the most time-consuming component of the research project as a whole, this phase was an important and integral part, given the potential for renal nurses to achieve competency in a new clinical skill. Another important element of this programme was the ability of the renal nurse to successfully highlight the major differences between the aorta and the IVC, as their diversity has previously been described as confusing (Zhang & Zhao, 2017). The incorrect identification of these vessels could have significant negative consequences on the expected learning outcomes and ultimately patient care. Overall, this programme has good potential to be successfully used by other clinicians in similar clinical settings and may be used in future by clinical educators to develop the skills for renal nurses for the same purpose.
This following article explains in detail the four-module education program devised for renal nurses in the skill of IVC-US and has been published on the 24th July 2018 in the Renal Society of Australasia Journal.
Pages 52-57 are not available in this version of the thesis as it includes the article:


The Open Access version of the article is available at:
Chapter 5

Assessing nursing competency in volume assessment using IVC-US

5.1 Introduction

The final step of the education programme consisted of a competency assessment of the nurses’ ultrasound skill validated independently by two sonologists. The mandatory number of 100 scans was decided in collaboration with the expert sonologist, who confirmed that this number of repeated scans should be sufficient to ultimately achieve competency in the skill of IVC-US. After completing 100 preliminary scans, firstly 30 supervised and then 70 independently performed by the renal nurse on a broad variety of HD patients, the renal nurse then performed and recorded 60 additional scans on a group of 10 patients without any direct supervision. During this phase of the project it was assumed that the renal nurse was now capable of performing routine IVC-US scans and to master the practical skill of high quality image acquisition. The renal nurse obtained scans on each individual of two different views of the IVC, one in longitudinal and one in transverse view, at the commencement, halfway and end of the dialysis session. Results of the second (transverse scan) of the paired scans was expected to confirm the finding of the first (longitudinal) scan, potentially supporting clinical findings.

Following this, the findings were assessed independently by two sonologists. As expert raters, the sonologists firstly assessed each single scan on image quality and then classified intravascular volume status into three different categories: hypovolemic, normovolemic and hypervolemic. All raters were blinded to each other’s results, so their rating results could be independently compared.

Achievement of competency of the skill IVC-US for the renal nurse was an important milestone and a key element in this research project, as it allowed for further independent assessment of patients prone to episodes of IDH in the final simulation phase of this research project. The renal nurse, which was the candidate, has had 18 years’ work experience in haemodialysis in a broad variety of clinical settings in Europe and Australia prior to the learning of the IVC-US skill and also holds a qualification as a Nephrology Nurse at a Masters level.

The following article describes the evaluation process of the IVC-US skills of the renal nurse by two independent sonologists. A STROBE checklist for cross-sectional studies was used for the reporting of the study.
results of this observational study. This article has been published in "Hemodialysis International" (2017), DOI: 10.1111/hdi.12606

The Open Access version of the article is available at: [https://ro.ecu.edu.au/ecuworkspost2013/3678/](https://ro.ecu.edu.au/ecuworkspost2013/3678/)
Chapter 6 is not included in this version of the thesis.
Chapter 7

7. Discussion

7.1 Introduction

This discussion chapter will explore the major findings from this thesis. Significant results of the five published articles will be considered, including the potential impact on current renal nursing practice and the capacity to inform policy and future research.

7.2 Overview of major findings

Results from each phase of this research project have provided findings that informs the initial research questions. These findings have provided important information and provide a better understanding of the issues regarding objective fluid assessment with different methods, prevalence rates of IDH and the usefulness of IVC-US in comparison with other objective methods.

7.2.1 IVC-US as a tool for renal nurses

The initial systematic literature review revealed that IVC-US could potentially assist in the setting of UF goals, has potential to reduce the risk of IDH and could change current nursing practice when added to clinical nursing assessment. Current standard fluid assessment methods by renal nurses are lacking in accurate and objective parameters for the determination of specific and safe UF goals. No previous peer-reviewed literature was identified where renal nurses used IVC-US, but it was found that this technique was already being applied by other nurses in other clinical areas. These studies indicated that nurses in a variety of clinical settings were able to learn and apply this practical skill and that the transfer of this aptitude could be successful. It has been shown that nephrologists with little ultrasound training have demonstrated satisfactory performance of IVC-US and have reached excellent and substantial agreement when their results were compared to those of a cardiologist trained in its use (Muniz Pazeli et al., 2014). Other nurses, in a variety of clinical settings such as emergency departments and heart failure clinics, have also achieved results comparable to ultrasound experts (De Lorenzo & Holbrook-Emmons, 2014; Gustafsson et al., 2015). These studies have shown that the skill of
the operator was the deciding factor for the success of the measurement, rather than the occupation of the operator (Dalen et al., 2015; De Lorenzo & Holbrook-Emmons, 2014; Muniz Pazeli et al., 2014).

Additionally, the review has indicated that IVC-US could be an effective measure in recognising volume related hypotension. Therefore, IVC-US performed during HD could be used to anticipate episodes of hypotension and should have minimal side effects on the patient. Hence, it was hypothesised that renal nurses should be able to use IVC-US for pre- and intradialytic volume assessment in satellite haemodialysis clinics after adequate training had been provided. The nurse would then be able to use this additional skill to diagnose imminent intradialytic hypotension, intervene clinically and avoid adverse patient outcomes.

In summary, the use of IVC-US adds an important clinical dimension for volume assessment, and the intravascular volume status could be monitored directly, swiftly and at any time during dialysis. This real-time visual impression of an individuals’ intravascular volume status could also potentially prompt renal nurses to reconsider initial decisions on UF goals. Historically, renal nurses who initiate and perform HD sessions have only pre- and intradialytic BP measurements and pre- and post-session weight measurements available when assessing patients for fluid-indicating parameters. These objective parameters, in addition to clinical observation and the nurses’ clinical experience are currently guiding them to define an individual UF goal. As renal nurses, they have the responsibility and obligation to make critical and safe decisions at the beginning of each treatment to ensure an event-free HD session. Given that almost a quarter (22%) of a dialysis population can be hypertensive yet euvolemic (Khan et al., 2017), this indicates the need for an additional objective measurement to better guide this decision-making process, which then could lead to improved patient outcomes. The candidate has hypothesised that IVC-US may be that additional measurement.

7.2.2 The prevalence rate of intradialytic hypotension (IDH)

The extent of the IDH problem in the local renal community was formerly unspecified and this research has contributed toward enumerating the scale of IDH. Episodes of symptomatic (S-IDH) and asymptomatic (A-IDH) hypotension were measured in a satellite haemodialysis clinic over three months and the results highlighted that IDH exists on a broader scale and affects more patients than is generally perceived. The phenomena of A-
IDH has previously been described (Bradshaw & Bennett, 2015; Bradshaw et al., 2017), but its prevalence has not yet been reported. Events of A-IDH may be generally underreported due to its latent nature and as a result may rarely be recognised by patients or nurses. This research showed that by including episodes of A-IDH, the total number of IDH events increased by almost a third.

Modelling also revealed that females had almost twice the risk of experiencing an event of IDH when compared to males, and patients diagnosed with glomerulonephritis had a significantly lower risk than patients with diabetes; phenomena both previously described in other studies (Rocha et al., 2015; Sands et al., 2014). This could be due to a variety of additional risk factors which are highly prevalent in patients diagnosed with diabetes such as vascular calcification and stiffness and autonomic dysfunction (Flythe et al., 2011).

Treatment duration also had a significant impact on predicting episodes of IDH, where patients with longer treatment hours (4.5-5 hrs) had a threefold or more chance to have IDH compared to patients receiving standard 4 hr treatments. It is possible that this increased risk correlates with the policy of generally using the maximum UFR of 1,000 ml/hr as default for every patient in our study unit, irrespective of their IBW and planned length of dialysis. This undifferentiated approach has been associated with detrimental effects and has been reported in previous publications (Agar, 2016; Flythe et al., 2011). In light of this, renal nurses and other healthcare providers involved in the care of HD patients must be made aware of the existence of A-IDH (Daugirdas, 2015), the prevalence of both S-IDH and A-IDH, and the significant consequences of these adverse events. Observed episodes of IDH, regardless of whether symptomatic or asymptomatic, need to be regularly documented by the treating nurses to acknowledge, validate and emphasise the existence of these evidently harmful events. Fundamental knowledge in this specific area might be beneficial to understanding the “bigger picture” and may encourage renal nurses toward improved patient care and outcomes.

In contrast, postdialytic overhydration (OH) was considerably less commonly observed than IDH. Despite Indigenous Australians proportionally experiencing the most IDH events, this ethnic group also had twice the risk than Caucasians to cease their first treatment of the week in an overhydrated fluid state. This could be due to the fact that these individuals generally are known to struggle more with fluid intake limitations over the weekend break. As Cass et al. (2002) have reported, there exists serious miscommunication between indigenous patients and non-indigenous healthcare workers in the quest to better adhere to and understand
treatment goals in the dialysis setting. Modelling showed that haemodialysis patients had a more than five times higher chance of OH on the first day of the week (Monday or Tuesday) than on the last day of the week (Friday or Saturday). This fact could potentially be due to renal nurses trying to place a careful limit on maximum UF goals on the first day of the week to avoid adverse events such as IDH, even when excessive fluid has been accumulated over the longer weekend interval. Anecdotally, such pre-emptive measures are known to occur when patients have no residual urine output, which dramatically limits their daily fluid intake allowance. Diabetics and patients diagnosed with hypertension had a higher risk of experiencing overhydration when compared to other causes. This may correlate with higher thirst distress occurring within this specific cohort of patients (Kara, 2016).

Other authors have previously described IDH as the most common intradialytic adverse event (Rocha et al., 2015; Stefansson et al., 2014). The results of this study have now confirmed this at the local level as well, showing an unacceptably high prevalence of IDH and highlighting the need for more objective fluid parameters to be made available to renal nurses. Due to a lack of accurate and objective fluid measures, renal nurses can only roughly estimate how much UF can be too much for an individual patient they treat. It also indicates the need for further education regarding the adverse effects of IDH and the identification of A-IDH events, aimed at decreasing the negative effects of these individual episodes on renal patients.

This study on the prevalence of IDH revealed and confirmed similar findings to previous studies (Rocha et al., 2015; Sands et al., 2014) where diabetics, females, indigenous and individuals with high UF goals had an increased risk of experiencing episodes of IDH. Therefore, renal nurses need to be more alert of these specific risk factors in order to identify subgroups of their patients with a heightened risk of IDH. Addressing potential knowledge gaps around the frequency of adverse events and patients most at risk could potentially lead to a paradigm shift in patient care. This new knowledge has potential to increase discussion amongst renal nurses and their patients at handover meetings and upon treatment initiation. Focusing their attention on this obvious problem could be one of the key features of future efforts to improve outcomes for patients.

In summary, renal nurses initiate treatments, decide on UF goals and UFR, and constantly observe patients during haemodialysis. Therefore, they need to be better equipped with knowledge about UF, BP and the negative impact of IDH, whether combined with symptoms or not. They are ideally placed to reflect on current
clinical practices, apply their critical thinking and implement new preventative strategies for IDH. Ultimately, satellite haemodialysis clinics need to have more effective preventative strategies and policies in place to reduce the prevalence of IDH amongst their patients. This should lead ultimately to improved health outcomes for patients and should enhance their quality of life.

7.2.3 The educational programme for renal nurses to perform IVC-US and to attain competency

The development of a structured four-stage educational programme was another important achievement during this study. As it is essential that renal nurses can independently perform IVC-US and subsequently use these findings for patient assessments, it was critical that this programme covered all relevant aspects of IVC-US. The programme was developed in order to transfer the knowledge and skill of performing and interpreting IVC-US scans. In collaboration with a sonologist, it was demonstrated that a renal nurse could master the skill of using IVC-US and interpret IVC-US results for intravascular volume assessment.

The theoretical framework by Benner (1984) has provided a solid foundation for the educational programme in this research. The structured pathway from theory to practice of a new clinical nursing skill, increasing in complexity over time culminated in technical competency of the new skill for the renal nurse. Further, the application of critical thinking and using IVC-US results in the context of other fluid-relevant clinical findings demonstrated proficiency of the renal nurse. Once competency in IVC-US is achieved and clinical findings are used in addition to other fluid-related parameters, IVC-US could be included in the daily fluid assessment routine in in- and outpatient haemodialysis clinics. Outpatient clinics in Australia often lack medical support for spontaneous fluid assessments and IVC-US could be particularly useful in this specific setting.

The first stage of this programme consisted of didactic training delivered by the sonologist and covered physiological principles of the IVC including dynamic changes during different volume status. This stage also included the technical handling of the ultrasound device, probe position and storage and transfer of recorded scans. The second stage aimed for the practical demonstration of the technique of IVC-US to the nurse in the clinical practice setting before, in the third stage, the renal nurse performed 100 IVC-US scans under supervision by the sonologist. In the fourth and final stage, two independent experts assessed the renal nurse
for competency. After successfully passing all four stages of the educational programme, the renal nurse was deemed competent to perform IVC-US by the two independent sonologists. These findings may have significant implications for clinical practice in future, in that the IVC-US technique could potentially also be transferred to other renal nurses.

Applying this programme to a larger group of renal nurses in educational initiatives should be the next useful step in introducing this additional fluid assessment method on a broader level in multiple satellite dialysis clinics. This novel educational programme offers a unique opportunity to enhance other renal nurses’ skills and encourage more accuracy in critical decisions for potentially improved patient outcomes. It has been found that this programme enabled the facilitator, in this study the sonologist, to transfer the skills to an ultrasound-naïve renal nurse. This renal nurse is now IVC-US competent and also has the potential to act as a prospective facilitator to teach other renal nurses in attaining the skill of IVC-US, using the same approach as this programme. As this approach was practical and provided a positive learning outcome, initially adhering to the same structure and using the same number of preliminary scans should then demonstrate competency in IVC-US in other renal nurses and validate the educational programme. This might appear at first as an onerous task considering the large number of necessary scans initially, but this would be essential for a solid foundation in such a repetitive task. Subsequent iterations of the educational programme would enable the trainer to ascertain the optimal number and type of scans required to achieve competency. It is accepted that individual perception in learning a new skill may vary and one may take a longer or shorter time to attain competency, but adding another element to the renal nurses’ skill set could be a strong motivator to embark on this journey. It is expected that once competent, trained renal nurses would then be able to share their knowledge and act as facilitators in the same way and IVC-US could potentially become a generally applied technique by the majority of renal nurses.

7.2.4 Assessing nursing competency in volume assessment using IVC-US

Once the educational programme was completed and the renal nurse deemed competent in IVC-US, it was then necessary to evaluate mastery in the skill of performing and correctly interpreting IVC-US with point-of-care ultrasonography on patients receiving HD in a trial. This trial resulted in good interrater agreement
between the nurse and the experts' findings, reported earlier. It was concluded that an ultrasound-naïve renal nurse could be successfully taught how to acquire, measure and interpret ultrasound images of the inferior vena cava. It was also demonstrated that, through multiple repeated performances of IVC-US in the same anatomical area, a non-expert in the skill of ultrasonography could obtain a valuable non-invasive skill. It further showed that the nurse was able to perform this skill independently from expert supervision, resulting in consistently correct visualisation of the anatomical area of interest. The recorded scans were retrospectively reviewed by two independent blinded experts, who then confirmed an accurate interpretation of the visualised fluid status by the renal nurse. It is suggested that the transference of skills would be complete when the newly competent renal nurse would then, after practice and experience, assume the role of the independent expert and subsequently confirm interpretations of scans performed by those renal nurses undergoing training.

These interpretations, based on the performed scans, would elicit critical information for the treating nurse, and in combination with other clinically relevant parameters like blood pressure and heart rate, could lead to a more holistic approach when assessing volume parameters and treatment goals. Adding this visual and non-invasive dimension to the traditional and established parameters of standard treatment could ultimately help with the often-difficult decision making processes by the nurse. Renal nurses with improved skills for objective volume assessment would be likely to better understand underlying anatomical conditions, and be more inclined to deliver a less troublesome treatment to patients. This in return, may lead to improved health outcomes for patients, such as avoiding subsequent hospital admissions and reducing cost.

In summary, for preparation of the pilot study, it was found that the structured educational programme devised in conjunction with an expert sonologist for an ultrasound-naïve renal nurse was successful in upskilling the nurse to perform ultrasound on the inferior vena cava.

7.2.5 Predictive value of IVC-US and BIS when observing for intravascular volume

Learning about the detrimental effects of IDH episodes led to a critical review of the current standard nursing practice of fluid assessment prior and during HD. Whilst good clinical nursing assessment and monitoring of the dialysis patient remains important in the attempt to avoid IDH, adding objective measure of fluid balance
measurements may enable more accurate predictions. It was found that available objective parameters are sometimes insufficient and misleading when used for a symptom- and burden free treatment. Adding further objective parameters to define a more precise UF goal would have been useful and could also have been potentially preventative for episodes of IDH.

The final stage of this research project was a simulative pilot study, where the ultrasound-competent renal nurse compared the usefulness of additional IVC-US measurements with BIS and traditional clinical fluid assessment methods. This study demonstrated that IVC-US and BIS were in agreement and that both would have predicted episodes of IDH. During this study, simultaneous BIS and IVC-US scans were attained over the course of a single treatment session on 30 patients and findings from these on pre- and intradialytic intravascular volume status were compared with the traditional clinical assessment method. Significantly, GEE modelling revealed that there was an almost 14-fold chance of an event of IDH in patients where IVC-US indicated hypovolemia during treatment compared to those subjects where IVC-US indicated euvoeemia.

Comparing the two methods of IVC-US and BIS revealed that both provided important information which could have been potentially useful in directing the nurse to change the current treatment and potentially avoid an adverse event. This last stage of this project also revealed that IVC-US can adequately estimate the intravascular volume status and its findings initially correlated with those of BIS. However, while BIS can only be performed prior to HD and display only an estimated forecast of the expected postdialytic fluid status, IVC-US can display intravascular volume status during a HD session and therefore could hold an informative advantage over BIS at any given intradialytic time. Nonetheless, it was found that both methods had good predictive value for the occurrence of IDH and that a specific algorithm to predict IDH could be derived that would be useful in predicting IDH.

This algorithm, a combination of four specific elements and thresholds has potential to have fundamental importance for the prevention of IDH. It comprises of a MAP < 70 mmHg, an UFR > 900 ml/hr, and IVC-US and BIS indicating hypovolemia, detailed below.

1. MAP < 70 mm Hg, or
2. BIS indicating hypovolaemia, or
3. IVC-US indicating hypovolaemia, or
4. UFR >900 ml/hr

Two of these parameters already exist in the standard pre-clinical assessment of HD patients. The UFR is set by the renal nurse and MAP is derived from the patient’s blood pressure. Pre-dialysis BIS was achieved through the use of the Body Composition Monitor (BCM - Fresenius), a device available on-site but generally unused by renal nurses in the clinics of this study. In simulation, adding IVC-US to these three elements showed application of this specific algorithm would have been predictive for all IDH episodes in this study. This algorithm predicted 11 episodes of IDH, 10 of which occurred. In the one case where the predicted IDH did not occur, tests indicated hypovolemia. This is significant, as this has not been previously reported in any other studies. For this patient cohort of 30 subjects, this algorithm showed a sensitivity of 95% and a specificity of 100%, which is an exceptional accuracy in such complex circumstances.

This study found that both IVC-US and BIS provided additional information that nursing staff could integrate into their patient assessment to best determine the UF goals and UF rates required. Further, when comparing both additional methods, they were in agreement, with IVC-US having the same predictive value for the occurrence as BIS. It is noted that none of the additional elements of the algorithm on their own would have been pre-emptive for every episode of IDH. However, this research found that combining IVC-US with BIS and traditional predialytic clinical assessment plus using MAP values would have been predictive and preventative for every episode of IDH. This is a significant result and should be explored further in future research.

Considering the characteristics and limitations of IVC-US and BIS, IVC-US holds some advantages over BIS. BIS can only be performed prior to a HD session providing simply an estimate for excess fluid but is unable to monitor fluid shifts occurring during HD. In addition, whether this estimated excess fluid is ultimately removed depends on sign and symptoms displayed by the patient during the treatment. This is where IVC-US holds a clear advantage over BIS, as it can provide accurate real-time intradialytic information to the observer, whenever it may be needed and in a swift and non-invasive way. Therefore, it could be assumed that IVC-US has eventually the potential to reduce morbidity and mortality in HD patients. Further, existing but unused strategies such as BIS could be reintroduced as a potential assessment tool with nurses being supported with evidence, creating an opportunity for better practice achieving better patient outcomes. With the addition of IVC-US, renal nurses would be able to use both these devices in a safe manner, allowing for a self-reflective
review of their routinely delivered nursing care in light of observations made when different methods are applied. IVC-US might initially appear to be more difficult to master than BIS and will require more initial investment from additional stakeholders, but it has been shown in this study that regular, routine use results in competency. Both methods, IVC-US and BIS require additional initial operator training and completion of training for BIS may be faster achievable than for IVC-US. However, initial cost for an ultrasound device or the BCM are similar and POCUS devices may already be readily available for complex AVF cannulations and they could potentially also be used for IVC-US. The investment in any of the devices and the operator training should be worthwhile and could outweigh the potential benefits in avoiding episodes of IDH causing hospitalisation and detrimental health effects.

Also, this study has shown that IVC-US is not just the domain of a specialist, and other health care professionals can gain competency when receiving adequate guidance. Despite multiple technical advances that have evolved in HD equipment over the past few years, intradialytic hypotensive adverse events still occur frequently. It seems to be crucial that these technical devices are applied on an ongoing basis, although it would be difficult to ascertain how frequently they are applied in individual dialysis units. IVC-US, in particular, clearly has the potential to change policy and procedures if applied on a larger scale and if renal stakeholders take ownership and apply this new knowledge.

7.2.6 Summary of major findings

Although the learning process to attain competency in the skill IVC-US for a renal nurse, including the correct interpretation of the scans, was time-consuming and challenging, it was worthwhile due to confirming its predictive value for IDH. This study has further implications for practice, as it has revealed that predialytic fluid assessment by renal nurses has needed more accurate parameters when aiming for accurate predictions of achievable euvolemia. It has also demonstrated that renal nurses may need comprehensive education to enhance their understanding and knowledge of excess fluid and intravascular fluid shifts during haemodialysis. Educating renal nurses in the use of IVC-US is an achievable goal if the learning process occurs in incremental steps, allowing for sufficient reflection and feedback on achieved stages under the guidance of an expert.
Results from this research have provided important information which could be useful in multiple ways. Firstly, it confirms that both symptomatic and asymptomatic IDH still remain the most common adverse event during HD, as previously described in many other scientific publications (Rocha et al., 2015; Schiller et al., 2015). The prevalence rate of IDH remains unacceptably high at both local and global levels. It seems that the renal community may sometimes become complacent and accept that IDH is an innate feature of the treatment, regarding it as occasionally unpreventable. Current measures for the prevention and identification of IDH are insufficient and more education for renal nurses is needed regarding the early recognition of IDH and enhancement of existing preventative measures (Bradshaw et al., 2015). It is essential to be vigilant for episodes of A-IDH when generally observing patients for IDH, as these have the same harmful effects as symptomatic episodes (Bradshaw & Bennett, 2015). This underscores the fact that IDH may be generally underreported and, as a result, particular episodes of A-IDH may have no consequences for a change in current nursing practice.

Additionally, more critical thinking amongst renal nurses may be required when aiming for improved health outcomes for patients. This includes renal nurses being more pro-active in improving the clinical outcomes from treatments they deliver to their patients. There exists a variety of technical devices and features built into HD machines and technical devices which could be more frequently used, including BVM, BIS, LUS and IVC-US (Mullangi et al., 2018). A recent national practice prevalence survey undertaken amongst HD units in the United Kingdom (UK) revealed that 78% of these units had no agreed policy for managing fluid balance in patients receiving HD (Dasgupta et al., 2016). Forty-four percent of the examined units did not assess fluid routinely and clinical assessment was the norm. These authors concluded that “There is an urgent need for establishing an evidence base on the optimal approaches to fluid management” (Dasgupta et al., 2016). This underscores again the necessity of more accurate and reliable fluid parameters in the day-to-day HD practice and the need for ongoing education and future research.

This new knowledge could possibly be used by nurse educators or clinical leaders to advance skills for renal nurses and set a path to delivering improved patient care. By keeping the focus on enhanced patient surveillance, this may translate to improved health outcomes for patients. It is considered the results of this study would be generalisable beyond the scope of the satellite clinics.
7.3 Limitations

This thesis was limited to two HD satellite clinics in the wider Perth Metropolitan area. Patient cohorts at tertiary hospitals receiving maintenance HD may present with additional and more complex health issues. Hence, results from this project may still be generalisable to other clinics, but caution should be exercised in their interpretation. Other local or global HD satellite units may also use different fluid assessment methods such as BVM, which can also be effective (Leung, Quinn, Ravani, & MacRae, 2014), but was beyond the scope of this thesis. Additionally, there might exist different strategies or preventative pathways for IDH in some units in Australia, and these have already established methods to observe patients for early signs of imminent IDH (Bradshaw et al., 2017), however these were neither discovered nor explored during this project.

This thesis is further limited to the education of one renal nurse in the skill acquisition of IVC-US. An educational programme was created and the renal nurse did achieve competence, however future research will need to demonstrate if these skills and knowledge are transferable to other renal nurses, could they be educated in a similar way, and would competency be achieved. The nurse in this study was highly motivated to master the skill of IVC-US and achieve competency. Motivation may vary within a larger group of renal nurses and this may impact on their attainment of this particular skill, however this would also warrant further research.

Cardiovascular conditions such as pulmonary hypertension, right heart failure and tricuspid regurgitation may influence CVP and subsequently results of IVC-US measurements (Simoni et al., 2016). It is therefore recommended to consider any IVC-US results for patients with any of these diagnosed conditions in the clinical context of other objective volume indicative parameters as well. It is also likely that patient cohorts may differ locally and/or globally, depending on dialysis vintage, nutritional status, causes of chronic kidney failure and other factors. Hence, results of these observations might appear differently.

Data collected during the 3-month phase where prevalence of IDH episodes was measured did not capture data on some factors such as dialytic age, antihypertensive medications and residual urine output from participants, so their significance as contributors to IDH could not be assessed. Additionally, IBW assessments and adjustments during this study period were only based on the clinical findings by nurses and could not be validated with BIS. The sample sizes in the patient cohort of the IVC-US vs BIS study and in the interrater
reliability study were comparably small, with 30 and 10 participants respectively, and both studies were conducted as pilot studies. Further sufficiently powered cohorts would inform the results derived from this study.

BIS also has some limitations, where it measures the total body water but cannot discriminate between intravascular water volume in the plasma and that in the extravascular compartment. The use of BIS has also been cautioned by Davenport (2013), as overzealous reduction of IBW based on BIS measurements alone could ultimately lead to loss of residual urine output function. Further, other authors have suggested that BIS underestimates volume removed from the trunk and marked obesity can deliver unreliable results (Alexiadis et al., 2017).

Whilst conducting this project, it was noticed that there was some resistance from clinical staff for this research to be undertaken, perhaps for logistical and/or personal reasons. Previous studies have demonstrated that nurses, although required to participate in continuing education, are sometimes unwilling or unable to leave clinical settings to do so (Coventry, Maslin-Prothero, & Smith, 2015). Nursing research might also not be well supported by some nurse unit managers as it could potentially distract the nurse from their regular nursing duties, and this has been identified as a common barrier (Bonner & Sando, 2008).

7.4 Recommendations for policy, practice and research

7.4.1 Policy

It is essential to provide renal nurses with more specific education to increase awareness of the overall negative consequences of each episode of IDH. This, in combination with highlighting the opportunities for IDH prevention, must receive more attention from everyone in the renal team. This includes regular and accurate documentation of S-IDH and A-IDH events according to commonly agreed definitions. Reviewing these documented observations on a regular basis and comparing them with existing preventative IDH strategies should reveal for each site the efficacy of their individual IDH prevention strategy. It is suggested that adding more objective parameters into the UF volume decision-making process prior or during HD sessions may
certainly help to reduce IDH events. Regular education sessions covering the major topics such as causes and consequences of IDH, preventative methods and the review of unit-specific guidelines may help to raise awareness of IDH at the local level. Additionally, introducing this topic at national and international renal nursing conferences may have a positive effect on renal nurses’ individual knowledge and perception and may subsequently influence their daily work practice. This may then initiate discussions within renal nursing teams, encouraging critical thinking and reflection on current applied nursing practices, ultimately affecting renal nursing policies.

7.4.2 Practice

The new knowledge about the prevalence rate of IDH and the increased risk for subgroups of patients has potential to open up discussions amongst renal nurses and their patients at handover meetings and upon treatment initiation. Therefore, all relevant aspects of the decision-making process by nurses upon treatment initiation should be a most important subject for future research studies.

This research has also revealed that current nursing assessments on fluid status may lack reliable, accurate and objective parameters, which are crucial for the delivery of a safe and uneventful treatment. Therefore, more consistent information is needed prior to and during HD sessions, to make necessary adjustments and to tailor treatments to the individual (Agar, 2016). The lack of objective parameters for fluid assessment is problematic and can lead to further complications for the patient. Using IVC-US as an adjunct to clinical fluid assessment has the potential to lead to better patient outcomes. The pervasion of a one-size-fits-all approach, encountered at least in the satellite clinics of this study, should be re-examined in terms of current nursing practice. Particularly, the commonly observed approach of 1000ml/hr UFR should be reconsidered for its safety and its potential consequences on clinical outcomes, such as IDH, needs to be re-evaluated. Knowledge evolving from recent research should be translated into enhanced clinical practice. This could be potentially achieved with specifically targeted education seminars or conference presentations for renal nurses and affiliated healthcare professionals covering the topic of IDH as the most frequent intradialytic adverse event.

This novel approach of renal nurses using intradialytic IVC-US has the potential to change clinical practice, especially if this skill could be successfully transferred onto other renal nurses. Notwithstanding some limitations of this project, it was shown that a satellite-based renal nurse could use IVC-US to potentially
improve patient outcomes. It was further demonstrated that once the skill of obtaining and interpreting ultrasound scans was achieved, it did not have to remain within the purview of the medical profession. Nonetheless, an essential element for the outcome of this research was the inclusion of the medical specialist, the sonologist, who initially directed the learning process. This emergency specialist was also a medical sonographer with complex technical skills, and enabled the skills transference of image acquisition and clinical interpretation of the obtained scans. Transferring this knowledge to the ultrasound-naïve nurse was crucial to make this project successful.

Looking forward, theoretically and practically IVC-US is an excellent non-invasive adjunct diagnostic tool, especially for real-time assessments of the intravascular fluid status. It could be used in every satellite dialysis clinic if an ultrasound device with a suitable transducer was on hand. POCUS devices are today often readily available in most satellite HD clinics (Mullangi et al., 2018), mainly to provide renal nurses with a non-invasive and swift support for complicated cannulations (Marticorena et al., 2015). When available, they are frequently and regularly used and renal nurses have adopted this tool as part of their daily clinical practice. The use of POCUS devices has already advanced the renal nurse’s skill set and added another essential component to improvement of direct patient care. Multiple studies in other clinical areas have demonstrated that specialised nurses from heart-failure clinics can successfully learn and apply the skill IVC-US (Dalen et al., 2015) (Gustafsson et al., 2015) and this has now also been proved in the renal nursing profession.

### 7.4.3 Research

Further research is needed for several topics resulting from this thesis. Future research investigating the prevalence of IDH will also need to include data on the residual urine output in HD patients, as this will most likely affect treatment goals and the likelihood of IDH events. To date, residual urine output in HD patients and its correlation with IDH has not been the focus of many renal research projects, although residual urine output plays a significant role in the quality of life for this patient cohort.

Another important topic for prospective studies is the process of decision making of renal nurses for individual UF goals. Anecdotally, this fundamental process varies somewhat amongst renal nurses and highlights the range and scope amongst individual nurses, who at times would assess the same patient differently for fluid status. This difference then has the potential to result in differing UF goals, subsequently affecting the
occurrence of IDH. Therefore, all relevant aspects of the decision-making process by renal nurses upon treatment initiation should be an important subject for future nursing research studies. Of further interest in this context would also be the observation of the process in finding and establishing individual IBW targets for patients including regular review. It is likely that there exists a broad variety of approaches in a variety of clinical practice settings in satellite clinics and how IBW’s are generally established. This includes finding an agreement on IBW’s through interprofessional conversation between renal nurses and renal consultants, and the renal patients who are sometimes included in this discussion.

It is now suggested that future research studies should investigate, on a larger scale, the transferability of the skill IVC-US by the trained nurse or a sonologist to other renal nurses. This research would explore if IVC-US during a haemodialysis session could be successfully performed, including correct conclusions drawn from the obtained scans and if this research would provide similar outcomes for operators. It should also be investigated if motivation to attain this skill varies amongst renal nurses and if this would affect outcomes.

As this simulative pilot study comprised of a relatively small patient cohort, future research will have to demonstrate whether IVC-US could hold an advantage over BIS when using these methods for the prevention of IDH. Most importantly, the algorithm derived from this research needs to be tested on a larger scale and warrants further exploration in the future, such as a randomised controlled trial comparing IVC-US and the proposed algorithm against standard clinical practices.

Several other aspects for future studies evolve from this thesis. A comparative study exploring the cost, time and operator training required for the three different fluid assessment methods which includes patient-reported outcomes, dialysis tolerability and which measures the inter- and intradialytic quality of life of haemodialysis patients would be warranted. Future studies may also investigate the detrimental effect of IDH episodes on cardiac and cerebral function, measured either per episode or observed over time in the most affected patient cohort (McIntyre & Goldsmith, 2015).
8. Conclusion

Several milestones were achieved during this project and each step provided new evidence to address some of the complexities within the field of fluid assessment in haemodialysis patients. This included a skill that is readily attainable by renal nurses.

The systematic literature revealed that renal nurses have not previously used IVC-US on haemodialysis patients to objectively assess their fluid status. However, it also revealed that IVC-US can be a useful objective method to assess a patient’s fluid status and other specialised nurses have successfully used ultrasound in their clinical speciality. Adding asymptomatic IDH events to symptomatic IDH events increased the prevalence of any IDH episode by almost a third during a three-month observational period. This underscored the importance of including symptom-free events when observing for IDH.

Knowing that multiple episodes of IDH are causing a multitude of detrimental patient outcomes, it became clear that renal nurses need more objective, accurate and reliable fluid assessment methods for the successful prevention of these adverse clinical incidents. IVC-US allows for a real-time visual observation of intravascular volume status in HD patients which directly correlates with both CVP and the well-being of a patient during treatment and could be an ideal addition to the skill-set of a renal nurse. Moreover, this project demonstrated that a staged education programme can be a valid and successful method to achieve competency for a renal nurse in the use and application of IVC-US. The application of IVC-US by the renal nurse in the last stage of this project demonstrated a potentially high level of usefulness for prevention of IDH. When compared to and used in conjunction with another established fluid assessment technique, BIS, both provided similar results.

This study has shown that current fluid assessment methods have limitations and more objective parameters to establish evidence for the optimal approaches to fluid management are needed. IVC-US is first and foremost a superior assessment tool to others as it can be used as both a pre-emptive assessment tool pre-dialysis and a proactive diagnostic tool intra- and post-dialysis. This research demonstrated that nurses can effectively acquire complex skills usually reserved for the medical profession, and it further showed that using these skills
could provide useful additional information when combined with other fluid-related parameters. This information could be critical when renal nurses strive for prevention of episodes of IDH.

Initially, this project set out to explore whether renal nurses could safely and efficiently perform IVC-US on HD patients during their treatments to obtain an objective assessment of their fluid status, and if these findings could potentially lead to improved health outcomes for patients. This was confirmed with the renal nurse acquiring competency to assess patient fluid status. Thereafter, it was possible to demonstrate in a simulative pilot study that IVC-US had the same predictive value for the occurrence of IDH episodes as BIS, but it could also provide a real-time intravascular volume trend at any intradialytic moment, holding an advantage over BIS. The pilot study allowed for a low-risk and meticulous observation of the potential impact of IVC-US, performed during HD treatment, compared in parallel with BIS and traditional clinical predialytic assessment methods. If the information provided by IVC-US in the pilot study had been available for the nurse who performed the HD, and they had initiated prompt preventative measures, the incidence of IDH episodes would have been significantly reduced.

However, this study has also revealed that although IVC-US could deliver important and essential information to the observer, it should not be used as the sole parameter for intravascular volume assessment. It should always be seen in the clinical context and as an adjunct to other objective parameters. When IVC-US is used in conjunction with two readily available clinical elements and BIS, and applied as a simple clinical algorithm, it is strongly predictive of the majority of IDH episodes.

Results of this thesis have created a unique and original contribution to nursing research, including the compilation of a learning package for future nurses who may aim to attain the same skill. Further, in simulation it was possible to demonstrate the value and the potential of IVC-US skills in making a positive impact on the clinical outcomes of HD patients.

The addition of IVC-US as another clinical dimension for assessing fluid has the ability to change policy and clinical practice in the future, given sufficient support from stakeholders and clinical leaders. It has good potential to change clinical practice for pre- and intradialytic fluid assessment if applied by more renal nurses on a broader scale.
There are constraints around its use, due to resource and logistical limitations, but it is recommended that IVC-US should at least be used as an adjunct to clinical fluid assessments, where it could provide valuable information and direct nurses to reassess their clinical decisions. A simple reconsideration of fluid management might hold the key to improved patient outcomes. It might also instigate a critical assessment of the local renal nursing practice and initiate reflection and discussion amongst nurses on patient outcomes. This may ultimately contribute to changes in policy and practice, resulting in improved morbidity and mortality outcomes for HD patients.
References


108


McIntyre, C. W., & Goldsmith, D. J. (2015). Ischemic brain injury in hemodialysis patients: which is more dangerous, hypertension or intradialytic hypotension? *Kidney International*, 87(6), 1109-1115. doi: 10.1038/ki.2015.62


113
Appendices:

Pages 114-117 are not available in this version of the thesis
Intradialytic hypotension – A daily challenge for each one of us – Could ultrasound of the inferior vena cava provide us with a better understanding of the intravascular volume status?

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Occurrence rates of up to 31% makes intradialytic hypotension (IDH) one of the most frequent intradialytic adverse events (Stefansson et al., 2014). Haemodialysis units worldwide use a broad variety of methods to approach this issue. Blood volume monitoring (BVM) or the Body Composition Monitor (BCM, Fresenius) can be helpful tools providing more objective data when assessing a patient for excess volume, however they have their limitations. Ultrasound of the inferior vena cava (IVC-US) has been used successfully by doctors to assess volemic status of haemodialysis patients (Muniz Pazeli et al., 2014).

During my work as a renal research coordinator, I gained good insight and understanding on the design of clinical trials. Dissatisfied with the frequency of IDH events in our working environment, I decided to use this knowledge. I developed a research question and applied for a research grant. I set out on a journey asking if renal nurses can successfully use IVC-US, to add another objective parameter when assessing a patient for their fluid status and investigate if there is any correlation with the patient’s ideal body weight (IBW) and blood pressure.

After being successful with the grant application and obtaining approval from our Ethics committee we were all prepared for a good start.

As a first approach, I reviewed the existing literature, seeking evidence of whether renal nurses were previously using the method IVC-US on haemodialysis patients. In this respect, I found a paucity of knowledge, which resulted in a peer-reviewed article accepted by the “Journal of Renal Care” (EDTNA/ERCA) which will be published in 2017 (Steinwandel, Gibson, Rippey, Towell, & Rosman, 2017).

In a second step, a satellite dialysis clinic in metropolitan Perth was audited over a three-month period on the frequency of symptomatic and asymptomatic IDH events. This was detected either by altered treatment parameters, or by an adverse event recorded by nurses in the progress notes.

Following this, the next step was to explore if a renal nurse can successfully learn the technique of IVC-US and draw the correct conclusions on hypov-, eu-, or hypervolemic from the scans, guided by an expert sonographer. We are currently...
PROJECT
Do ultrasound measurements of the inferior vena cava (IVC-US) by nursing staff improve assessment of intravascular volume status in the satellite haemodialysis clinic settings

CLINICIAN RESEARCH FELLOW
Dr Ulrich Steinwandt

Aims of the Project
1. To determine the reliability of clinical assessment of dry weight in comparison to IVCUS.
2. To determine the incidence of intra-dialytic adverse events that are related to ultrafiltration.
3. To determine whether the additional use of IVC-US in determination of haemodialysis patients’ volume status is able to reduce the incidence of ultrafiltration related adverse events.

Progress Report
The WA Department of Health/Raine Fellowship has allowed me to investigate the fluid status of haemodialysis patients while they are on their clinical treatment. Patients with chronic Renal Failure need haemodialysis treatment to survive. Fluid removal during haemodialysis can have significant side effects such as circulatory collapse and loss of consciousness which is undesirable. With the use of ultrasound nurses have the opportunity to understand the fluid status of their patients better and to adjust the fluid removal of an individual, so that negative consequences from the treatment itself can be avoided. It also offers a visual impression of the direct impact of a medical treatment on the health of a patient.

These findings can lead to a novel approach in the assessment of a patient’s fluid status by renal nurses which, in return, could deliver a better and safer treatment to haemodialysis patients. The addition of ultrasound measurement could potentially improve the health outcomes for haemodialysis patients. This may include a direct positive impact on their quality of life.

This Fellowship also enabled me to significantly progress my academic pathway to a PhD in Nursing. It allowed me to perform research relevant tasks while at the same time I was able to advance my scholarly skills. It empowered me to attend a broad variety of scientific seminars and to gain more experience in the field of clinical research. Additionally, I was able to refine my clinical skills in performing ultrasound and it will allow me to train other nurses in this specific expertise. I also feel deeply grateful and thrilled by having this fantastic opportunity to further my clinical career and to network and collaborate with like-minded scientists.
PROJECT TITLE
Do ultrasound measurements of the inferior vena cava (IVC-US) by nursing staff improve assessment of intravascular volume status in the satellite haemodialysis clinic settings?

CLINICIAN RESEARCH FELLOW
Dr Ulrich Strehwandel

PROJECT OVERVIEW AND AIMS
The initial objectives of this project were:

1. To determine the incidence of intradialytic adverse events that are related to ultrafiltration.
2. To determine if a renal nurse can perform IVC-US and reliably assess the obtained scans on intravascular volume status, classifying a patient in either hypo-, eu- or hypervolemic status.
3. To determine whether the additional use of IVC-US in determination of haemodialysis patients’ volume status can reduce the incidence of ultrafiltration related adverse events.

A total of 2357 haemodialysis sessions in 64 patients were investigated on the prevalence of clinical events of symptomatic and asymptomatic hypotension over a retrospective 3-month period. It was found that symptomatic intradialytic hypotension was the most common adverse event during 221 (9.4%) of all sessions, while hypervolemia was found after 103 (4.4%) treatments. Asymptomatic hypotension occurred during 88 (3.7%) of all sessions. Indigenous Australians, females and diabetics had the highest prevalence of hypotensive episodes. Combining asymptomatic and symptomatic hypotension resulted in a prevalence of 13.1% and underscores the need for more preventative strategies and/or more objective parameters for volume assessment.

Upskilling of the renal nurse in the use of ultrasound was provided by an expert Sonologist from Emergency Department Sir Charles Gairdner Hospital. After receiving substantial training, the renal nurse performed 100 preliminary scans of the IVC on a variety of patients to refine the technique and to comprehend the relationship between clinical findings. After receiving appropriate feedback on these scans the nurse then performed 60 scans on 10 patients, assessed them and categorised these into the appropriate fluid status according to the “Guidelines for the Echocardiographic Assessment of the Right Heart in Adults, American Society of Echocardiography.” Two blinded expert reviewers found a good interrater agreement between the nurse and any of the experts.

In the current and final stage of this project the renal nurse investigates 30 randomly selected patients and their trend in the IVC diameter over the course of a treatment session, compared to an initial bi impedance measurement, while observing for clinical symptoms. Data collection is now almost completed and preliminary data analysis from the first 10 patients demonstrated that only 2 out of 10 were classified hypervolemic upon treatment initiation while 8 were euvoletic. This information could have been beneficial for the nurse when initially deciding for an ultrafiltration goal.

Figure 1. IVC longitudinal view – maximal diameter (IVCd max) at expiration.

Figure 2. IVC longitudinal view – minimal diameter (IVCd min) at inspiration.
SUMMARY
We have found that IV-C-US can add valuable information when assessing for intravascular volume status. Additionally, we are confident to state, that it is potentially possible to train an ultrasound naive health professional in the skill of performing an ultrasound on the inferior vena cava, which is a big step forward in advancing renal care. It has good potential to have an impact on the fluid assessment routine for haemodialysis patients and may be reflected in clinical guidelines, once approved by the relevant institutions as an additional valid non-invasive method. When applied on a broader scale with more patients and nurses, it has potential to result in beneficial health outcomes for the patients we treat.

Publications

Grants
Winner of the Barry Marshall Travel Grant 2017, Spinnaker Health Research Foundation.

ACKNOWLEDGEMENT
The financial support during the Fellowship allowed me to spend significant time with data collection at the bedside, statistical analysis and interpretation of data and finally creating publishable information on the findings. I am very grateful that I had this opportunity to contribute to the body of knowledge and advance the renal nursing care. As we renal nurses spend a significant amount of time with patients, I see the absolute necessity for us to gain a better understanding of a patient’s condition and tailoring individual treatment concepts to deliver improved health outcomes.
PROJECT TITLE
Do ultrasound measurements of the inferior vena cava (IVC-US) by nursing staff improve assessment of intravascular volume status in the satellite haemodialysis clinic settings?

CLINICIAN RESEARCH FELLOW
Dr Ulrich Steinwandel

RESEARCH PROJECT OVERVIEW AND AIMS
Previous research has shown that renal nurses have limited objective parameters available prior to the initiation of a haemodialysis session. These parameters are crucial when a renal nurse decides the treatment goals (fluid removal) for an individual. If these goals are chosen too high, episodes of low blood pressure (intradialytic hypotension = IDH) can occur subsequently. These episodes are the most common unwanted side effects of haemodialysis. It is also known that they can have a negative impact on various organ systems and the quality of life of patients with chronic kidney disease receiving haemodialysis. The study aims are:

(i) To provide evidence of whether a renal nurse can reliably assess the intravascular volume status of haemodialysis patients during treatment using abdominal ultrasound on the inferior vena cava (IVC-US); (ii) To determine if renal nurses can draw the correct conclusions from these findings with the potential to amend treatment goals and to ultimately improve patient outcomes; (iii) To determine the prevalence rate of IDH in a local satellite haemodialysis clinic in the Perth metropolitan area. In this step, two fluid assessment methods, bioimpedance spectroscopy and IVC-US, will be compared to determine their usefulness as an additional parameter when made available to renal nurses; and (iv) To raise the awareness of the existence of the dilemma of IDH in the local and wider renal community, amongst stakeholders and to offer some potential solutions.

The findings could potentially be used by local senior nurses (e.g. Clinical Nurse Specialists, CNSs), staff development nurses and other stakeholders to inform policy, as well as changing current nursing practice. This study found that prevalence rates of IDH at local haemodialysis units remain unacceptably high, and more awareness about their negative consequences and measures for prevention are needed. The work further demonstrated that a renal nurse can be successfully trained and upskilled to perform IVC-US, drawing the correct conclusions, similar to other clinical experts. This additional skill has good potential to reduce adverse outcomes for haemodialysis patients when applied in dialysis clinics in the near future.

ONGOING CLINICAL DEVELOPMENTS
Research Translation and Diffusion
Research findings from this study have been presented and positively received by local stakeholders during medical meetings at Fiona Stanley Hospital (FSH) and at a local conferences for renal nurses. Follow-up conversations with individuals have shown that there is great interest (nurses and medical staff) in addressing the problem of IDH, an ongoing issue that the renal community is well aware of. To date, only one nurse has been educated to perform IVC-US; clearly, there is the need to educate more renal nurses and other healthcare professionals with the same skill to achieve better patient outcomes. Translation of research findings into clinical practice will need strong support on multiple levels. For this to be achieved, collaboration with local stakeholders of the renal community (clinical nursing educators, nurse unit managers (NURMs), CNS and medical staff) are required. The technique of IVC-US has also been practically demonstrated to medical staff at FSH, but it will need further education and repeated training of individuals to implement this method successfully in a local renal department of WA Health. Therefore, active support would be essential for the success and implementation of this novel technique in the hands of renal nurses.

In addition, existing ultrasound devices in the local renal units might also need to be equipped and upgraded with abdominal ultrasound probes to technically allow for IVC-US to be performed. Most current ultrasound machines readily available in the local renal units are commonly equipped with probes only suitable for cannulations of fistulas, but not for IVC-US. This project has shown that existing devices for fluid assessment (e.g. Body Composition Monitors (BCMs) using bioimpedance spectroscopy), are currently not being used, although they are available in some dialysis units (e.g. Fresenius Medical Care, a private company) and have been proven to be similarly effective as IVC-US. From discussions with renal nurses who work overseas (e.g. Europe), Dr Steinwandel learned that the use of IVC-US by renal nurses is more common and is successfully used in their units.
FELLOWSHIP OUTCOMES

Advancing Knowledge

Publications

- Steinwandel U. Intradialytic hypotension – a daily challenge for each one of us – could ultrasound of the inferior vena cava provide us with a better understanding of the intravascular volume status. Renal Society of Australasia Communicator. 2017; 20: 11-12.

Conference Presentations


Capacity Building

Grants

One grant application for this project was successful in 2017, namely the “2017 Barry Marshall Travel Grant”. These funds were used to attend a conference presentation in Sydney.

Collaborations

Throughout the project multiple local academic collaborations evolved. Dr Steinwandel was able to establish a strong collaboration with Professor James Rippey, an expert sonologist at the Emergency Department of Sir Charles Gardiner Hospital. He is also affiliated with UWA and with Professor Johan Rosman, Renal consultant at Royal Perth Hospital and Medical Director at Curtin University. Another strong partnership developed with Dr Richard Parsons, a senior statistician at Curtin University, who was frequently consulted and made significant contributions to this project. Finally, through Dr Steinwandel’s PhD studies at Edith Cowan University, and the ongoing support of his supervisors Dr Nick Gibson and Dr Mandy Towell, this project has achieved strong relationships amongst mentors from several local universities.

ACKNOWLEDGEMENTS

Dr Steinwandel is sincerely grateful for the extraordinary opportunity provided by the WA Department of Health and the Raine Medical Research Foundation.
Certificate of Appreciation

Awarded to
Uli Steinwandel

for delivering a presentation entitled
‘Meeting the Challenge of Fluid Assessment’

at the RSA WA Branch Symposium
held on
Saturday 12 August 2017

Debbie Fortnum
WA Branch Chair
Renal Society of Australasia Ltd
Renal Society of Australasia WA Branch Symposium Program 2017

**WA Branch Symposium: Changing Climate**

- **Topic**: Changing Climate: Meeting the Challenge
- **Date**: 12 August 2017
- **Start Time**: 8.30am
- **End Time**: 4.00pm
- **Venue**: Parmelia Hilton, Argyle Ballroom, 14 Mill St, Perth WA 6000
- **Contact Name**: RSA Office
- **Contact Phone**: 1300 841 480
- **Contact Email**: events@renalsociety.org
- **Website**: www.renalsociety.org
- **Attachment**: Download Meeting Flyer
- **Max. Attendees**: 120
- **Who Can Register**: Anyone

The theme of the 2017 RSA WA Branch Annual Symposium is meeting the challenge of a changing climate. The aim is to update clinicians on clinical developments in WA and challenge them to change practice to meet the challenges. One day symposium with a variety of speakers. There will be trade display and catering is provided.

**Download the Event Flyer here**

**Cost:**
- **Members**: Early bird now closed!
  - $125
- **Non-Members**: $220

**Program:**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>8.00am – 8.30am</td>
<td>Registration and Trade Stands</td>
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<tr>
<td>8.30am – 8.40am</td>
<td>Welcome</td>
<td>Debbie Fortnum</td>
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<td></td>
<td></td>
<td>Chair WA Branch, RSA</td>
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<tr>
<td>8.40am – 9.25am</td>
<td>The challenge of staying on your feet</td>
<td>Ben Bull</td>
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<td>Physiotherapist, SGSH</td>
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<tr>
<td>9.25am – 10.00am</td>
<td>Ultrasound by nurses – meeting the challenge of fluid assessment</td>
<td>Ulrich Steinwandt, NP</td>
</tr>
<tr>
<td>10.00am – 10.30am</td>
<td>Morning Tea</td>
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Presented to

Uli Steinwandel

for delivering a presentation entitled
Ultrasound of the inferior vena cava for volume assessment - can renal nurses master this skill? A cross sectional study

at the

2017 RSA Annual Conference

19-21 June 2017

F. Donnelly
President
Renal Society of Australasia Ltd
9. Ultrasound of the inferior vena cava for volume assessment - can renal nurses master this skill? A cross sectional study

Ulrich Steinwandel1, Dr Nick Gibson2, Dr Amanda Towell-Barnard2, Dr James Rippey3, Prof. Johan Rosman4
Fremantle Hospital, Western Australia1, Edith Cowan University, Western Australia2, Sir Charles Gairdner Hospital, Western Australia3, Curtin University, Western Australia4

Background: Ultrasound of the inferior vena cava (IVC-US) has been used to estimate intravascular volume status. Knowledge of intravascular volume status is of specific interest for renal nurses in the haemodialysis setting. To date, no study has examined whether renal nurses can reliably perform IVC-US for volume assessment. This study aimed to determine if a renal nurse could master the skill of performing and then correctly interpreting IVC-US on patients receiving haemodialysis.

Method: After receiving adequate theoretical training and performing 100 training scans, 60 nurse-performed ultrasound scans were categorized by the nurse into hypovolemia, euvoolemia or hypervolemia through visual estimation of the maximal diameter and degree of collapse of the inferior vena cava (IVC). Scans were subsequently assessed for adequacy and quality and were then interpreted by two expert sonologists, who were blinded to each other’s and the nurse’s results.

Results: The intrater reliability (IRR) of 60 scans was good, with ICC 0.79 (95% confidence interval (CI) =0.63 to 0.87) and with a good intrater agreement for the following estimation of intravascular volume (Cohen’s weighted Kappa kw = 0.62), when comparing the nurse to an expert sonographer.

Conclusions: A renal nurse can reliably perform ultrasound of the IVC in haemodialysis patients, obtaining high quality scans for the purpose of volume assessment of haemodialysis patients. This novel approach could be more routinely applied by other renal nurses to obtain objective measures of patient volume status in the dialysis setting.
Predicting healing rates of hand fractures

Researchers: Dr JF Anakkal and Dr AJ Perumpanin
Sponsor: Fremantle Football Club
Amount Awarded: $10,000

The scaphoid bone is one of the carpel bones in the area of the wrist and is the most common carpel bone fractured – usually through a fall on to an outstretched hand.

Predicting whether a scaphoid fracture can heal itself is difficult so most are operated on.

Historic data indicate the rate of non-union in scaphoid fractures is only about five per cent, which suggests that 95 percent of fractures are over treated through surgery.

This study will devise a predictive test for non-union of scaphoid fractures in the early weeks after a fracture.

The test will also help to better care for fracture patients in areas where surgery is unavailable because it will enable high-risk patients to be transferred for surgery rather than treated with ultimately unsuccessful non-surgical approaches.

Chasing a cure for intestinal fibrosis

Researcher: Dr Angela Chew
Sponsor: Austal Ships Staff and Management
Amount Awarded: $15,000

Intestinal fibrosis in patients with Crohn’s disease (a form of irritable bowel syndrome) is a frequent and debilitating complication not only resulting in small bowel obstruction but eventually repeated bowel resection and short bowel syndrome.

Preliminary studies by our group have demonstrated that the fatty acid phosphatidylcholine, a major component of biological membranes, has potent anti-fibrogenic properties.

In this study we aim to determine how phosphatidylcholine operates to reduce intestinal fibrosis in an effort to develop a new treatment to prevent and cure intestinal fibrosis in patients with Crohn’s disease.

Sponsored by: Austal Ships Staff and Management

Using ultrasound to better manage kidney dialysis

Researcher: Mr Ulich Steinwandel
Sponsor: Fremantle and Attadale Rotary Clubs Charity Golf Day
Amount Awarded: $16,632

Fluid removal or ultrafiltration is a crucial component of blood dialysis for kidney disease patients.

However the ultrafiltration target, which is partly determined subjectively by dialysis staff, is often inaccurate.

Excessive ultrafiltration leads to low blood pressure and troublesome symptoms that can lead to hospitalisation of dialysis patients.

This study will assess the additional use of an ultrasound method to determine more accurate ultrafiltration targets before hemodialysis.

It is hoped the new method will prevent low blood pressure and its related symptoms and subsequent hospitalisation.

Sponsored by: Rotary Clubs of Fremantle and Attadale
## STROBE checklist for cross-sectional studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
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</table>
| **Title and abstract** | 1 | *(a) Indicate the study’s design with a commonly used term in the title or the abstract  
(b) Provide in the abstract an informative and balanced summary of what was done and what was found* |
| **Introduction** | 2 | Explain the scientific background and rationale for the investigation being reported |
| **Objectives** | 3 | State specific objectives, including any prespecified hypotheses |
| **Methods** | 4 | Present key elements of study design early in the paper |
| **Study design** | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| **Setting** | 6 | *(a) Give the eligibility criteria, and the sources and methods of selection of participants* |
| **Participants** | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| **Variables** | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group |
| **Data sources/measurement** | 9 | Describe any efforts to address potential sources of bias |
| **Bias** | 10 | Explain how the study size was arrived at |
| **Study size** | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| **Quantitative variables** | 12 | *(a) Describe all statistical methods, including those used to control for confounding  
(b) Describe any methods used to examine subgroups and interactions  
(c) Explain how missing data were addressed  
(d) If applicable, describe analytical methods taking account of sampling strategy  
(e) Describe any sensitivity analyses* |
<p>| <strong>Statistical methods</strong> | <strong>Results</strong> | <strong>130</strong> |</p>
<table>
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<tr>
<th>Section</th>
<th>Numbers/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>13*</td>
</tr>
<tr>
<td>Descriptive data</td>
<td>14*</td>
</tr>
<tr>
<td>Outcome data</td>
<td>15*</td>
</tr>
<tr>
<td>Main results</td>
<td>16</td>
</tr>
<tr>
<td>Other analyses</td>
<td>17</td>
</tr>
<tr>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>Key results</td>
<td>18</td>
</tr>
<tr>
<td>Limitations</td>
<td>19</td>
</tr>
<tr>
<td>Interpretation</td>
<td>20</td>
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<tr>
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<td>21</td>
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<tr>
<td>Other information</td>
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<tr>
<td>Funding</td>
<td>22</td>
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</table>

**Participants**

1. Report numbers of individuals at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed.
2. Give reasons for non-participation at each stage.
3. Consider use of a flow diagram.

**Descriptive data**

1. Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders.
2. Indicate number of participants with missing data for each variable of interest.

**Outcome data**

Report numbers of outcome events or summary measures.

**Main results**

1. Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included.
2. Report category boundaries when continuous variables were categorized.
3. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.

**Other analyses**

Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses.

**Discussion**

1. Summarise key results with reference to study objectives.

**Limitations**

Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.

**Interpretation**

Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.

**Generalisability**

Discuss the generalisability (external validity) of the study results.

**Other information**

1. Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.
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data for each variable of interest

(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)

<table>
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<tr>
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| Other analyses | 17  | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses |

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