Title: Bioimpedance as a predictor of survival in renal failure and associated comorbidities.

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Abstract

Background: Renal failure requiring dialysis is associated with a high mortality. One of the contributing causes is overhydration. Overhydration can be assessed by bioimpedance analysis (BIA)– the non-invasive electrical measure of small current through the tissues that estimates the proportion of fluid that is intracellular water (ICW, typically muscle which is healthy) and extracellular (ECW, which in excess causes tissue oedema and is potentially dangerous). Several studies indicate that a extracellular water to total body water (TBW) ratio is associated with increased risk of death in dialysis patients but it is not clear if this is independent of other risk factors for death, namely comorbidity.

Aims and objectives: To establish the prognostic value of BIA in the prediction of survival on dialysis in the context of other known predictors of survival or hospitalisation. With further analysis of the applicability of the same scenario to heart failure patients.

Methodology: To conduct a systematic review using a standardised approach including a pre-specified research question, search terms and criteria for study inclusion. With independent selection for inclusion in the study and quality appraisal by multiple authors with different backgrounds and experience.

Results: 2701 studies identified by literature search, plus an additional 4 through reference checking. 38 papers included in final analysis, 4 of which were regarding heart failure cohorts. Analysis of the research shows that BIA is an independent predictor of mortality.

Conclusion: BIA shown to be an independent predictor of mortality in dialysis patients, further research needed to extrapolate to heart failure (HF) populations.

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Introduction and Literature Review

1. Renal Failure

Background

Established renal failure is also known as End Stage Renal Disease (ESRD). This is a chronic, irreversible condition that often requires renal replacement therapy (RRT) to sustain life. It is a condition that carries a high burden for both the individual and the National Health Service.

Patients using RRT have a relative risk of death of 6.2 compared to the general population. (1) It is also associated with a large lifestyle adjustment because of the nature of its management. Patients may have many co-morbidities. These often demonstrate a causal relationship in the case of diabetes and cardiovascular disease, but may also develop as an outcome to renal disease.

The prevalence of these co-morbidities are increasing and as such is the incidence of ESRD. In societies such as the United Kingdom (UK) or the United States (US), this is most likely due to a population that is ageing and becoming more obese.

In the UK there has already been a large increase in older people. This increase is predicted to rise and by 2039 and there are expected to be 3.6 million over 85's and an increase in over 65's to 16.5 million from 12.4 million in 2014(2). With regards to prevalence of obesity in England, there has been an increase from 15% to 26% from 1993 to 2014. (3)

The National Health Service (NHS) is thought to spend a little over 2% of its budget on RRT. (4) This is despite the 53,207 service users in 2011 representing approximately 0.08% of the population, as of 2011 (1)

Renal failure is a high impact disease however you choose to measure it. As such research into this area is needed, especially since this problem is likely to get worse due to our society's projected demographics.

Classification

The US National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) has identified ESRD as Stage five in their classification of chronic kidney disease (CKD). (5) This Classification (See figure 1.1) accounts for evidence of damage to the kidney and a measure of function, the glomerular filtration rate (GFR). This is irrespective of the diagnosis.

Figure 1.1 - Table representing stage of chronic kidney disease

Stage	Description	GFR (ml/Min/1.73M^2)
1	Kidney damage* with normal or increased GFR	>90
2	Kidney damage* with mildly reduced GFR	60-89
3	Moderately reduced GFR	30-59
4	Severely reduced GFR	15-29
5	End stage renal disease	<15 or on dialysis

*** Kidney damage is considered Proteinuria, Haematuria and pathological anatomical changes on imaging.**

Figure 1.1 Stages of chronic kidney disease. Adapted from N/DOQI clinical practice guidelines for Chronic Kidney Disease: Evaluation, classification and stratification. (5)

Glomerular filtration rate.

The measurement of GFR is key in both the diagnosis and management of CKD. It is an overall measurement of kidney excretory function, herein lies its importance. The function of the kidney is the ultrafiltration of plasma across a semi-permeable membrane down a pressure gradient. The GFR is the sum total of the functional capacity of every healthy glomeruli, of which in a healthy kidney is approximately 10^6. (6)

Traditionally kidney function is measured by using serum creatinine, a breakdown product of creatine phosphate in muscle. For this method to be accurate, creatinine metabolism would have to be constant, be produced and excreted at the same rate and for it to be a perfect marker of GFR. This would result in a linear inversely proportional correlation, in other words, as serum creatinine doubled, GFR would half.(7) However creatinine metabolism is not constant between individuals, particularly in disease states and it is also secreted by the proximal tubules.(8) It is also subject to various analytical methods creating inter-laboratory differences. Despite the fact creatinine measurement is relatively cheap, the inaccuracy does not allow the distinction between moderate changes in renal function. As such attempts have been made to use creatinine in combination with other analytical methods to improve it as a test.

Currently in clinical practice prediction equations are used to estimate GFR. They allow the use of serum creatinine measurements to be more accurately represented to clinicians by factoring in population data and allowing for other factors that affect serum creatinine other that renal excretion. There are numerous papers relating to prediction equations for GFR. The two most important and widely known are the “Cockcroft–Gault formula” (9) and the “modification of diet in renal disease” formula (MDRD) (10)

Originally published in 1976, the Cockcroft-Gault formula (figure 1.2) was the first widely used formula to be used in this context. It has been widely accepted as step in the right

direction. Concerns over its development from healthy patients and the availability of patient's weight data in laboratories has however resulted in the widespread acceptance of the MDRD formula (figure 1.2). The MDRD formula was developed using patients with known CKD and only require age, gender and ethnicity demographics

International guidelines now recommend the use of MDRD including the national institute for health and care excellence (NICE) and the renal association this advice is summarised in the renal association's CKD electronic guide. (11) This is due to the improved accuracy of results in comparison to the Cockcroft-Gault formula in CKD populations. (12)

Figure 1.2 - The Cockcroft-Gault and MDRD formulas

Cockcroft-Gault formula

$$eC_{Cr} = \frac{(140 - \text{Age}) \times \text{Mass (in kilograms)} \times Constant}{\text{Serum Creatinine (in } \mu\text{mol/L)}}$$

MDRD formula

The 6-variable (or original, or equation 7) MDRD formula

$\text{eGFR} = 170 \times \text{SCr}^{-0.999} \times \text{age}^{-0.176} \times \text{SUN}^{-0.170} \times \text{SAlb}^{0.318} \times 0.762 \text{ (if female)} \times 1.180 \text{ (if black)}$

The 4-variable (or abbreviated, or modified) MDRD formula

$\text{eGFR} = 186.3 \times \text{SCr}^{-1.154} \times \text{age}^{-0.203} \times 0.742 \text{ (if female)} \times 1.212 \text{ (if black)}$

Figure 1.2 The Cockcroft-Gault and MDRD formulas from Cockcroft DW, Gault H. Prediction of creatinine clearancee from serum creatinine. Nephron. 1976;16(1):31-41 and Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Annals of internal medicine. 1999 Mar 16;130(6):461-70 respectively

Causes, compilations and management of end stage renal disease

There are numerous causes of ESRD, these vary greatly within different populations and demographics. However, the causes are categorised by the presence or absence of systemic disease and anatomical location of the pathology within the kidney by the international society of nephrology. (13) Systemic diseases cause ESRD would include (but not exclusively):

- Glomerular diseases - diabetes, systemic auto-immune disorders and systemic infections.
- Tubulointerstitial diseases - toxins, myeloma, (autoimmune and infections may also be included).
- Vascular diseases - atherosclerosis, hypertension, emboli, systemic vasculitis.
- Cystic and congenital diseases - polycystic kidney disease, alport syndrome.

While those effecting the kidney without systemic features would include (but not exclusively):

- Glomerular diseases - diffuse,focal or crescentic glomerular nephritis, focal and segmental glomerularsclerois.
- Tubulointerstitial diseases - stones, urinary tract infections or obstruction,
- Vascular diseases - ANCA renal limited vasculitis.
- Cystic and congenital diseases - renal dysplasia, medullary cystic disease.

With regards to the UK population in the most recent renal registry report the prevalence of each primary renal disease in incident patients starting renal replacement therapy is diabetes 29.4%, glomerularnephritis 14.1%, hypertension 6.3%, polycystic kidney 6.8%, pyelonephritis 5.7% renal vascular disease 5.9%, other 16.9%, uncertain 14.9% and unreported 14.4%. (14)

With regards to complications of ESRD patients there can be manifestations and complications of the disease in almost every system in the body. There are several complications which are more common, have implications for mortality and morbidity, and are widely described in the literature. These would include: cardiovascular disease, anaemia, mineral and bone disorders, metabolic acidosis and electrolyte disturbances, uraemic symptoms, salt and water retention and nutritional problems. (15, 16)

Cardiovascular disease in ESRD is the leading cause of mortality with 22.7% of deaths for UK renal replacement patients. (14). While there is an increase in atherosclerotic disease in ESRD there is also an increase in non-atherosclerotic causes of deaths. (17) However, it is generally accepted that treatment of traditional risk factors for atherosclerotic disease such as hypertension, diabetes and dyslipdemia is beneficial in renal patients.

Anaemia is common in ESRD patients with 23.9% of prevalent renal replacement patients in the UK. (14) There are multiple causes for anaemia in renal failure iron, b12 and folate deficiencies, GI bleeding. However decreased erythropoietin synthesis is the most disease specific aetiology of anaemia in renal failure. Treatment would include the use of iron supplementation and the use of erythropoietin stimulating agents.

Mineral and bone disorders are prevalent in ESRD patients, there are a spectrum of disorders of bone turnover and mineralisation that are affected by changes in phosphate, and vitamin D metabolism due to renal disease. Collectively known as renal osteodystrophy are associated with fractures and worse outcomes. (18) This is a result of hyperparathyroidsm secondary to high serum phosphate levels and hypocalcaemia. This is driven by the kidney's reduced ability to excrete phosphate and also the reduced activation of vitamin D exacerbating hypocalcaemia. Management would include the monitoring of phosphate levels and treatment which could include dietary measures, phosphate binders, vitamin D supplementation and calcimimetics.

Metabolic acidosis would commonly be present in patients with ESRD as the excretion of acids slows, resulting in a reduced serum bicarbonate. The effects can be associated among other problems with muscle wasting and increased mortality. (19)

Symptoms of uraemia such fatigue, nausea, pruritis, restless legs and sleep disturbances are prevalent in patients with CKD, management for most symptoms aside renal replacement therapy treatments for ESRD would include symptom control medications such as anti-

histamines for pruritus and anti-emetics for nausea.

Salt and water retention will be discussed further in this thesis. However, a key complication in renal failure is fluid retention and its assessment and management.

Nutritional problems are very common in ESRD as nutritional requirements are altered and the creation of a catabolic state driven by a number of factors including metabolic acidosis, gut dysbiosis, uremic toxin accumulation, systemic inflammation and anabolic hormone resistance. (20) The development of nutritional problems has been shown to have a poor effect on outcomes with the subjective global assessment score shown to be an independent predictor of mortality. (21) Another consideration with worsening nutrition is the confounding of fluid assessment. When faced with a stable weight the reduction in body mass could hide worsening fluid retention.

The management of ESRD would include the monitoring of disease progression, the monitoring and treatment of complications as above, which if not properly managed could hasten disease progression. Ultimately for a majority of patients' management would be renal replacement therapy after sufficient counselling to check agreement and suitability for treatment.

Renal replacement therapy is broadly separated into three types; haemodialysis, peritoneal dialysis and renal transplant. Haemodialysis describes the use of an intravenous catheter or arteriovenous fistula to divert blood through an extracorporeal circuit. This uses an artificial semipermeable membrane to create diffusion of electrolytes and waste products between the blood and another solution (dialysate) running counter-currently. The makeup of the dialysate allows for correction of electrolyte and acid-base disturbances and changing the hydrostatic pressure of the dialysate allows for the removal of excess fluid. (22) Haemodialysis can be provided at home or in Centre.

Peritoneal dialysis involves the insertion of a catheter into the abdomen, dialysate is introduced into the abdomen, allowing the use of the peritoneum as a semipermeable membrane to allow diffusion to occur similar to the artificial membrane used in haemodialysis. Solutes such as glucose are used in order to create osmotic pressure to remove excess fluid. There are two main types of peritoneal dialysis continuous ambulatory peritoneal dialysis (CAPD), whereas the dialysate is exchanged normally four times a day. Secondly there is automated peritoneal dialysis (APD) whereas the dialysate is exchange via an automated machine overnight while the patient is sleeping. (23)

Renal transplant is the transplanting of either a donor or cadaveric kidney into a patient, it would usually offer the best outcome for patients with ESRD providing they are eligible and a suitable kidney can be identified. The donor kidney not only takes over the filtration aspects of the the native kidney which is no longer functioning but also the endocrine role unlike both forms of dialysis. Renal transplantation is associated with better outcome in terms of quality of life and mortality compared to dialysis. (24)

With regards to dialysis patients both haemodialysis and peritoneal dialysis both have their advantages and disadvantages and each patient will have their preferences, the outcomes for either type of dialysis are similar in terms of survival.(25) In the UK the proportions of patients in each modality are 37.3% in Centre haemodialysis, 2% home haemodialysis, 5.4% on peritoneal dialysis and 55.2 % with a transplant. (14)

2. Body Composition and Fluid Status

Body compartments

The development of a compartmental model for the body has evolved significantly in the literature. The 2-compartment model of fat free mass (FFM) and fat has developed into the more complex multi-compartment model. (26) Use of the 2-compartment model is still prevalent in the literature because of the association of excess body fat with cardiovascular disease. As body water is part of the FFM compartment, calculations of TBW can used to calculate body fat. This can be done using the equation: Body Fat = Weight- FFM. FFM is calculated by FFM= TBW/0.73. The figure 0.73 is called a hydration constant and represents the percentage of water in the FFM compartment. This figure has been shown to approximately correct for healthy adults. However as the FFM compartment is very heterogeneous it has been shown to vary between 67% and 80%, in both physiological circumstances, such as age, or in diseased states.(27)

The Multi-compartment model divides the body into 5 different levels or views. The 2 compartmental (total body), atomic molecular, cellular, tissue (figure 2.1). For each level there are equations allowing for the calculation of each individual constituent. There are also cross over equations for calculations that cross multiple levels. (28)

Figure 2.1- The multi-compartment model

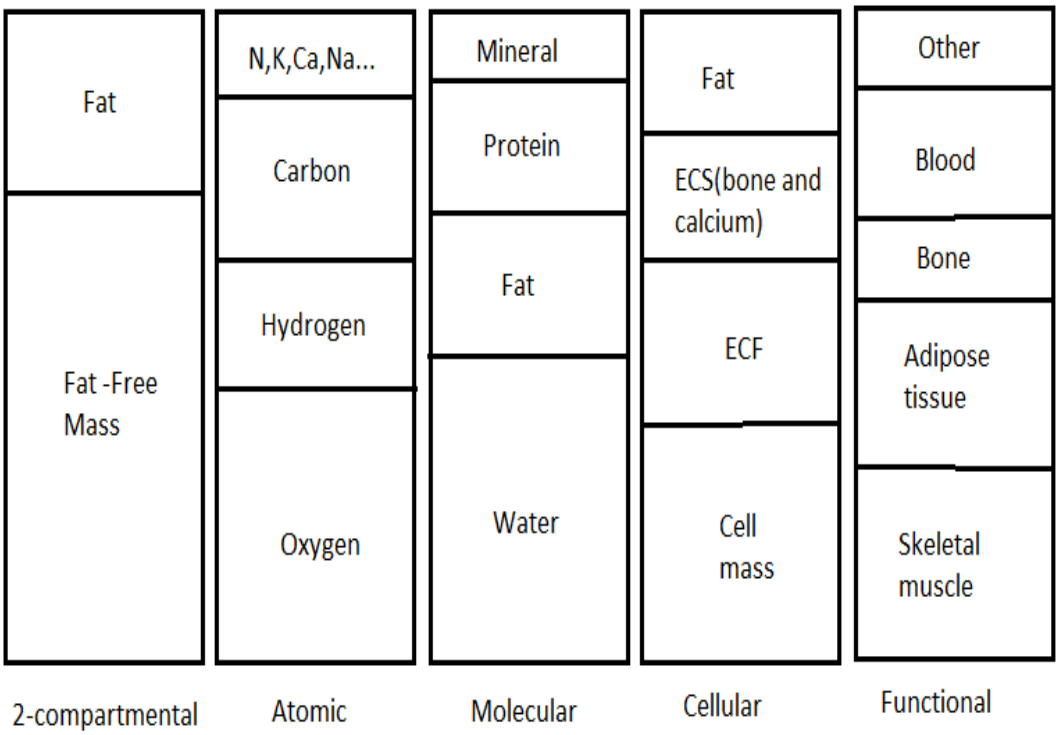


Figure 2.1 - adapted from Wang Z, Heshka S, Pierson Jr RN, Heymsfield SB. Systematic organization of body-composition methodology: an overview with emphasis on component-based methods. The American journal of clinical nutrition. 1995 Mar 1;61(3):457-65.

Fluid compartments.

Fluid distribution in a healthy person should be fairly stable. Fluid compartments are split into intracellular water (ICW) and extracellular water (ECW). The ECW compartment is further split into plasma volume and interstitial fluid. The normal distribution should be 44% of body weight as ICW and 29% as ECW, however there is some variation in normal individuals due to variations in fat mass (29)

However, this distribution is affected in renal patients, in addition, it is affected differently in patients with other co-morbidities. In renal patients there is a tendency for an increase in ECW, both in relative and absolute terms. In a percentage of these patients ICW will stay the same. This is the situation in which blood pressure is increased and given a dependable measure of ECW: TBW a clinician could improve outcomes. However other co-factors come into play and affect the body composition and it affects the clinical picture. In obese patients for example there may be a reduction of ICW, due to increased fat and decreased muscle mass. (30)

There is a growing theme in the literature about the role of inflammation and malnutrition of renal patients, with a high prevalence of systemic inflammation in renal patients and its interaction with co-morbidities and also fluid status.(31) In this population ECW would be increased, however the clinical picture may well be disguised as ICW may decrease reflecting the loss of muscle mass. This can lead to a situation where clinical assessment and weight measurement leave ECW expansion undetectable. In this situation the problems of co-morbidity are compounded with the problems of long-term over-hydration.

Osmoregulation and the control of tissue hydration

There are significant differences between the ECW and ICW compartments. The solute composition is predominately sodium (Na+) in the ECW and potassium (K+) in the ICW compartment. This is maintained by Na+ K+ ATPase transporters. As cell membranes are semi-permeable, the osmotic pressures of the ECW and ICW compartments are equal despite differences in composition. This is because water is free to move throughout both compartments in order to equalise the osmotic pull of both solutes. As a result, the concentration of a solute such as Na+ has an affect on the volume of both the ECW and ICW compartments.

In other words, Na+ displays characteristics of effective osmolarity. Osmolarity is the concentration of a solute in a body of water. However not all solutes exhibit effective osmolarity as they do not create osmotic pressures. Solutes that cannot cross membranes exhibit effective osmolarity as they force water to move across the membrane as compared to solutes that are equally distributed. This is an important distinction because in uraemia, the solute urea is free to pass through membranes and so does not cause fluid shifts.

A healthy adult is required to drink between 2 and 3 litres of water a day. This water is lost in a variety of ways, the obligate amount of urine a healthy person excretes in order to excrete solutes, evaporated water in exhaled air, gastrointestinal loses and cutaneously through sweating. The regulation of our intake and excretion is done in a variety of different ways in order to maintain physiological osmolarity. Regulation of excretion is done in the form of anti-diuretic hormone (ADH), which due to more understanding in this field has been re-designated argenine vasopressin (AVP). Thirst is the desire that regulates increased intake. (32)

AVP is produced in the neurohypophysis, which is part of the posterior pituitary gland.

AVP acts in multiple ways, firstly by activating type II vasopressin receptors(2VR). A 2VR is a G protein coupled receptor that increases collecting duct permeability by increasing the membrane expression of aquaporin type 2. This allows osmosis to change the osmolarity within the interstitium to reduce water loss. It also increases the osmolarity of the interstitium by increasing Na+ adsorption in the ascending limbs of the loop of henle. Finally, it increases urea excretion without hindering the ability of the kidney to concentrate the urine.

There are both osmotic and non-osmotic stimuli for the release of AVP. The neurohypohysis is made up of magnocellular neural cells. Osmotic stimuli directly act on these cells; however, the affect of an osmotic stimulus is significantly stronger in the hypothalamus, especially the organum vasculosum laminae terminalis (OVLT). (33) This allows intricate sampling of blood osmolarity, to allows the sensitivity and control of blood osmolarity within a small variation. (34). Effective solutes such as sodium appear to stimulate this system more than non-effective solutes such as urea. (35)

Non-osmotic regulation is also an important part of AVP secretion, Hypovolemia and nausea being two of the major stimuli. Hypovolemia represents a significant stimulus, which evolutionarily makes sense, this stimulus is a direct result of baroreceptor signaling. (36) Nausea has been shown to be a powerful stimulus, which again is an evolutionary advantage but it is unlikely to be of clinical significance. (37)

In a normal physiological state thirst should not be considered a mechanism to regulate plasma osmolarity. In truth in countries where water is plentiful people should be drinking water, far in excess of actual 'need'. Plasma osmolarity regulation should be controlled by AVP secretion. However, when our water intake, which is largely unregulated and habitual, fails meet the required amount of water, thirst develops as a result of increased osmolarity. Osmotic thirst is a result of similar pathways as AVP secretion, involving osmoreceptors in the hypothalamus. However, whether it is the same mechanism remains unknown. (33) It appears however that the drive to thirst is proportional. (38)However cleverly the sense of thirst fulfillment is met with a relatively low decrease in plasma osmolarity, most likely to stop overhydration.(39) Other stimuli of thirst include hypovolemic drive, however this has not been well defined, but again is likely to be similar to AVP secretion mechanisms and be due to baroreceptor reflexes. Another powerful stimulus is also as a result of conditioning and habit.

In chronic kidney disease (CKD) accompanying the decrease in GFR is a decrease in the kidneys ability to excrete Na+, this is concurrent with a decreased ability to excrete water. As plasma osmolarity increases the patient has less capacity to control their osmolarity through the AVP and excretion routes, so increasing fluid intake becomes the primary method. This produces a situation where fluid gathers out of proportion to Na+ in the ECW. This causes a situation of increased total Na+ but a state of relative hyponatraemia. (32)

Abnormal Fluid status

One of the key aspects of managing a patient with advanced renal failure remains achieving normo-hydration. (40) The challenge is with little or no urine output, and without an objective target, finding the balance between the detrimental effects of under-hydration and over-hydration. (41) The affects of excess extracellular water are especially problematic in this patient population.

The fluid distributes itself in the tissues, this leads to impaired organ function and as a result the symptoms of pulmonary oedema, obstructive sleep apnoea, constipation and can also affect mobility due to peripheral oedema.(42) The fluid also distributes itself into the circulation causing high blood pressure and the resulting vascular and cardiac damage, such as left

ventricular hypertrophy.

As discussed previously, there is a tendency of fluid accumulation in ESRD, due to sodium accumulation.(43) However over correction causing ECW depletion can cause unpleasant symptoms such as cramps, postural hypotension or organ under perfusion during dialysis treatments.(41,44) Under-hydration or over correction also has a detrimental affect in both peritoneal dialysis (PD) and haemodialysis patients where it can cause loss of residual renal function(RRF) which is important for long term outcomes.

Chronic over-hydration.

There are many consequences of over-hydration for renal patients. Patients with renal disease the normal mechanisms and as a result an increased extracellular volume (ECV) ensues which causes other effects in the body. For example, the ECV expansion triggers a reflex arterial vasoconstriction to protect end-organs from hyper-perfusion. This causes a rise in blood pressure (BP).

Hypertension further increases the tension on the vascular wall leading to change increased endothelin, platelet-derived growth factor B and basic fibroblast growth factor production (45). This changes the morphology of the vascular wall increasing vascular stiffness. (46) Vascular stiffness has been shown to be an independent risk factor for cardiovascular and all-cause mortality in patients with ESRD. (47)

Increased vascular stiffness in combination with an increased ECV leads to an increased preload and hypertension. This causes left ventricular hypertrophy (LVH) and impaired cardiac function. Impaired systolic cardiac function, in the form of a reduced ejection fraction, is seen in approximately 20% of dialysis patients on echocardiogram. (48) Severe cardiac dysfunction may result in a low systolic blood pressure. Perhaps somewhat accounting for the counter intuitive situation where haemodialysis (HD) patients with low blood pressures have a worse survival.(49) Similarly in PD patients where a low blood pressure is correlated with worse survival if they are not listed for transplants whereas the opposite is true for those that are listed.(50) However it is likely that other factors such as co-morbidity also affect this phenomenon.

Less appreciated effects of chronic over-hydration are haemodilution and dilutional anaemia and also bowel oedema. Bowel oedema can cause constipation (51) and some studies have indicated that it may contribute to elevated inflammatory markers and malnutrition in patients that are chronically fluid overloaded. (52)

This is following the damage to enterocytes and the breakdown of the protective barrier of the gut wall. This allows for infiltration of intestinal microflora and pro-inflammatory endotoxins. (53) There is also suggestion that the uraemia in CKD patients may also compound this problem. (54) Bowel oedema may also contribute to malabsorption, in a patient group that is often malnourished. This has been shown in heart failure patients, but also is likely to apply to any patient that is chronically fluid overloaded. (55,56)

Contributing factors to cardiovascular disease.

As discussed earlier, body sodium content determines the size of the ECW compartment. Therefore, ECW overload is equivalent to sodium overload. (44) The affects of sodium overload on fluid compartments, especially with regards to cardiovascular disease are well described. While there can be no denying this is the main causative factor, a growing body

of evidence shows direct consequences of sodium retention, again especially in cardiovascular disease.

While it is difficult to estimate the direct affect of sodium compared to the “indirect” affect of an increase in ECW, it remains an important area of discussion. The main reason is that it fits with our current understanding of blood pressure control. Hypertension is caused by a raise in intravascular volume which is not compensated by a reduced total peripheral resistance (TPR). The reason for this may be explained by vascular stiffening but also other mechanisms.

Inadequate changes in TPR have been attributed to sympathetic over-activity, high angiotensin II activity, reduced vasodilation and vascular re-modelling. (57)

The presence of sympathetic over-activity in renal disease has been well documented. (58,59) It is, for example a cause of a reduced baroreceptor reflex in renal failure patients. Patients that have received medications to block sympathetic stimulation have also shown a marked reduction in their hypertension. (60) A working theory has been proposed that excess salt is an oxidative stress. This along with substances such as nitrous oxide can lead to increased afferent sympathetic nerve activity, originating from the kidney. (61) This process is likely to be supported by high angiotensin II activity, (57,62) which enhances central sympathetic activity (63) and in turn may stimulate renin secretion. (64)

Furthermore, the Na+/K+ ATPase pump in smooth muscles are becoming more implicated in the evidence as having an involvement in the increase of vascular tone in renal failure. There is evidence to suggest that sodium retention can lead the release of digitalis-like substances. Digitalis-like substances have been shown to cause contraction of smooth muscle cells in the vasculature. The high concentration of sodium has been shown to activate the Na+/K+ ATPase pump, causing an increase NA+/K+ ratio intra-cellularly. A decrease in membrane potential causes voltage gated calcium channels to allow an influx of calcium, resulting in contraction. (65) Digitalis like factors can also cause activation of the renin-angiotensin system, again most likely through central sympathetic activity. Which activates a feedback loop in which other digitalis-like substances are released. (66)

Dry weight

Introduced in the 1960's, the Concept of dry weight was a strict fluid management policy designed to remove excess ECW by driving down blood pressure (BP) to hypotensive levels during a haemodialysis session.(67) The belief was that it would give the patient some 'breathing room', to allow them to put on weight (ECW) before the next dialysis session without becoming hypertensive. There are multiple flaws with this definition, which will be discussed later. Today these flaws have certainly not been corrected, however a much more favourable definition is more widely accepted in which dry weight is equivalent to the body weight at a physiological state. (43)

Without using direct measures, the assessment of dry weight can be done in two ways, however in practice both are used. Firstly, the non-clinical dry weight assessment involves the normalisation of BP (or rather to a degree of hypotension) and the weight recorded at this level. Dialysis prescriptions, by adjusting the ultrafiltration rate are designed to achieve this ideal weight. Indirect measurements of plasma volume such as atrial natriuretic peptide (ANP) and inferior vena cava measurements can also be carried out in this method.

The clinical assessment of dry weight is based on the history, clinical examination and often involves 'probing' of the dry weight. A case history is often taken of the patient looking for dyspnoea, headache and excessive salt intake which could indicate an increase of ECW.

Whereas symptoms of dizziness or cramps could indicate ECW depletion. The clinical examination including weight measurements and blood pressure measurements are taken. This could show a postural drop, increased weight, oedema or a raised jugular venous pressure if fluid overloaded or hypotension and weight loss if fluid depleted. X-rays to show the cardiothoracic index or hematocrit levels may be used to add strength to a clinical assessment.

Probing for dry weight involves the systematic step down of dry weight in dialysis sessions. It is decreased until symptoms of hypovolaemia occur. This is unpleasant for the patient and also predisposes patients to intradialytic hypotension, cardiac arrhythmias and ischemic events. (68) This 'point' of hypovolemia does not necessarily truly represent true dry weight because of the intermittent nature of haemodialysis and the interaction with comorbidities that preclude the possibility of achieving this goal. Furthermore, in intermittent dialysis treatments (e.g. haemodialysis) there is a constant change in the equilibrium between intravascular and extravascular space, such that there is significant lag time in the vascular refiling from the interstitial fluid. Therefore, blood pressure alone is limited in the monitoring of dry weight as post-dialysis it tends to underestimate the size of the ECV.

As discussed earlier, malnutrition is common in renal patients. A patient's weight and clinical assessment is inaccurate in showing long term changes in ECV. Patients can therefore deteriorate in silence, and dry weight assessments become increasingly inaccurate as nutrition worsens due to weight being stable even though a patient is wasting due to fluid retention. Correction of this problem can of course, also cause problems in assessing dry weight. When nutrition is improved muscle tissue can be rebuilt, replacing ECW excess with ICW. This can lead to overestimation of dry weight, causing increasing frequency of intra-dialytic hypotension. Therefore, the development of other techniques that provide a more encompassing estimation of body water and distribution, such as BIA for clinical practise could in theory help: (1) improve patient experience of dialysis, (2) improve clinically measurable outcomes, (3) aid as a prognostic tool

Difficulties in achieving fluid balance

As discussed, one of the key problems in achieving fluid balance is the accurate assessment of dry weight, however another important consideration is the reliability and reproducibility of these assessments. It is clear that co-morbidities and nutrition play a large part in fluid status. As such any assessment of dry weight needs to be repeated at sufficient intervals to pick up long-term changes in ECV. Other difficulties with maintaining fluid balance are inherent in the process of dialysis. For dialysis to be at its most effective a patients euvolemic state needs to be maintained. The problem is that sustained ultrafiltration is needed for this. Haemodialysis provides short intervals, and the idea of more regular dialysis further reduces patients control over their lives. However, with regard to Peritoneal dialysis there is the opportunity for sustained ultrafiltration. The preservation of residual renal function allows for better prognosis leaving a common scenario of finding middle ground between probing for euvolemia or preserving RRF.

The role of co-morbidity in fluid status is on many levels. Firstly, it may worsen renal function. Secondly cardiac dysfunction reduces the ability of the clinician to remove sufficient volume to achieve the desired dry weight. On top of these problems it is likely that co-morbidity acts to increase inflammation in the body, causing muscle wasting, reduced appetite and can even compound hypoalbuminaemia. Therefore, nutritional support is important in this regard, and also in following low sodium diets. The role of hypoalbuminaemia is still yet to be fully considered however it is clear that it is linked to worsening fluid status in dialysis patients. This also appears to be correlated with co-morbidity in peritoneal dialysis patients. (69,70,71) A

working theory is that impaired nutritional status and inflammation reduced the body's protein synthesis capability, this in turn causes the redistribution of excess fluid to favour the extravascular space. (40,72)

3. Measuring Fluid Status

Background to measuring fluid Status

One of the key aims in managing dialysis patients is maintaining normal fluid status. Despite this clinical assessment of dry weight is the most widely used assessment of fluid balance. Clinical assessment is not always accurate necessitating the development of alternative methods that also have their faults, but also have their advantages.

Anthropometric estimations are perhaps the easiest way to estimate TBW. The simplest measure would be 58% of a patients' body weight. More complex equations are often derived for use in different populations. Many are validated against more accurate techniques, such as deuterium dilution or the Watson formula. (73) However, these population groups are often narrow, and many are derived from healthy subjects. It has been shown that there can be large differences in estimated TBW in patients with conditions that affect fluid balance. Many equations seem not to take account of variations of adipose tissue and do not take extremes of body mass index (BMI) into account. (74)

The 'gold standard' measurement of TBW is by tracer dilution. However practically they are infeasible as the materials may be hard to obtain, analysis can be difficult and results may take weeks, while in clinical practice measurements may be needed daily or at short notice. A tracer is a chemical that is distributed throughout all water compartments equally, that doesn't undergo metabolism and is only distributed in water. After dosing intravenously or orally and a sufficient amount of time has passed for it to equilibrate, the body fluid compartments are sampled. This normally entails saliva, blood and urine collection, depending on the tracer. The concentration of the tracer is then measured, chemically or through mass spectrometry, corrected for background levels to calculate the volume from the concentration.

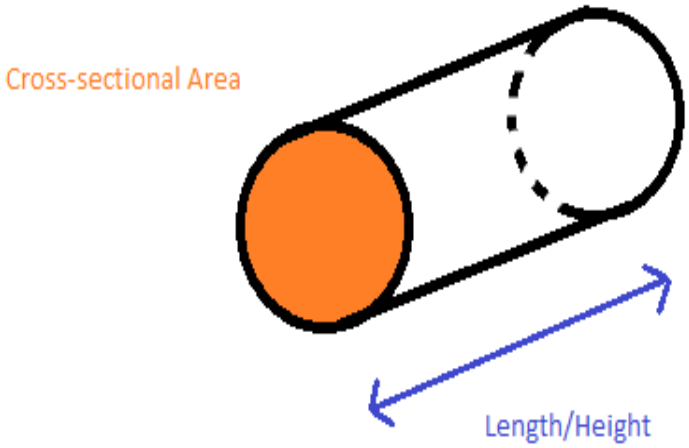
Principles of Bioimpedance analysis

The resistance of a homogeneous cylinder made of a conductive material is proportional to its length and inversely proportional to is cross-sectional area. In Bioimpedance the human body is regarded as a cylinder. Volume of the 'cylinder' can be calculated from measuring resistance. (figure 3.1)

Figure 3.1 - pictorial representation of volume calculations of a cylinder

Key:

- Resistance = R
- Resistivity = ρ
- Length = L
- Cross-sectional area = A
- Volume = V



Resistance=ρ x L/A = ρ L/A

Volume = L x A

1. If resistance is = ρ L/A and Volume =L x A
2. Multiply by L/L then resistance = ρ L^2/V
3. If R = ρ L^2/V, then V= ρ L^2/R

Therefore, volume = Resistivity x $Length^2$/Resistance

Although the human body is far from a uniform homogeneous cylinder, this model is applied in Bioimpedance measurements to form the impedance quotient ($length^2$/Resistance). This, as shown above, is inherently linked to the volume. When this is applied to BIA measurements it is more practical to calculate height, as opposed to conductive length. Therefore, the impedance quotient is often referred to as $Height^2$/Resistance. The volume aspect of this equation, is also altered. As the body is not in fact homogeneous, the volume does not relate to the size of the object being measure per se, it relates to the conductive volume of the object being measured. In the body this is represented by the volume of water that contains ions that allow the conduction of electrical current.

However, as the human form is not completely uniform, appropriate coefficients need to be applied to the impedance quotient in order to improve the accuracy. The coefficient varies depending on different factors. For example, changes in resistivity between segments measured, and to allow variation in body shape and body segments, (as resistance decreases with shorter or thicker segments).

To add another degree of difficulty in measuring Bioimpedance, the human body exhibits two forms of resistance to the passage of electricity. Resistance, (the physical restriction of flow of a current) arises from both the ICW and ECW. Capacitive resistance (reactance, a build-up of an electrical field, which resists a change in current) arises from the

cell membranes. Impedance is the combination of the two and represents the oppositional force to an alternating current (AC).

At a high frequency or extrapolated infinite frequency the current is able to pass through both the ECW and ICW; this is because it can penetrate cell walls which then behave as a capacitor (allowing the flow of AC current but increasing the phase angle figure - explained later in this section -see figure 3.3). At a low or zero frequency the cell membrane acts as an insulator, allowing current to pass through ECW but not ICW. This is often represented in a series circuit, originally attributed to Fricke in 1932(Figure 3.2a), but is often shown better diagrammatically. (figure 3.2b)

Figure 3.2 (a)representation of an AC current passing through the body as a series circuit. (b) pictorial representation of an AC passing through the body

Figure 3.2a

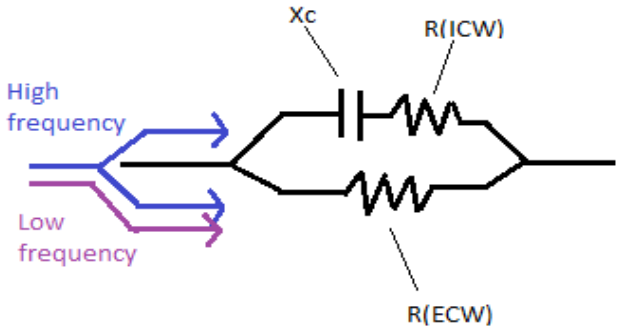


Figure 3.2b

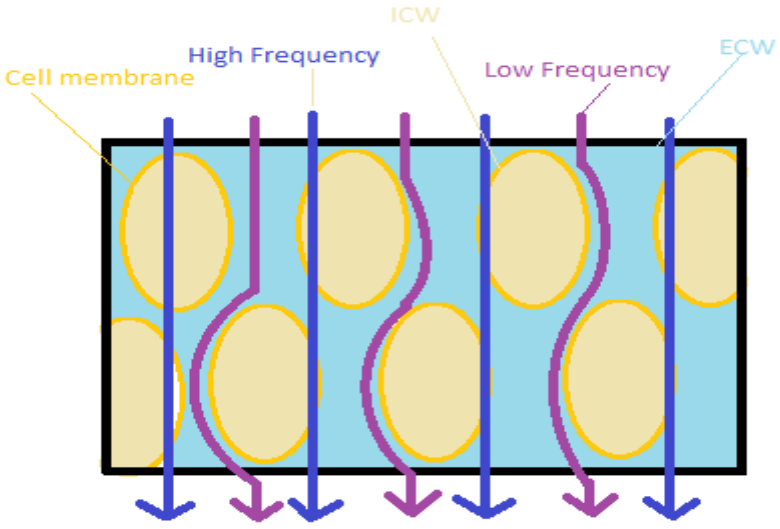


Figure 3.2 (a)representation of an AC current passing through the body as a series circuit. (Fricke H. XXXIII. The theory of electrolytic polarization. The London, Edinburgh, and Dublin Philosophical Magazine and Journal of Science. 1932 Aug 1;14(90):310-8.) **(b)** pictorial representation of an AC passing through the body

The relationship of reactance (Xc) resistance(R) and impedance(Z) can be expressed as $Z^2=R^2+Xc^2$. This is often represented on a Cole-Cole plot (figure 3.3) so that the extrapolated infinite and zero frequency values can be expressed. The relationship is such, that at a low frequency the impedance equals resistance and there is no reactance of the cell membranes. As frequency increases, so does the reactance, up to a maximum point. Then it begins to decrease. At infinite frequency the resistance will equal impedance once again. Phase angle introduced earlier in this section, is one measure of impedance. It can be calculated from the inverse tangent of the ratio of reactance to resistance (Xc/R) as seen in figure 3.3. It is the delay between the waveform of the voltage and current (the electrical potential across the circuit and the actual rate of flow of charge - i.e. the opposing force to the current).

Figure 3.3 - Cole-Cole plot with superimposed phase angle.

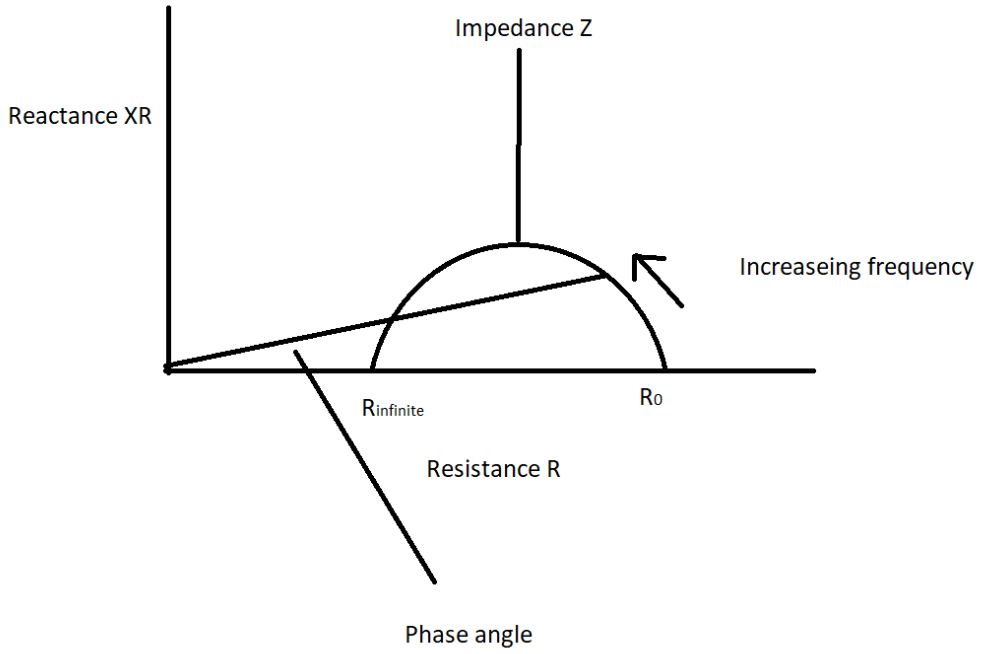


Figure 3.3 Cole-Cole plot with superimposed phase angle - shows that with increasing frequency phase angle will increase to a point before decreasing. Cole KS, Cole RH. Dispersion and absorption in dielectrics I. Alternating current characteristics. The Journal of chemical physics. 1941 Apr;9(4):341-51.

Single frequency and multi-frequency BIA

In the development of BIA as a method there has been a shift in the use of single frequency to multi frequency BIA. In single frequency BIA (SF-BIA), a single frequency of 50kHz is generally used. This frequency has been demonstrated to be effective in measuring fat free mass (FFM) since 1985. (75) However, at this frequency the current passes through both ICW and ECW, although the proportion depends on different tissues. Using this single frequency does not truly measure TBW but is estimated using empirical equations developed from healthy participants. It also relies on the assumption of 'mixing theory' and how this is

incorporated into the final outcome of the Bioimpedance measurement.

Mixing theory suggests that as more non-conducting or, in the case of the body, semi-conducting materials (the cell membranes) are present, the overall resistance increases. This is best thought of as the current having to take a longer route around the resistant material in order to avoid obstacles in its path.

The development of multi frequency BIA (MF-BIA), which uses linear regression models for different frequencies to evaluate FFM, ECW, ICW and TBW, has led many studies evaluating the two in different situations.(76,77,78) Frequencies used in MF-BIA are often 5,50,100,200 kHz, as poor reducibility has been shown at either end of this spectrum.(79)

The use of BIA for renal patients was developed by Chertow in 1995 (80), validating it's use when previously there was scepticism, due to concern that significant changes in electrolyte composition could affect the conducting properties of ECW.

Whole body and segmental BIA

As discussed previously, the human body is far from homogeneous. A potential major stumbling point in the accuracy and applicability of whole-body BIA in clinical practice reflects this. The trunk of a patient naturally has a high relative body mass in comparison to the limbs. However, this is not reflected in the resistance. Firstly because of a high cross-sectional area there is less resistance. Secondly the resistance is lower due to the different tissues that make up internal organs, as opposed to the musculature in the limbs. To put this in perspective despite the trunk accounting for typically 50% of the weight, it contributes to 10% of the resistance.(81) This is particularly problematic in patient populations where there is significant shift of fluid into the 'third space' (a collection of fluid in an area that it does not normally collect, e.g. pleural cavity; as such it does not behave in a physiological manner). The inability for whole body BIA to accurately account for third spacing can lead to a significant underestimation of fluid status in many patients.(82) If this technology is to be used to provide fluid assessment of these peritoneal dialysis patients, this would need to be accounted for but would not represent a problem as peritoneal fluid could be removed for measurements or measured directly.

The use of segmental BIA, measuring the limbs and trunk separately, has been developed to minimise this problem. (83) Studies have shown an improved accuracy using this technique in both healthy subjects (84) and in conditions where there can be fluid shift. (85)

Bioimpedance spectroscopy

Bioimpedance spectroscopy (BIS) is a term used to describe a particular development of BIA technology. It uses multiple frequencies to predict R_0 and R_i on the Cole-Cole plot. It does this using prediction equations derived from healthy populations, (often based on mixture theory and further adjusted for the effects of BMI). Despite this fact there is a growing support in the evidence for this technology's use in patients with renal disease. (86) This rests mainly on the fact that there appears to be a high correlation of accuracy between deuterium and bromide measurements and Bioimpedance measurements in both healthy and unhealthy subjects. However, there were reservations over extrapolating relevant data because currently resistivity values that are needed to calculate volumes are also derived and validated for healthy subjects. The role of electrolyte differences effecting resistivity values between healthy patients and those with ESRD are probably overstated. However, there was fear that the effects of wasting and malnutrition of renal patients, could have resulted in different resistivity values, limiting the ability of BIA to offer fully accurate volumetric measurements in previous body composition

models. The development of a subsequent body composition model by chamney et al, which is used in the fresenius body composition monitor has helped to more easily calculate volumetric measurements. This model is discussed later.

Application in renal failure patients

Ultimately improving the assessment of dry weight is one of the main aims of this technology and several steps have been made in this area. Further evaluation of BMI dependent equations in renal patients have shown that they are largely accurate and concerns about differences in resistivity are most likely overstated.(87) One approach has been to the use ECW/TBW ratio rather than absolute values, and comparing this to age matched controls.(88) As opposed to converting BIA values into volumetric measures they may simply be viewed as a derivation from normal and may be used to help clinical judgement. Using this approach an increase in the ECW/TBW ratio has been associated with worse outcomes, eg mortality in dialysis patients - as shown in this review.(89) The hydration score, a further adaptation of this principle, was developed in PD patients and is based on standard deviations of ECW/TBW from gender and age matched controls.(90) It has been used in clinical cases with dialysis patients and could well be developed further in the future.(91)

Other notable developments in applying Bioimpedance technology for the assessment of dry weight include the intersecting slope theory. (92) In this technique ECW measurements from healthy individuals are plotted on a graph against weight as a normal reference line (Snv). In the example shown a series of new HD patient had their ECW plotted on the same graph against weight (Shv). Hypothesising that a linear relationship exists between ECV volume and weight in both healthy subjects and patients. Therefore, by slowly reducing target weight, and plotting ECW measurements on the graph, eventually the slope of normovolemia and hypervolemia would cross, this would become that patient's dry weight. (figure 3.4) This strategy resulted in a statistically significant BP reduction and an 86% drop in use of anti-hypertensives.

Figure 3.4- Intersecting slope theory

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Figure 3.4. graphical representation of the intersecting slope theory. Snv - normal reference line, Shv hypervolemic patient line. Chamney et al (92)

Zhu et al also suggested an alternative method to make this technology viable for clinical practise. On the understanding that the most appropriate place to take ECW measurements, because of gravity causing excess fluid to pool would be in the lower limbs, continuous intra-dialytic BIA measurements of the calf were taken. The results were plotted on a graph and dry weight was assumed as the curve flattened and that they correlated with normal subjects (93) This potential method of using BIA may be useful in a clinical setting as it allows the continuous monitoring of patients, and is likely to be highly adaptable for clinicians who are used to reassessing dry weight continuously. However further clinical evaluation on a larger scale is needed.

Chamney's body composition model and the Fresenius body composition monitor

Chamney et al. have developed a new approach to modelling body composition that uses the concept of normally hydrated tissue, as determined from body composition studies (I.e. the hydration of normal muscle and fat) and thus expressing overhydration as the excess fluid observed. (Figure 3.5) The advantage of this approach is that it enables quantification of overhydration independent of abnormal body composition, e.g. muscle wasting or obesity (94). This has been Incorporated into use with the Frenesius body composition monitor (95)

Figure 3.5 - Chamney body composition model

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Figure 3.5 - from chamney et al (94). New 3 compartment model (A) showing normally hydrated lean tissue mass, excess fluid mass and normally hydrated adipose tissue mass. Compared to model B, showing equivalents from more traditional body composition models.

Application as nutritional assessment tool.

As discussed earlier the nutritional aspect of chronic diseases play an understated part and have direct affects of mortality and morbidity. BIA can also be used to estimate muscle mass and adipose tissue. (80) It can also explain abnormality in fluid balance, such as a disproportionate loss of muscle mass 'hiding' fluid overload, or even low albumin levels causing a ECW overload without a resultant rise in blood pressure.

The development of Bioimpedance vector analysis (BIVA)(figure 3.6)(96), a means of expressing phase angles in a graphical form, has many uses but is useful in nutritional assessment. By normalising phase angle with height at 50kHz (Xc/H and R/H) and giving it a graphical representation, not only do you have a vector but also a magnitude, it can then be represented with an ellipse against healthy individuals. It can also be used to show increasing cachexia and fluid status. It is worth mentioning that BIVA techniques show a large variation of vectors depending on the diagnosis of the patient, and was originally believed to have some diagnostic value, however it shows nicely the complexity and variation in the field of fluid assessment in general.

Figure 3.6 - Graphical representation of BIVA

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figure 3.6 from Piccoli et al (96). representation of a healthy population, patients with renal failure, nephrotic syndrome and an obese population plotted on a BIVA graph.

Application as a prognostic tool.

The purpose of this systematic review is to understand the role in which BIA can help prognostically. Primarily this is to determine the link between worsening BIA results and mortality, but also, it's affect on morbidity in the form of hospital admission. It is anticipated that numerous studies in the literature support this hypothesis. Furthermore, we will search for

evidence of the role of co-morbidity affecting both worsening BIA measurements and establish whether the prediction of mortality is independent of this interaction. We will also include data from heart failure studies because of the similar clinical problems these patients face with fluid management and because it is prevalent in renal patients.

Methodology

1. Introduction

The purpose of a systematic review is to synthesise and present a large amount of research in an accessible format. It has become a necessary in healthcare research as it is an effective process to inform clinicians and policy makers, who have to make decisions based on this evidence, many of whom may lack the time, resources or skills to find, interpret and appraise the unmanageable amount of information that is published every year. They are also extremely helpful in research planning, identifying research questions and determining areas that need more time and financial commitment. Systematic reviews aim to collate data using pre-set eligibility criteria to answer a specific research question. This is done using a strict methodology that has been shown to reduce bias and give more accurate and reliable results. Theoretically bias is reduced by drawing conclusions from the entire scope of the literature as opposed to looking at an individual research paper. Systematic reviews also help to show the generalisability of results that are otherwise limited by the different variables and settings of the individual studies included in the review.

An essential methodological aspect of systematic reviews is that the process is undertaken by a team of people who have different skills and experience. It is important that there is a member of the group who had expertise in the review area but also for a member with systematic review experience to advise about the development of the review. It is also advantageous to have an author with less experience to offer new insights into the research topic without preconceived ideas.

The Cochrane library (97) is an organisation very well respected in the research community that offers a database of peer-reviewed systematic reviews. They state that the key characteristics of a systematic review are:

- Pre-defined eligibility criteria and a clear set of objectives.
- Explicit and reproducible methodology.
- A systematic search for all eligible studies.
- A quality assessment of the studies.
- Presentation of data in a systematic manner.

The first step in designing a systematic review is the development of the review objectives and the placing of them in the context of the wider literature. Objectives can be categorised as broad or narrow, both approaches having advantages and disadvantages. A broad scope increases the generalisability and may be more useful in answering a more general clinical question. However, it requires a much broader search in order to include all studies that may be helpful and researchers risk having a difficult time interpreting the data due to significant heterogeneity in the study designs. Narrow scope reviews are often a lot more manageable however evidence may well be sparse and the findings may have less consequence because of the lack of generalisability.

2. Our Research Question.

We wanted to determine what importance could be placed on the prognostic value of bioimpedance analysis (BIA) in patients with advanced renal failure. It has been shown in several studies that mortality is increased in dialysis patients who have higher degrees of overhydration (however this is represented). Furthermore, it is likely that comorbid conditions, also important determinants of survival, increase the likelihood that overhydration is worse. So in this study we wanted to see if we could establish BIA as an independent prognostic indicator of mortality rather than a surrogate for the severity of comorbid conditions.

To do this we felt that it was important to have a wide scope for the review to identify studies that had the investigation of the relationship of BIA and mortality but also to look at studies that investigated that relationship with co-morbidities and any related multivariate analyses and will also help in the narrative synthesis to place our results in context so answering our research question. If BIA is established as an independent predictor it could open the way for an interventional trials to demonstrate that normalising fluid status could improve outcomes. For the purpose of this review we also decided to include studies that evaluated both mortality and hospitalisation rates as a marker of morbidity. We also decided to include studies that evaluated heart failure. Heart failure is an important co-existing co-morbidity in patients with renal failure and both conditions are associated with overhydration. By evaluating heart failure as well as renal failure we hoped to show generalisability to different patient groups that overhydration plays an important part in the clinical outcomes observed.

3. Designing our review protocol.

The next step was designing the systematic review protocol, a key step in the planning of a systematic review. This structured approach is used to plan the inclusion and exclusion criteria of the review, the methods of the review and the presentation of the results. The development of the inclusion criteria is perhaps the most critical stage in the protocol development since this directly affects your search strategy and ultimately what studies you will find. We used the PICO method of determining our inclusion criteria. (98) This is because it has been shown to be a useful tool for determining clinical questions, allows for accurate literature searches and is an easy and popular tool. It was also familiar to myself and most of the other co-authors.

PICO is a mnemonic for Population, Intervention, comparison and outcome. Using these headings, the inclusion criteria of the review should be added, the goal of this tool is to allow your review question to be focused without risking unnecessary exclusions of studies. Not all research questions will fit into this model, and equal emphasis does not need to be placed on each section, however each heading offers an important aspect for the review team to consider.

The population heading is used to describe the demographic characteristics of the study group and the condition in question. This section can also include the way in which the condition is diagnosed, any demographics of the participants such as race or gender. The settings of the studies are also sometimes included under this heading or as a separate heading altogether. In this review our population was defined as “adults with renal failure undergoing dialysis” or “adults with heart failure”. Our rational for this was that we didn't want to exclude any causes of renal failure.

By including that they must be undergoing dialysis however we aimed to only include patients with ESRD and therefore patients that are more likely to be fluid overloaded. As

already argued, we felt it would be a useful comparison to include heart failure patients in the systematic review. By defining a population in this way, a clear definition of the condition and a wide spectrum of patients should be included and any major subsets of this population that may react differently should be identified and excluded.

Under the intervention heading, the investigation or the treatment of interest should be defined where possible. Where possible this should include any specific method or protocol, duration or timing. When designing this section, the goal is to clearly set out the intervention of interest and planning which variations in the delivery of the intervention would be acceptable. The intervention in this review is "bioimpedance analysis". We did not feel it was appropriate to put limits on how the bioimpedance was performed due to the huge variation of methods and analysis as we would then have excluded potentially valuable evidence. However, we discounted those studies that carried out BIA during dialysis as we felt there were too many variables to make valid comparisons. We decided to include studies that were investigating other interventions as they could still potentially give valuable data to the study.

The comparison section is for defining the control that the review is interested in, but this may not be applicable, such as in this review. However, it may be important to consider other baseline characteristics (covariates) that may influence the outcome of interest or how the intervention may have different results in participants with different characteristics. As such we decided we would, if possible, like to make comparisons between patients with different co-morbidities.

The outcomes section is when the authors set their primary and secondary objectives. Objectives should be measurable objectively and how they are recorded and any scales should be validated. Unlike the other sections of the PICO, most reviewers do not use the outcome variable in their initial search strategy as systematic reviews should include all outcomes that are likely to be relevant to all interested parties, for example clinicians, policy makers and the public. By including outcomes in the initial search strategy, the review team risks overlooking important outcomes. However reviewers should aim to avoid trivial outcomes as it diminishes the main aim of a systematic review by failing to supply a clear answer to the clinical question. Furthermore, adverse outcomes associated with an intervention or important economic data should also be outlined under the outcomes heading for inclusion criteria if appropriate. This is because they may be important considerations in whether policy makers should take on board the recommendations of a systematic review. It is also good practise for outcomes of each accepted paper to also be included in the review if relevant, even if it is not the objective of the review.

Our primary outcome was mortality and then hospitalisation as a proxy measure of morbidity as our secondary objective. We decided not to qualify a follow up period for the studies to adhere to, as we believed it may cause the unnecessary exclusion of studies. We felt our outcomes were easily measurable and could provide an accurate outcome for our findings. We did not feel that there were any significant adverse outcomes associated with BIA measurements to be aware of.

Another important aspect of designing a systematic review is to decide how it will treat different study designs a priori. Most systematic reviews focus on randomised control trials, as their intervention is normally well defined and have strict protocols which are most often conducted using a randomised methodology. The value of applying this methodology is that it can identify publication bias, increase the generalisability of the observations and lend itself to meta-analyses of the data. However, our study question is problematic to answer as a randomised control trial (comorbidity cannot be assigned randomly) and so our systematic review will mainly focus on other non-randomised observational cohort studies (NRS). A major concern of NRS is that they may be confounded by unmeasured biases e.g. unidentified

prognostic covariates and confounders. However, there are many aspects to NRS that are beneficial to systematic reviews. For example:

- They are more beneficial in showing neglected areas of research and showing where the weakness of the current research is.
- They allow the study of topics or interventions where randomisation is not easy
- They allow the study of long-term outcomes or those that are particularly rare.
- They are often less selective in terms of their inclusion criteria and thus more generalisable to routine daily clinical practice

We feel that our review is correct to use predominantly NRS as all four of the issues listed above are mirrored in our study objectives. However, because we are using NRS we have to take into account extra precautions, for example using a validated tool to assess each study for bias and listing this in our protocol. If our study intervention (BIA analysis) was not a measurement but would directly affect the participants outcomes, we would also have to identify a list of known confounders and check each study for their presence. For the purpose of our review we decided to exclude case studies as we felt they could be heavily biased and not likely to identify and further information.

Finally, the review protocol should identify the individuals in the review team and their roles.

4. Development of our Search strategy

Development of a search strategy should be based on the PICO criteria in the protocol and should follow a similar layout. However, the nature of the intervention and outcome will have a large impact to how broad a search strategy is to ensure its capture. For example, if the outcome or intervention is unlikely to be recorded as a primary outcome in some papers then the search strategy will need to be broader, as was the case with ours, and will include more generic terms. Conversely if an intervention very precise, with clear outcomes and well-known side effects a search strategy is more likely to be narrow and contain much more limiting terms. Most systematic reviews will develop their search strategy for three main databases COCHRANE, MEDLINE, EMBASE. Additionally, references in reviews and accepted papers should be checked, ongoing studies or unpublished studies should be actively searched for.

The search protocol should include free text and MESH (category searches) for each PICO section then collaborated. It should also be limited to language and an appropriate date limit. The development of each search protocol should be similar for each database. However, each database categorises each study differently so there needs to be some adaptability in changing the search strategy to fit each database. It is also recommended by the Cochrane library to involve health librarians or another experienced person to help to check search strategies and to develop them to not overlook important evidence.

From our point of view developing our search strategy (shown below) took a number of attempts, as we realised we were missing relevant studies that we were already aware of in the literature, so we gained advice from the health librarian who helped us by making our search strategy sufficiently broad. We also remained flexible changing our search terms to pick up more relevant literature and carefully entered the synonyms of our search terms. Ultimately however a balance is struck between the sensitivity of the study and the precision.

After searching for eligible studies duplicates are removed and using a systematic methodology are assessed as to their relevance and eligibility against inclusion and exclusion criteria that were decided upon in the protocol. The search strategy for our systematic review for each of the databases medline, embase and cochrane are shown in figures 4.1a, 4.1b and 4.1c respectively.

Figure 4.1a - Medline database search strategy

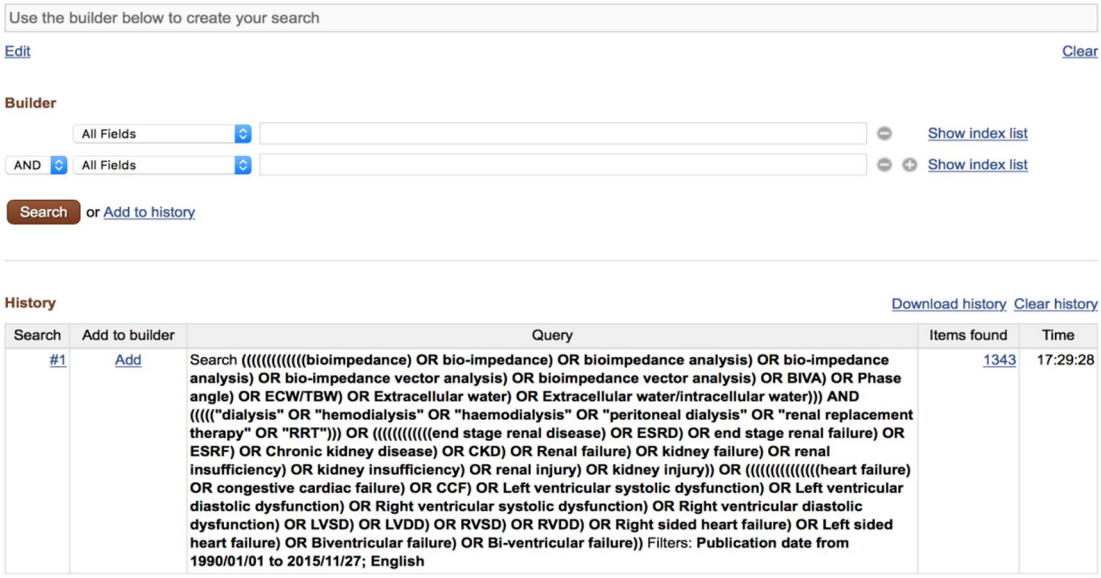


Figure 4.1a - Medline database search strategy screenshot. Database available from national library of medicine.www.nlm.nih.gov/bsd/medline.html

Figure 4.1b - Embase database search strategy

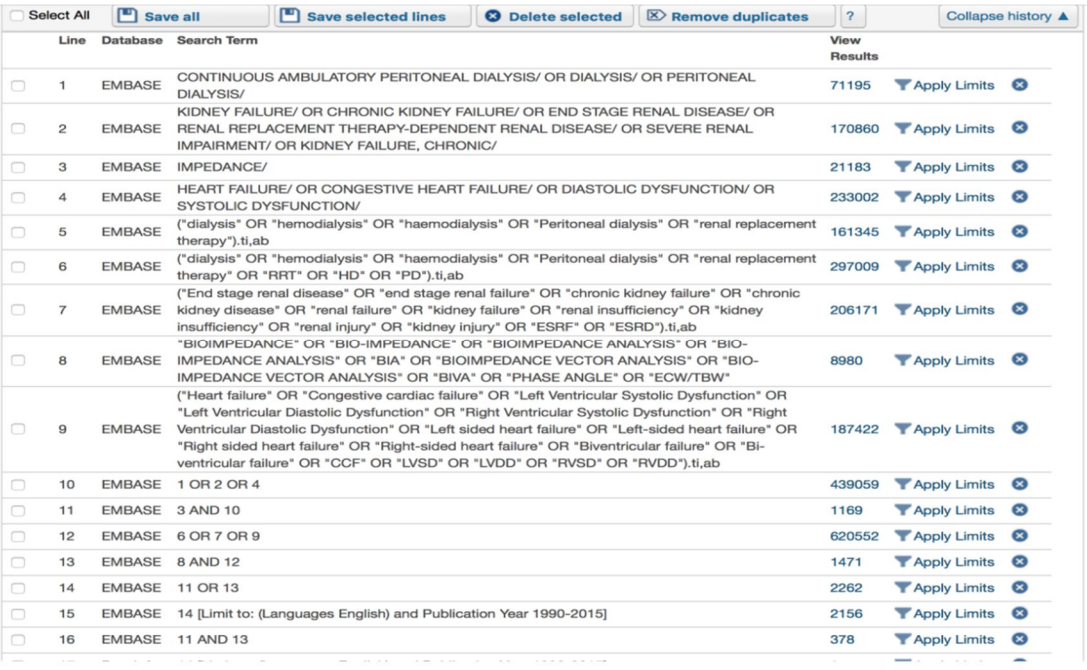


Figure 4.1b Embase database search strategy screen shot. Database available from elsevier. https://www.embase.com/

Figure 4.1c. Cochrane database search strategy

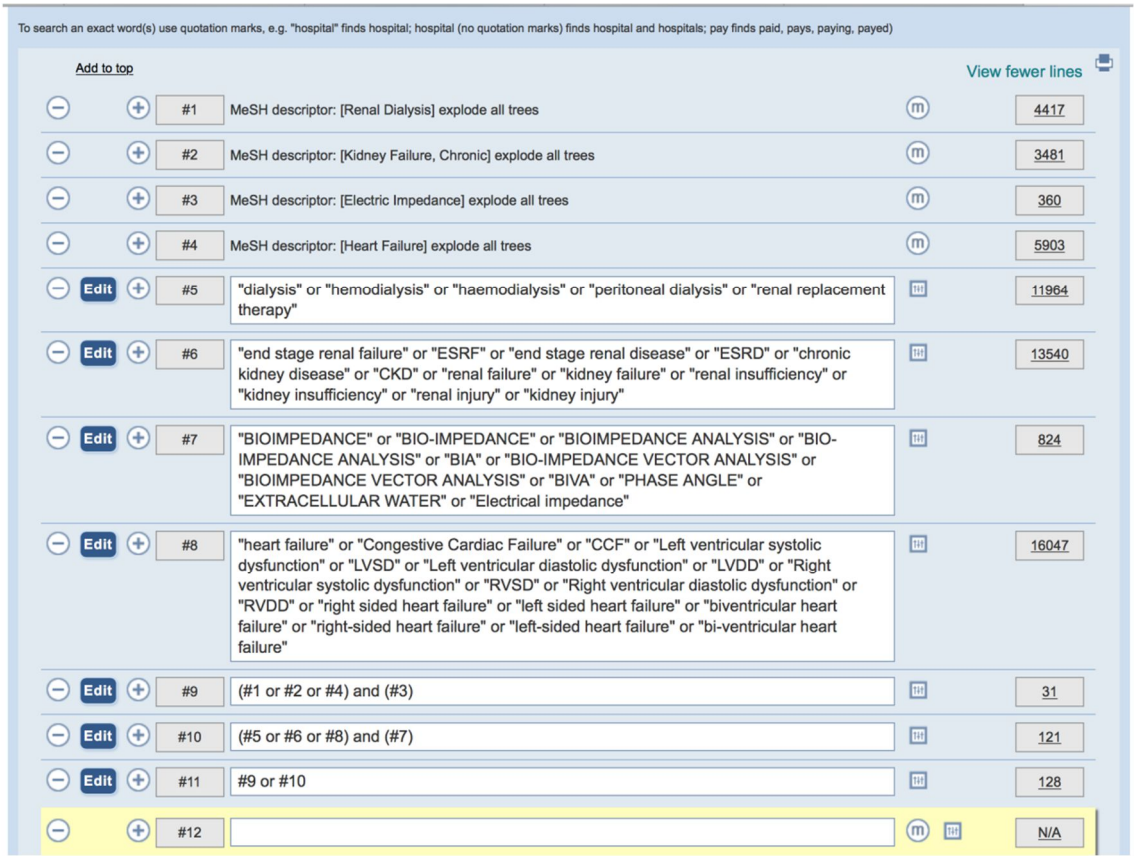


Figure 4.1c Cochrane database. Database available from cochrane library. www.cochranelibrary.com

5. Development of review strategy

Our strategy for review was developed in line with the standards outlined by the Cochrane library. This included having two reviewers to assess the literature that was found in the search, to agree on what should be included and also the quality of the literature to be included. (85) Our chosen method of quality assessment in the literature was the QUIPS (Quality in prognosis studies) tool. (100) This tool is a peer reviewed and widely used tool when quality assessing prognostic literature and includes 6 main domains of review to assess for potential of bias, which include:

1. Study participation
2. Study attrition
3. Prognostic factor measurement
4. Outcome measurement
5. Study confounding
6. Statistical analysis and reporting

The tool offers several points, prompts and considerations under each domain and a guide to how much these considerations may have biased the research, allowing the grading of each domain into a high, moderate or low risk category.

Results

1. Overview

Our search strategy resulted in 2701 individual studies being identified for review. (full list in appendix 2). Each study was assigned a number for the purpose of review. Each study title and abstract was then reviewed independently by two authors for inclusion in the next stage of review (Michael Dudson, Matthew Tabinor or Emma Elphick). Of which 131 were identified for the next stage of review. At this stage of the review each paper was read in full to decide if it met inclusion criteria for our review, again independently by two authors(same as above), with any disagreements between the two authors on the inclusion of the study being decided on by the most senior author in the review team(Prof S Davies). We also included a further 4 studies from reference checking and by knowledge of the literature that were not picked up by our search strategy, however unfortunately one was not accessible to the review team so was not included.

The studies that were selected for analysis were then summarised and checked by a secondary author. They were quality appraised using a standardised quality in prognositic studies (QUIPS) appraisal tool (discussed previously) by two authors independently (Michael Dudson, Matthew Tabinor or Emma Elphick). If there were disagreements with regards to quality appraisal for each study, discussion and compromises were undertaken to assign levels of quality to each segment of the quality appraisal tool.

In total 38 studies were analysed in this way. Of which there were 5 that were regarding heart failure and 33 regarding ESRD. There were a number of studies identified in the list which had the same or partially the same cohorts, so were analysed together. There was also one study in which we were unable to gain access. The studies selected for review can be summarised in the table below (figure 4.2).

Figure 4.2 Summary table of accepted papers

Paper number	Year	Diagnosis	Treatment modality	N	PRD	Follow up (years)	Primary outcome	Secondary outcome
10	2011	ESRF	HD + PD	164	Y	6	Mortality	n/a
141	2006	ESRF	PD	53*	Y	5	Mortality	n/a
194	2014	ESRF	HD	91	N	3	Mortality	n/a
195	2014	ESRF	HD	250	Y	17 months	Mortality	n/a
370	2007	HF	N/A	242	N/A	Single measurement	NYHA classification	n/a
371	2012	HF	N/A	519	N/A	3	Mortality	n/a
401	2012	ESRF	HD	158	N	6.5	Mortality	Elevated BP
407	2007	ESRF	PD	227	N	3	Mortality	n/a
422	2000	ESRF	HD	3009	N	Variable 2 days -18 months	Mortality	
486	2012	HF	N/A	389	N/A	3	Mortality	NHYA classification
574	2013	ESRF	HD+PD	145	Y	16 months	Cardiovascular even	Mortality
635	2004	ESRF	HD	128	Y	Unknown ??4790 months	Mortality	n/a
670	2010	HF	N/A	41	N/A	5	Comparison with CM	Mortality (cardiac).
140	2010	ESRF	PD	62	N	8	Mortality	n/a
766	2008			53				
768	2002	ESRF	PD	45	Y	mean 6.93 months	Mortality	n/a
790	2009	ESRF	HD	90	Y	3	Mortality	hospitalisation
946	2015	ESRF	PD	307	N	38.4 months	Mortality	Cardiovascular mortality
948	2013							
1021	2015	ESRF	HD	241	N	30 months	Mortality	n/a
1230	2011	ESRF	PD	128	Y	2.2-2.3	Mortality	n/a
1459	1996	ESRF	HD	131	Y	mean 26.6 months	Mortality	n/a
1527	2015	ESRF	HD + PD	99	N	2	Mortality	n/a
1692	2014	ESRF	PD	529	Y	4 year follow up	Mortality	n/a
1742	2014	ESRF	HD	131	Y	3.5	Mortality	Adverse events
1745	2015	ESRF	HD	221	Y	66 months	Mortality	cardiovascular deaths
1777	2010	ESRF	HD+PD	753	N	mean 16.7 months	Mortality	cardiovascular deaths
1814	2015	ESRF	PD	455	Y	Mean 24.5 months	Mortality	n/a
1860	2004	ESRF	HD	3009	N	2 days to 18 months	Mortality	n/a
1928	2015	ESRF	PD	129	Y	Mean 25.47	Residual RF	Mortality
1994	2015	HF	N/A	130	N/A	6 months	Event free survival	n/a
2055	2009	ESRF	HD	149	N	Mean 13.5 months	Mortality	n/a
2056	2014							
2178	2013	ESRF	HD	96	N	Median 406 days	Mortality	n/a
2179	2015			173	Y	Median 21.3months		
2546	2009	ESRF	HD	269	N	3.5	Mortality	n/a
2703	2015	ESRF	HD	240	Y	2	Mortality	hospitalisation
2704	2016	ESRF	HD	697	N	1	Mortality	n/a

Figure 4.2. Summary table of results - ESRD papers in green, HF papers in red. Summarising key elements of papers

2. Summary and analysis of identified studies

The summary and analysis of each paper can be found below including their quality appraisal score (Red = high risk of bias / Yellow = moderate risk / Green = Low risk) :(numbers above table correspond to list of papers reviewed)

10

Objective	To study the relationship between phase angle (PA) and other nutritional markers with the prospective risk of mortality.
Sampling	164 dialysis patients (127 HD, 37 PD), from a secondary care setting in Madrid, Spain. Mean age 61.1 years, 60.3% male.
Design	• Prospective observational study • Baseline BIA measured, prior to HD in the middle of the week • 6 year follow up
Results	• 100 patients (61%) died, 22 (13%) transplanted, 4 (2%) transferred to other centre, 38 (23%) remained on dialysis. • Mean PA 7.8, divided into three groups pa 5-6,7-8, >8. • PA >8 on Kaplan-Meier survival analysis showed superior survival outcomes. (log rank 14.9, P<0.001)
MVA (multi-variate analysis)	• Cox multivariate method. • Age, Gender, vintage, co-morbidity index and various BIA measurements included. • After adjustment for co-morbidity index and age, PA<8 and co-morbidity itself significant predictors of mortality.
Strengths	• Long follow up time. • High number of endpoints. • Detailed characterisation of cohort at baseline. • Included multiple BIA measurements in multivariate analysis.
Weaknesses	• Doesn't categorically state censoring method. • Doesn't state source of data used for Charlson index

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)					
SP	SA	PFM	OM	SC	SAR

140 + 766

Objective	To Explore the relationship between nutritional status measured by extracellular mass/ body cell mass (ECM/BCM) (140) or ECW/ body surface area (BSA) (766) and survival in PD patients.
Sampling	Two studies – 140 had 62 PD patients, whereas 766 (an earlier study from 2008, using the same cohort) had 53. Both studies run from the same secondary care setting in USA. For final cohort (in study 140) - Mean age 54, 55% were women, 65% were African American and 24% were diabetic.
Design	• Prospective observational studies. • Baseline BIA measured in each. • 8 year cumulative follow up (in study 140).
Results	• 21 patients (34%) died, no other endpoints stated. • Diabetics had higher ECM/BCM ratio in study 140. • ECM/BCM ratio correlated with age and inversely correlated with albumin. • Multivariate regression analysis ECM/BCM was significantly predicted by albumin and diabetes.
MVA	• Cox multivariate proportional hazards model. • In study 140 (2010), after adjustment for age, race, gender, diabetes and HIV status enrolment ECM/BCM significant predictor of mortality (RR 1.035 p=0.018). • In study 766 (2008), after adjustment for the same covariates (with the addition of vintage), ECW/BSA was also a significant predictor of mortality (RR 1.50, p=0.03). • Patients censored for transplantation, change of modality or centre transfer.
Strengths	• Included HIV status as high proportion of African Americans (link with ApoL gene). • Stated censored outcomes.
Weaknesses	• Doesn't state proportion of cohort that in censored. • Doesn't state primary renal diagnosis. • Relatively small number of endpoints.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

141

Objective	To explore the relationship of nutritional markers and inflammation as predictors of mortality in PD patients.
Sampling	177 PD patients of which 53 PD patients had BIA data, from a secondary care centre in USA. 59% women, 60% African Americans, 37% diabetic.
Design	• Prospective observational study • Baseline BIA measured in 53 patients since 2001. • Total cohort had baseline nutritional parameters measured since 1991, and CRP measured at baseline and at "mean follow up point". • 5 year cumulative follow up (for BIA), 15 years for total cohort.
Results	• Mean enrolment phase angle 6.15. • In nutritional parameters analysis of total cohort 50% died during follow up. • Prealbumin independent predictor of mortality, when diabetes adjusted for becomes non-significant predictor. • C- reactive protein (CRP) independent predictor of mortality if >15 mg/L • PD patients who survived had significantly higher mean phase angle (6.53 compared to 5.35).

MVA	• For BIA analysis - Cox multivariate method.
	  ○ Adjusted for age, race, gender, diabetes.
	  ○ Number of endpoints not defined.
	  ○ Phase angle >6 compared to <6 significant prediction of cumulative survival.

Strengths	• Asses multiple nutritional markers.
Weaknesses	• BIA analysis appears to addition to existing study. • BIA MVA has no endpoint data, does not explain censoring mechanism.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

194

Objective	To determine the effect of serial changes of nutritional and inflammatory markers over time on changes in phase angle and subsequently on maintenance HD patient mortality.
Sampling	91 prevalent HD patients, from a secondary care centre in Israel. Mean age 64 years, 37% women, 49.5% diabetic, 55.3% CVD. (cardiovascular disease)
Design	• Prospective observational study – two phases: longitudinal follow up phase (which lasted for 2 years) and survival ascertainment phase (which lasted a further year). Total of 3 years follow up provided. • Phase angle measured at baseline and at four predefined follow up points 6 months apart. (IL-6 also measured at follow up). • Patients divided into tertiles on change in phase angle from baseline at follow up points. • Post HD BIA measure (30 minutes post HD).
Results	• Mean baseline phase angle 5.1, mean baseline IL-6 6.1pg/ml. • During study there were 38 deaths of which 18 died of sepsis, 14 died of CVD and 6 died of other causes. Additionally, there were 13 transplanted, 13 transferred to other units and 1 changed modality (PD). • During longitudinal phase, a mixed effects model was used to assess the factors contributing to changes in phase angle - ECW, IL-6, fat mass were all significant predictors.
MVA	• Cox multivariate method, adjusted for age, gender, diabetes, vintage, CVD. • Patients with the smallest change in phase angle, when divided into tertiles, had smaller hazard ratios for mortality when compared to those with larger changes in phase angle. • Additionally, patients with smallest change in phase angle had smaller rises in IL-6.
Strengths	• Good description of attrition in study • MVA adjusts for well-known confounders. • Included ROC and cut off analysis for PA and IL-6 in prediction of mortality.
Weaknesses	• Could have represented phase angle changes in a simpler way.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

195

Objective	To determine the utility of PA in determining clinical surrogates of muscle function, health related QOL (quality of life) and clinical outcomes (inc. mortality / hospitalisation).
Sampling	250 HD patients from a secondary care centre in Tel Aviv, Israel. Mean age 68.7yrs, 36.8% female, 58.4% diabetic. Exclusion criteria included those with a life expectancy of < 6/12, those with a major cardiovascular event in the last 6/12, patients with BMI > 35 / < 16, patients with HIV and amputees. Most common PRD was diabetic nephropathy.
Design	• Prospective observational study. • Baseline BIA measure (PA). • Post BIA HD (30 minutes post HD). • Follow up for 17 months. • Co-morbidity index designed by Liu (2010) used, specifically for dialysis patients.
Results	• During the study there were 64 deaths – 48% due to CVD / 26% due to sepsis / 25% due to other causes. In total, throughout study period, 10 patients excluded from analysis – 6 due to transplantation, 2 due to modality switch and 2 due to transfer to another unit. • At baseline, significant differences between PA tertile groups (≤4°: n = 87, 4.1-5°: n=86 and ≥5.1°: n=77) in albumin*, IL-6, MIS, handgrip strength, BMI, RRF, Smoking status, co-morbidity, diabetic status, age and gender. • Interestingly, SF-36:QOL domains were assessed, and compared with the lowest tertile for PA (≤4°), significant differences in SF-36 domains were seen with progressive increases in PA (SF36 difference overall, between PA≤4° and PA≥5.1° = 15.1 SF36 points, p<0.001).

MVA	• MVA analysis was a multivariate Cox regression analysis: separate analyses run for mortality risk and hospitalisation risk.
	• Crude model (model 1) was then added to (with unclear statistical strategy), using 5 different models, both for mortality and hospitalisation risk:
	  ○ Model 2 was "Model 1" adjusted for age / sex / vintage and Kt/V.
	  ○ Model 3 was "Model 2" + adjustment for DM / CMI / smoking and RRF.
	  ○ Model 4 was "Model 3" + adjustment for IL-6 level.
	  ○ Model 5 was "Model 4" + adjustment for MIS.
	• For all cause and CVD related mortality, Models 1-4 were demonstrated that a rise in PA by 1° was a significant independent predictor of outcome (all-cause mortality HR 0.72, 95%CI 0.54-0.96, cardiovascular mortality HR 0.67, 95%CI 0.45-0.99). Hospitalisation risk was significant through all model iterations, including Model 5 (addition of MIS).

Strengths	• Excellent summary of study participants + outcome (flow chart) • Compared to previous study (194), PA represented in a more understandable way
Weaknesses	• Unclear statistical model building strategy (not stated forward / backward / Wald) • Not included albumin in MVA

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

370

Objective	To ascertain role of BIA in heart failure when predicting functional status.
Sampling	242 heart failure patients. 139 with HFSD (heart failure with systolic dysfunction), 107 with HFPSF (heart failure with preserved systolic function), from a secondary care centre in Mexico City. Excluded ESRD patients. 58.6% and 42.8% of cohorts were male in the HFSD and HFPSF groups respectively.
Design	• Cross-sectional study. • Patients stratified according to NYHA (new york heart association) score; NYHA I-II and NYHA III-IV. Score determined by independent cardiologist. • BIVA method used, measured at single point. • Comorbidity data collected at same point.
Results	• IN HFSD group phase angle significantly predicted NYHA classification. P= 0.04 • In HFPSF group phase angle significantly predicted NYHA classification. P= 0.01 • Significant differences in vector position of vector analysis graphs in HFSD and HFPSF in women, and a trend was found in men. • Vector was shorter and more downsloping in NYHA III-IV groups in both HFSD and HFPSF compared with the vector for NYHA I-II.
MVA	• N/A
Strengths	• Validated measure used for outcome.
Weaknesses	• NYHA functional class only determined by one cardiologist. • No follow up data. Therefore, prognostic utility of study limited.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

371

Objective	To investigate whether BIVA cachexia is a prognostic indicator in stable heart failure.
Sampling	519 consecutive stable heart failure patients admitted to a HF clinic in Mexico. Patients with ESRD, HIV, amputations, malignancy and unstable CVD excluded. 55.1% males, mean age 62.5 years, 45.4% diabetics, 12.5% had CKD.
Design	• Prospective observational study. • Baseline BIVA • Stratified into with or without BIVA-cachexia groups (defined as above the 95% tolerance ellipse, in the lower right quadrant, compared to a gender specific normal population). • Follow up 36 months, clinic attendance or telephone follow up.
Results	• Patients with BIVA – cachexia at baseline had significantly worse renal function, were more symptomatic (according to NYHA classification). • There were multiple differences in anthropometric parameters between groups. • There were 39 deaths (19.9%) in BIVA – cachexia group and 38 deaths (11.7%) in the BIVA-without cachexia group. Kaplan-Meier survival analysis showed significantly worse cumulative survival in BIVA-cachexia group ($p<0.0001$).
MVA	• Cox regression model, included age, ejection fraction, BIVA-cachexia, renal dysfunction, NYHA classification and hypoalbuminaemia. • Significant independent predictors of mortality at 36 months were BIVA – cachexia (b coefficient 1.66, $P=0.03$) and hypoalbuminaemia (b coefficient 2.95, $p<0.0001$).
Strengths	• Large sample size and reasonable number of endpoints. • Adjusted for ejection fraction in multivariate analysis. • Clearly defined baseline characteristics.
Weaknesses	• Unclear study attrition methods. • Did not included diabetes in the multivariate analysis.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

401

Objective	To analyses the impact of hyperhydration on mortality.
Sampling	Two cohorts – Tassin centre, France (n=50) and Giessen centre, Germany (n=158). • Tassin cohort highly selected – multiple exclusion criteria, clinically optimised, use dry weight probing method to set dry weight and low salt diet encouraged. 3 x weekly HD with low flux membranes performed up to 8h per session. Used as reference group. Mean age 72.5 years, 14 % were diabetics (30% in the Tassin centre are diabetic). • Giessen cohort – all HD patients that had no pacemaker or amputation and consented to study were included. No salt restriction enforced.3 x weekly HD with high flux membranes performed for 4-5h per session. Mean age 64.7 years with a diabetes prevalence of 37% in the non-hyperhydrated group. Mean age 65.4 years with a diabetes prevalence of 23% in the hyperhydrated group.
Design	• Prospective observational study. • BIA measured pre dialysis after a short interval in dialysis sessions. • 6.5 years follow up. • Relative overhydration measured against normal population adjusted for body mass. Giessen cohort stratified into two groups – hyperhydrated group and non-hyperhydrated group • Hyperhydration defined as >15% on the relative overhydration index.
Results	• No significant differences between Giessen Groups other than crude mortality and overhydration indices over 6.5 year follow up period. • Transfer to a different centre occurred in 4% of Tassin patients and 4.9% / 5.7% of the nonhyperhydrated / hyperhydrated Giessen group respectively. • Transplantation occurred in 22% of Tassin patients and 12.2% / 5.7% of the nonhyperhydrated / hyperhydrated Giessen group respectively. • Unadjusted Kaplan-Meier survival analysis demonstrated worse cumulative survival for hyperhydrated patients in the Giessen cohort compared to the other cohorts.
MVA	• Cox adjusted model (Tassin Group is used as reference cohort). It included gender, age, diabetes, haematocrit, pre dialysis systolic BP, vintage, BMI and albumin. • There was no significant difference in adjusted mortality hazard ratio between the Tassin and the Giessen Non-hyperhydrated group (HR = 1.26, 95% CI 0.66-2.41, p = 0.48). • There was a significant difference in an adjusted mortality hazard ratio between the Tassin and the Giessen hyperhydrated group (HR= 3.41, 95% CI 1.62-7.17, p<0.0001).
Strengths	• Multiple comorbidities included in multivariate analysis. • Clearly defines differences between groups. • Good number of endpoints. • Allows good comparison between two Giessen groups.
Weaknesses	• Multivariate analysis didn't compare the two Giessen groups directly. • Significant differences in nephrology practises between Tassin and Giessen and Tassin cohort is highly selected (as noted by low diabetes prevalence and high transplantation rate).

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

407

Objective	To explore the relationship of body fluid distribution (expressed as ECW/ICW) and patient survival in incident PD patients.
Sampling	227 Incident PD Patients from a secondary care centre in China. Mean age of 59.5yrs, 44.1% male, 24.7% of cohort had diabetes mellitus and 54.9% were hypertensive. Average CCI index score was 5.41.
Design	• Prospective Observational study. • Followed up at 2 and 3 years, with censoring if transplanted or had a change of dialysis modality (on new modality, such as HD, for > 3 months). • Data collection of BIA, clinical and demographical parameters at baseline.
Results	• In total there were 58 endpoints – deaths were due to cardiovascular / cerebrovascular disease (17), multiple organ failure (4), cancer (12), infection (7) and economic reasons (12). 6 deaths were due to an unknown cause. • Survival in the cohort, at 2 years was 74% and at 3 years was 65%. • Univariate analysis showed age, sex, Charlson comorbidity index, kT/V, malnutrition, albumin, pulse pressure and ECW/ICW ratio were predictors of mortality. These were subsequently added to the MVA.
MVA	• Cox proportional Hazards Model. • Used a stepwise entry approach for those predictors deemed significant on the univariate model. Cut off for entry to the MVA was a significance level of $p < 0.05$. • Only significant predictor for mortality was ECW / ICW – at baseline and as a time dependent variable, ECW/ICW was a significant predictor of mortality*.
Strengths	• Includes comprehensive comorbidity index • Good analysis of differences in demographics between survivors and non-survivors.
Weaknesses	• Little information of BIA procedures or exclusion criteria. • Stepwise entry method for MVA.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

422

Objective	To investigate the relationship between dialysis vintage and all-cause mortality. Additional analyses included effect of BIA measurement added to models.
Sampling	3009 HD patients from 101 Fresenius medical care dialysis units in the USA. Patients with major limb amputations excluded.
Design	• Observational study. • Variable follow up (2 days to 18 months). • Patients classified according to dialysis vintage (<1, 1-2, 2-3, 3-5, 5-10, >10 years). • Predialysis BIA, before midweek session within the first 6 months of 1995).
Results	• Phase angle progressively increases for first 2 years on HD, and then progressively decreases. This similar pattern is mirrored in serum albumin levels. • Interestingly black patients appear to have better cumulative survival on dialysis. • Unadjusted analyses showed vintage did not predict cumulative survival. • During the study 82 patients were transplanted, 18 recovered renal function, 287 transferred to a different centre, 42 withdrew from dialysis and 8 were lost to follow up.
MVA	• Cox regression analysis after adjustment for age, gender, ethnicity, diabetes, albumin, cholesterol, Kt/V and ferritin, a 1 year increase in dialysis vintage yielded a RR of all-cause mortality of 1.06 95% CI 1.03 to 1.09. • Following addition (using a saturation stepwise entry approach) of phase angle, TBW and body weight no material change in risk ratio was observed. • Significant interactions found between vintage and weight/TBW.
Strengths	• Very large sample size across multiple centres.
Weaknesses	• No overall statistics around the overall demographics of the study population. • Highly variable follow up. • Unclear outputs from statistical analyses, which appeared ad-hoc. • Study not designed to answer objective of systematic review directly.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

486

Objective	To asses prognostic value of phase angle in heart failure independent of other predictors of poor outcome.
Sampling	389 heart failure patients attending a secondary care centre in Mexico. Heart failure defined by echo criteria. Patients excluded if demonstrated dysthyroidism, hepatic failure, suspected malignancy, unstable IHD or evidence of potential malignancy.
Design	• Prospective observational study. • Patients divided into groups on baseline phase angle criteria (PA <4.2, PA 4.2-4.9, PA 5-5.6 and PA >5.7) – equivalent to quartiles. • Follow up 3 years – data collected from medical records and heart failure clinic registry.
Results	• 66 deaths (31 due to CVD, 35 due to other or unknown causes). • Unadjusted Kaplan-Meier analysis showed significantly improved survival if PA >5.7, compared to the other three groups. Survival progressively worsens as phase angle decreases. • Significant group differences in baseline presence of renal failure. • NYHA classifications significantly different between phase angle groups.
MVA	• Cox regression analysis using stepwise entry of explanatory variables into model. • After adjustment for age, HB and Diabetes phase angle <4.2 was an independent predictor of all-cause mortality (RR 3.08, 95% CI 1.06-8.99).
Strengths	• Clear inclusion and exclusion criteria. • Secondary outcomes clearly demonstrated.
Weaknesses	• Modelling technique based on statistical rather than theoretical assumptions.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)					
SP	SA	PFM	OM	SC	SAR

574

Objective	To Investigate the association between BIA and cardiovascular events.
Sampling	145 ESRF patients, 36 PD and 109 HD from a secondary care setting in Botucatu, Brazil. Excluded patients included those with LVSD (left ventricular systolic sysfunction), amputees, cancer, hepatic insufficiency and HIV/AIDS. 49.7% male, 54.9 mean age, 35.9% diabetics.
Design	• Prospective observational study. • BIA performed at baseline – for HD patients this was 30 mins post HD. For PD it was performed after complete dialysate drainage. • Patients stratified into groups with or without cardiovascular events at follow up at 16 months.
Results	• During study period 27.6% of patients developed a cardiovascular event. All-cause mortality was 8.9% and cardiovascular mortality 3.4%. • Of the cardiovascular events 40% were hypertensive emergencies, 37.5% were ACS events.7.5% developed arrhythmias, 5% thrombotic events, 5% sudden death, 2.5% TIA, 2.5% heart failure. • Those suffering cardiovascular events were older, had higher CRP levels and higher ECM/BCM ratios. • Unadjusted cox analysis showed that a lower phase angle (HR 0.76, 95%CI 0.59-0.99) and higher ECM/BCM ratio (HR 7.78, 95%CI 1.01, 2.76) was associated with cardiovascular events. • Kaplan Meier Survival curves showed PA < 6 and ECM/BCM >1.2 associated with poor cardiovascular prognosis.
MVA	• Cox analysis adjusted for age, CRP, dialysis modality and diastolic BP. • Phase angle and ECM/BCM significant predictors of cardiovascular events in non-diabetic patients, whereas this relationship did not persist in the diabetic group.
Strengths	• Good documentation of endpoints and sampling criteria.
Weaknesses	• Relatively underpowered study. • Could have included ethnicity and HIV patients. • Used post HD BIA measurement – is not routine practice.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

635

Objective	To determine the prognostic value of the Charlson comorbidity index on mortality and to determine the prognostic value of other nutritional markers including phase angle on survival.
Sampling	515 ESRF patients from 111 dialysis centres in Italy. Mean age 63.6 years, mean BMI 24.56. Most common PRD (primary renal disease) - diabetic nephropathy (28%).
Design	• Prospective observational study. • 128 participants underwent BIA. Post HD BIA performed. • Divided into two groups in follow up (alive or dead).
Results	• 15 months follow up period in total. • 75 patients died (15%) during follow up period. • Causes of death included cardiac (24), vascular disease (12), infection (5), cachexia (12), undetermined (10) – these numbers do not match total numbers of death (? Unreported cause of death). • Univariate analysis demonstrated that when comparing alive vs dead groups, patients in the dead group had significantly greater levels of hypoalbuminaemia, anaemia, hospitalisation, lower phase angle (<3). • Linear correlation demonstrated between phase angle and Charlson comorbidity index. (R^2=0.56).
MVA	• Cox proportional hazards model, adjusting for HB, albumin, days of hospitalisation, Charlson comorbidity index and phase angle. • Phase angle demonstrated to be independent predictor of mortality (coefficient=0.98, p=0.043, RR=2.5).
Strengths	• Able to show clear correlation between comorbidity and phase angle.
Weaknesses	• Used post HD BIA method. • Unclear number of endpoints, i.e death. • Unclear length of follow up as includes 4790 months follow up in main body of text.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

670

Objective	To assess and compare epicardial adipose tissue (EAT) quantity derived from cardiac magnetic resonance imaging (MRI) and bioimpedance parameters of body composition among patients with severe CHF and healthy controls.
Sampling	41 patients with severe CHF + 16 healthy controls from a secondary care setting in Germany. Patients with pacemakers and claustrophobia were excluded. Mean age 63, 88% male.
Design	• Prospective observational study. • Participants had Cardiac MR, echocardiogram and BIA at baseline. • Follow up at 5 years.
Results	• EAT correlated with PA $r = 0.31$; $P = 0.01$ • LVEF was the only factor independently associated with EAT on multivariate analysis. • 8 cardiac deaths in follow up. • PA predictor of cardiac death on univariate analysis (AUC = 0.86; 95% confidence interval (CI) = 0.72–1.0, $P = 0.01$), indexed EAT (AUC = 0.82; 95% CI = 0.70–0.94, $P = 0.04$), LV-EF (AUC = 0.68; 95% CI = 0.51–0.88, $P = 0.09$).
MVA	• No survival multivariate analysis
Strengths	• Shows prognostic value of PA is high in comparison to other makers of cardiac dysfunction.
Weaknesses	• Hasn't included if there were non-cardiac deaths. • No survival MVA. • Did not record comorbidities.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

768

Objective	To determine the usefulness of BIA in assessing the prognosis of PD patients.
Sampling	45 PD patients attending a secondary care centre in USA. Mean age 50 years, 56% female, 24% diabetes, 70% African American. Most common cause of ESRD was hypertensive nephropathy (38%), 7% classified as HIV nephropathy. Mean time on PD 55 months.
Design	• Prospective observational study. • Post dialysis BIA at baseline. • Mean follow up time 6.93 months. • Patients divided into two groups – phase angle <6 and >6.
Results	• Diabetic patients had lower phase angle compared to non-diabetic patients (5.4° vs 6.4°, P=0.05). • 4 patients died; all were in the phase angle <6 group.
MVA	• Phase angle correlated with all biochemical markers of nutrition (serum albumin in multivariate regression analysis was the only significant predictor of phase angle.) • No multivariate analysis of survival (only 4 endpoints).
Strengths	• Recorded ethnicity.
Weaknesses	• Small cohort, with limited endpoint data. • No multivariate analysis of survival. • Uses post HD BIA. • Unusually high proportion of hypertensive nephropathy for USA population. High proportion of African Americans in cohort -? Hypertensive nephropathy misclassification (? higher proportion of HIVAN).

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

790

Objective	To examine different approaches for detection of malnutrition for HD patients and to show their prognostic value in assessing survival.
Sampling	90 HD patients, single outpatient dialysis centre in Germany. Mean age 61 years, 53% males, 98% Caucasian. Mean dialysis vintage 42 months.
Design	• Prospective observational study. • Post dialysis BIA at baseline. • 3 year follow up. • Patient parameters measured at 0,12,24,36 months.
Results	• 36 patients died, 52% died of cardiovascular events, 22 % of infection, and 14% of malignancy. • Hospitalisation events- 333 admissions, 2.4 admissions per patient year. • Phase angle <4 in a univariate analysis significantly predicted frequency of hospitalisation, as did other nutritional markers such as MIS, NRS, SGA. Albumin was also a predictor of frequency of hospitalisation. • In univariate analysis malnutrition defined as SGA B/C, NRS positive, MIS >8, prealbumin<29mg/dL, CRP>10.4mg/mL and Phase angle <4.8 all significantly predicted mortality.
MVA	• Cox regression analysis adjusted for age, gender, vintage and diabetes. • All nutritional markers identified in univariate analysis were independent predictors of mortality. • In particular phase angle <4 significantly predicted mortality (HR=2.34, 95%CI 1.06,5.14, P<0.05). • Authors state BIA not the strongest predictor.
Strengths	• Includes hospitalisation as an outcome factor (not in multivariate analysis). • Assess various measures of nutrition against BIA. • Censors transplantation.
Weaknesses	• Uses post HD BIA. • Doesn't include comprehensive comorbidities in MVA.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

906

Objective	To categorise the protein-energy wasting (PEW) in a Spanish HD population and to assess its potential affect on mortality.
Sampling	122 prevalent HD patients in a satellite unit in Toledo, Spain. All patients who had not been hospitalised in the past two months were included. Mean age 63.6 years. Excluded if hospitalised at start of study. Most common cause of ESRD was hypertensive nephropathy. Comorbidity assessed by Davies criteria.
Design	• Prospective observational study. • Post HD BIA • Assessed for PEW at 0, 12, 24 months. BIA assessed every 6 months. • 2-year study 10 further months of follow up.
Results	• During study period there were 26 deaths, 17 transplants and 5 transferred to another centre. • Of these deaths 31% were due to cardiovascular disease, 4% malignancy, 19% infection, 23% general deterioration, 15 % due to other causes and 7% due to unknown causes. • Prevalence of PEW within the population remained constant over time. • On multivariate regression model (for predictors of PEW) the only clinical variables were OH, ICW, ECW/ICW and ERI (EPO dose per week). • Survival analysis demonstrated that of the factors that determine PEW only loss of lean muscle mass significantly predicted survival (univariate Kaplan-Meier survival analysis).
MVA	• N/A
Strengths	• Comprehensive characterisation of baseline cohort.
Weaknesses	• No multivariate analysis • Doesn't account for comorbidity in survival analysis.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

946+948

Objective	To determine the prognostic utility of BIA in CAPD patients. 946 was 2015 study, with survival analysis. 948 was initial study, looking at determinants of fluid overload.
Sampling	Same cohort used for 948 + 946. 307 CAPD patients in a Chinese secondary care centre in Guangzhou. Exclusion criteria included patients with PPM (permanent pace maker) / amputations and significant disability I.e. cannot stand for 3 minutes. Mean age 47.8years, 43% male and 16% diabetic. No data on PRD. Co-morbidity assessed via the CCI (Charlson comorbidity index).
Design	• Prospective observational study. • Standard BIA protocol for PD patients – dialysate remained in the abdomen. • Probable baseline BIA measurement normalised against 6520 Koreans (healthy). • Follow up was 38.4 months.
Results	• Patients stratified for analysis into survivor (n=255) and non-survivor (n=52) groups. • Univariate analysis demonstrated age, diabetes, DBP, CCI, ECW/TBW, PD fluid constituents, CRP, Albumin and blood glucose significantly different between groups; particularly greater degree of fluid overload in non-survivors compared with survivors (ECW/TBW 0.41 vs 0.40) • In total, 52 patients died, 28 changed dialysis modality, 44 were transplanted, 7 had a change in dialysis centre, 1 patient withdrew from treatment and 3 were lost to follow up. • Detailed list of "clinical events" provided – stratified according to cut off for fluid overload (ECW/TBW≥4) – higher rates of peritonitis, cardiovascular and cerebrovascular disease in fluid overloaded patients. • Of the mortality outcomes, 28 died from cardiac disease, 9 from cerebrovascular disease, 10 from infectious diseases and 5 from other unspecified causes.
MVA	• Cox analysis performed, adjusted for age, gender, DM, CCI, CRP, Albumin, DBP, D/PCr, Kt/V and glucose concentration in the PD solution. • When adjusting for all known co-variates, ECW/TBW > 0.4 independent predictor of all-cause mortality (HR 13.58, 95% CI 1.15-170.11); similarly, when adjusting for only age, gender, DM and CCI, a similar relationship was found (HR 9.73, 95%CI 1.15-82.56). • Similarly, both these models showed that ECW/TBW>0.4 was independent predictor of PD technique failure.
Strengths	• Good description of events that occurred in follow up. • Clear identification of the cohort + characterisation of the cohort.
Weaknesses	• Did not include primary renal diagnosis. • CCI used, but some overlap with use of "DM", and not able to clearly delineate from paper which co-morbidities particularly affect the ECW/TBW ratio. • Not specific in their BIA measurement time points. • Number of endpoints low for number of factors adjusted for in main model.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1021

Objective	To assess prognostic value of cardiac biomarkers and hydration status on long term survival of patients on HD.
Sampling	241 HD patients from a centre in Poznan, Poland. Patients grouped on dialysis vintage – short vintage (SV) <24 months and long vintage (LV) >24 months. Within the SV and LV groups respectively, the Mean age was 62 / 61.7yrs, 64.7% / 68% were male and 34.5% / 8.2% were diabetic.
Design	• Prospective observational study. • Patients stratified into SV and LV groups (as above). • Pre-HD BIA before midweek session. • 30 months follow up.
Results	• Longer HD vintage is associated with worse survival although this is unclear from the presentation of the papers statistics. • Patients that with longer HD vintage have a greater degree of overhydration. • OH% is correlated with intraventricular septum thickness (IVS) and left ventricular wall thickness.
MVA	• Logistic regression analysis of all-cause mortality markers. • Model 1 including troponin and OH% shows OH% independent predictor of mortality. • Model 3 including troponin, OH%, albumin, cholesterol and IVS show that OH% does not independently predict mortality, although the overall p value for the model was significant.
Strengths	• Demonstrates troponin may be a predictor of mortality in HD patients.
Weaknesses	• Very unclear follow up plan. See figure 1 vs follow up period in methods. • Unclear definition of BIA measurement (OH %). • Multivariate analysis does not adjust for confounders.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1230

Objective	To determine whether the normalisation of bioimpedance indices improved prognostic outcome in CAPD patients.
Sampling	128 CAPD patients were recruited from a single secondary care in Malaysia. 64 Malays, 50 Chinese, 14 Indians. Diabetic nephropathy was the commonest primary renal disease. 54% were female.
Design	• Prospective observational study. • Baseline BIA following complete drainage of abdomen. • CAPD patients compared to control 322 healthy volunteers – approximately the same distribution of ethnicity. • Follow up was 2.2-2.3 years.
Results	• Comparing the normal population with the CAPD population, CAPD patients have significantly smaller phase angles and significantly bigger capacitive indices. • 35 patients died, 54% due to infectious causes, 26% due to cardiovascular causes. • Of the 47 patients with diabetes 43% died compared to 19% of non-diabetic patients. • Comparing survivors and non-survivors enrolment phase angle and capacitive index were significantly different between groups. When adjusted for albumin and diabetes this significance remained.
MVA	• Cox analysis method adjusted for age, gender, diabetes, vintage, blood pressure, albumin, phosphate and Kt/V. • Four predictive models using cox regression designed- using capacitive index, BCI, phase angle and reactance/height. • All BIA parameters were significant predictors of mortality and age was a significant predictor of mortality in all analyses except in the phase angle model.
Strengths	• Adjusted for many covariates in multivariate analyses. • Uses multiple nutritional markers in multivariate analyses.
Weaknesses	• Doesn't censor for alternate endpoints. • Doesn't adjust for HIV status. • Potentially insufficient numbers of endpoints.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1459

Objective	To determine the role of Bio impedance and other nutritional markers on mortality in HD patients.
Sampling	131 HD patients from three secondary care centres in Italy. Mean age 62.5 years, mean dialysis vintage 75 months. The commonest primary renal disease was glomerulonephritis. The normal values for BIA determined from 272 age and gender controlled healthy participants.
Design	• Prospective observational study. • All members had thrice weekly HD – 44 patients treated with high efficiency HD (for shorter periods). • Pre and post HD BIA measurements. Have carried out assessment of reliability of readings, and demonstrating differences between pre HD and post HD BIA values (table 1), authors felt reliability of post HD BIA warranted the use the post HD BIA. • Mean follow up was 26.6 months.
Results	• 23 patients died, 6 transplanted and 3 transferred to another centre or started PD. • Causes of death included cachexia (17.4%), infection (26.1%), stroke (13%), cardiovascular disease (13%), GI Haemorrhage (9%) and other causes (22%). • 65% of deaths occurred in patients who had phase angle values within the lowest quartile of baseline.
MVA	• Cox regression analysis assessing whether various nutritional markers are independent predictors of mortality. • Adjusted for Age. • Phase angle independent predictor of death in this cohort compared to other nutritional markers.
Strengths	• Attempts to define normal BIA measurements using normal population. • Clearly defines endpoints.
Weaknesses	• No multivariate analysis adjusting for comorbidity/ known covariates.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1527

Objective	To assess the nutrition and hydration status of prevalent HD and CAPD patients and to observe the impact in predicting 2 year mortality.
Sampling	85 HD patients and 14 CAPD patients from three secondary care centres in India. Patients with pacemakers, cirrhosis, infections, HIV, malignancy and those with irregular dialysis (due to financial constraints) were excluded. Mean age was 55.26, 78.79% were male and 39.4 % diabetic.
Design	• Prospective observational study. • Pre dialysis BIA in HD patients and with dialysate removed in PD patients at baseline along with other nutritional and biochemical markers were taken, they were then repeated at 2 year follow up. • Some HD patients underwent twice rather than thrice weekly HD. • 2 year follow up.
Results	• 41 patients died in the follow up period, 12 patients underwent transplantation and 13 lost to follow up. • The only significant different between non survivors and survivors at baseline were overhydration in Litres (p=0.02) and BMI. (p=0.017). • At follow up ICW and overhydration of survivors were significantly different along with other non BIA nutritional parameters. • No significant differences in twice vs. thrice weekly BIA in survival.
MVA	• Multiple logistic regression analysis adjusted for Fat tissue index and BMI showed overhydration in Litres was an independent predictor of mortality (adj OR 2.963, 95%CI 1.038, 8.460, p=0.042).
Strengths	• Good description of baseline characteristics of cohort.
Weaknesses	• Known significant comorbidities not adjusted for in multivariate as no significant difference between survivors and deceased. • Differences in HD regimes. • No primary diagnoses established for cohorts.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1692

Objective	To determine relative usefulness of various BIA measurements in determining prognostic outcome in PD patients.
Sampling	529 PD patients – 225 incident and 304 prevalent. Recruited from secondary care centres in London, UK. Mean age of 57 years, 62% male, 33% diabetic and 48% deemed suitable for transplantation.
Design	• Prospective observational study. • Follow up period 4 years and 8 months. • BIA measurement at baseline and then quarterly, dialysate in situ (baseline BIA used for survival analysis).
Results	• 18% of the cohort died (approximately 95 deaths). • Age, vintage, gender, ethnicity and CRP were univariate predictors of mortality. • Interestingly in the multivariate cox regression analysis diabetes, transplantation suitability and albumin were not significant predictors of mortality. In univariate analysis albumin remained a non- significant predictor of mortality.
MVA	• Two cox analyses performed – adjusted for diabetes, gender, age, vintage, suitability for transplantation, ethnicity, albumin and CRP. • Model 1 – predicting prognostic value of overhydration value + OH/ECW + ECW/TBW in all dialysis patients. When adjusted for the above confounders, ECW/TBW was not a significant independent predictor of mortality, but the overhydration indices were independent predictors of mortality. • Model 2 – Selected patients with severe overhydration (patients deemed to be in the top 30% of overhydration values). All three measurements of BIA were independent predictors of survival.
Strengths	• Appropriate number of endpoints for MVA. • Multiple covariates adjusted for in MVA. • MVA demonstrated greater predictive value of mortality in severely overhydrated patients. • Recognition of potential selection bias by authors.
Weaknesses	• Large differences in mortality between men and women. • Albumin in multiple analyses not predictor of mortality; could suggest selection bias.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1742

Objective	To determine whether the use of BIA in the care of HD patients improves clinical outcomes.
Sampling	Single centre randomised controlled trial (RCT), with 131 patients who were eligible to participate. Exclusion criteria included patients with metallic prostheses, cardiac PPMs, decompensated cirrhosis, amputations, twice weekly HD schedules, refusal to participate, patients with < 1year to live and the absence of permanent vascular access. Patients randomised to two groups – standard clinical care (n = 69) and BIA group (n = 62).
Design	• Randomised controlled trial: single (patient)-blinded, single centre pragmatic RCT. • Block randomisation method used; not clearly stated randomisation process. • Analysis strategy stated, in flow chart, as "ITTA", and in the prose of the paper stated that censored for transfer from centre / transplantation. • Baseline BIA measurement (presumably post randomisation) and then 3 monthly BIA assessments. Clinicians non-blinded, and from BIA measurements, given recommended target weights to achieve dry weight. Additional measure of fluid overload used as reference – that of pulse wave velocity (PWV) • Trial period for intervention was 2.5years, followed by another year of "washout" to determine whether cessation of BIA guided dry weight targets reverted BIA indices back to baseline.
Results	• Following randomisation, no differences between trial arms in baseline variables, including BIA measures*. • When comparing BIA and clinical group at baseline, no significant difference in RFO (between group mean difference 0.78L, 95%CI -2.80, 4.36, p=0.9). • At the end of the intervention period, a statistically significant difference in RFO was noted between the BIA and clinical methods group (3.77L, 95%CI 2.20-7.35, p=0.03). Similarly, PWV values significant differed between groups (2.19, 95%CI 0.42,3.96, p=0.005). • When comparing the change in each group (from baseline to end of intervention), the changes in RFO and PWV remained statistically significant. • Kaplan Meier analysis of survival, comparing BIA and clinical methods group, showed significant differences in survival (censored for transplantation / transfer from centre), with a survival advantage in the BIA group (p=0.008).
MVA	• Cox model, adjusted for age / gender / cardiovascular disease / DM / vintage / BMI / BP / Albumin / RFO. • HR for mortality in BIA group, compared with clinical methods group, was 0.10 (95%CI 0.01-0.81, p=0.04).
Strengths	• First RCT of BIA vs clinical methods. • Had a pragmatic approach to blinding, which was beneficial for the clinician. • Compared BIA with PWV measurements (way of validating BIA data).
Weaknesses	• 8.5% of study cohort had diabetic nephropathy as PRD. According to Turkish Renal Registry report from 2014, 39.3% of all Turkish incident HD patients have diabetic nephropathy as their ESRF aetiology. High chance of significant selection bias**. • Small number of endpoints. • Did not do a "washout" period for BIA after the end of the RCT, whereas did do a PWV. Would have been useful to see this.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)					
SP	SA	PFM	OM	SC	SAR
Randomised Controlled Trial (RCT) – QUIPS not validated for methodological assessment of RCT*					

1745

Objective	To assess whether the relationship of BIA overhydration and survival is maintained once adjustments are made for echocardiography parameters
Sampling	221 HD patients from a secondary care centre in Romania. Mean age 53.8 years, 52.5% male, 10.4% diabetic and 51 have cardiovascular comorbidity. Patients excluded with metallic joint prostheses, pacemakers, decompensated liver disease and amputations.
Design	• Prospective observational study. • Follow up period 66 months. Censored if moved centre / transplanted / switched to PD. • BIA measurement Pre-dialysis, patients underwent thrice weekly high flux dialysis for 4 hour sessions. • Echo data performed after short dialysis by blinded independent cardiologist.
Results	• Patients divided into RFO (relative fluid overload compared to normal population) <15% or >15%. • 59 patients had RFO >15% had higher dialysis vintage, greater mortality rate and greater cardiovascular event rate. • During study there were 66 deaths of which 45% had a cardiovascular cause of death, 30% sudden death, 19.7% had sepsis, 1.5% malignancy and 3% had cirrhosis. • Patients who had RFO>15% had 2.12 and 2.46 increased risk of all-cause mortality and cardiovascular events respectively (Kaplan-Meier survival analyses log rank p=0.002 and p<0.01 respectively).
MVA	• Cox regression analysis adjusted for age, gender, vintage, diabetes, cardiovascular comorbidity and hypertension. • RFO>15% independently predicted mortality and cardiovascular events. • RFO>17.4% independently predicted mortality and cardiovascular events. ROH>17.4% remained an independent predictor of mortality / cardiovascular events when echocardiological data was added to the model, whereas ROH (relative over-hydration)>15% did not. • Interestingly, ROH > 17.4% Cox model had a better goodness of fit compared to model with 15%; specifically, improving predictive value of ROH > 17.4% in predicting all cause hospitalisation and decompensated heart failure hospitalisation.
Strengths	• Good multivariate analysis and attempts to account for different OH levels in the modelling process. • Includes echo data in multivariate analysis. • Demonstrates using higher cut-offs for ROH increases prognostic accuracy of BIA.
Weaknesses	• Low diabetic prevalence, possible limited external validity to other nations (prevalence in study does match national prevalence of diabetes

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1777

Objective	To determine whether NT-pro-BNP is an independent risk factor for mortality / cardiovascular events in the dialysis population.
Sampling	753 prevalent dialysis patients from 14 centres - patients randomly selected. Centres are within Mexico. Exclusion criteria applied – HIV / Cancer / Immunosuppression. 55% male, 44% diabetic, mean age 48.6yrs. 365 patients on PD / 388 on HD.
Design	• Prospective observational study. • Enrolment ECW/TBW measured - ? pre/post HD. • BNP measurements additionally taken at enrolment. • Follow up was a mean of 16.7 months.
Results	• During study period, 182 deaths (24.2% of total cohort). Of these deaths, 85 from cardiovascular events (AMI / CCF / Arrhythmia / Stroke / PVD / Sudden death), 22 from complications of ESRF (uraemia / hyperkalaemia / acidosis), 21 from infections, 9 from peritonitis and 25 from unknown causes. Other causes listed in table 3 of study. • Univariate analysis showed age, BP, ECV, BNP, CRP and albumin predictors of cardiovascular death. For call cause mortality, Univariate analysis showed significant predictors included age, BMI, diabetes, TBW, ECFv, glucose, BNP, albumin and creatinine levels. • NT-pro-BNP: split into quartiles: those in the highest quartile had lowest cumulative survival.
MVA	• Two separate analyses – all cause mortality AND cardiovascular mortality. Adjusted for age, gender, diabetes, dialysis modality, waist/hip ratio, body fat, BP, albumin, CRP, ECW/TBW, NT-pro-BNP and Troponin T. • In both analyses, ECW/TBW ratio and NT-pro-BNP were independent predictors of mortality.
Strengths	• Large number of endpoints (would allow for adjustment for 18 separate variables). • Good description of CV co-morbidity. • Good MVA including both BNP and BIA.
Weaknesses	• Did not specify primary renal disease. • Did not specify timing of BIA measure.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1814

Objective	Does SGA (subjective global assessment) and FTI (fat tissue index) independently predict survival in ESRF patients (independently of hydration status)
Sampling	455 PD patients from a UK centre. Mean age 56.1years, 61% were male, 33% were diabetic and mean dialysis vintage was 27.4 months. 64% non-white in terms of ethnicity. No exclusion criteria stated. 11% deemed suitable for transplantation.
Design	• Prospective observational study. • Not a clear BIA strategy r.e. timing or frequency of measurement. • Mean follow up was 24.5 months.
Results	• During the follow up period, there were 72 deaths. • Patients stratified according to SGA status – "normal" score or "low" score. • When comparing patients according to SGA group, significant differences were noted in transplant suitability, multiple bioimpedance measures (including OH/ECW, OH and FTI / LTI), residual renal function, albumin and CRP levels. • On univariate analysis, SGA scores, LTI, FTI, OH/ECW, age, DM status, vintage, gender, suitability for transplantation, albumin, Asian ethnicity and CRP were significant predictors of mortality.
MVA	• Unclear statistical method. • In MVA analysis, adjusted for age, gender, diabetic status, dialysis vintage and ethnicity, both OH/ECW (HR 3.12, 95%CI 1.86-5.23, $p<0.0001$) and LTI/FTI (HR 3.52, 95%CI 2.06-6.02, $p<0.0001$) were independent predictors of all cause mortality.
Strengths	• Directly compares multiple nutritional markers with OH/ECW in a MVA.
Weaknesses	• No clear attrition data. • No statistical method stated. • No clear causes of death stated. • Does not state about BIA methodology (r.e. timing)

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1860

Objective	To investigate the relationship between BIVA vector length and mortality in HD patients
Sampling	3009 prevalent HD patients across multiple centres in the United States (Fresenius). Mean age 60.5yrs, 47.2% were women, 46.9% were African American, 37% were diabetic. Excluded amputees.
Design	• Prospective observational study. • Pre dialysis BIA (before midweek session) – at baseline. • Follow up ranged from 2 days to 18months.
Results	• 12 death rate over 1yr. • Univariate analysis demonstrated relationship between age, ethnicity, proxies of nutritional status, albumin, diabetes mellitus status and creatinine with mortality.
MVA	• Unclear MVA method – but included covariates of age, ethnicity, DM(diabetes mellitus), gender, vintage, albumin, creatinine, HbA1c, ferritin and phase angle. • Vector length independently predicted risk of mortality
Strengths	• Large number of endpoints.
Weaknesses	• Unclear characterisation of endpoints. • Unclear MVA analysis method. • Dubious linkage in MVA between PA and BIVA vector length (mathematical relationship) • Unclear description of the population.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)					
SP	SA	PFM	OM	SC	SAR

1928

Objective	To determine primarily the role of residual renal function in predicting the survival of PD patients. Secondary outcome was to determine role of bio-impedance markers and RRF on predicting mortality.
Sampling	129 PD patients, from multiple centres (x2) in Korea. Mean age 49.7years, 62.1% male, 48.5% diabetic, 100% of patients were hypertensive. Overall residual renal function – 660.05ml/day. Excluded patients with anuria, amputations, pacemakers and in those whom BIA could not be measured.
Design	• Retrospective study. • Follow up (retrospective) 25.47years. • BIA – single measurement, in the past (post-dialysate drainage).
Results	• 11.6% of patients died during follow up period. • Stratified into ECW/TBW < 0.39 + ECW/TBW > 0.39; most groups had no significant differences in chosen baseline variables (except albumin). • In Kaplan Meier survival analysis (adjusted) – survival superior in ECW/TBW < 0.36 compared with ECW/TBW > 0.36 group.
MVA	• Cox analysis, adjusted for age, gender, DM, peritonitis rate, albumin, BUN, creatinine, initial UO, initial Kt/V, initial ECW/TBW. • ECW/TBW independent predictor of mortality, as is albumin. Initial UO however is not.
Strengths	• Includes RRF in MVA.
Weaknesses	• This is a retrospective study. • Low number of endpoints for the analysis undertaken. • Limited generalisability as excludes anuric patients.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

1994

Objective	To develop and validate methods for quantifying degree of fluid accumulation in acute decompensated heart failure (ADHF) patients, using methods such as BIA.
Sampling	130 patients admitted to a tertiary centre with a confirmed diagnosis of acute decompensated heart failure in Osaka, Japan. Controls (n = 60) selected as age / sex matched emergency admissions with no evidence of heart failure. Age was 75 / 74 years, the number of patients who were diabetic was 20% and 48% and the admission serum creatinine was 0.91 / 1.24mg/dl for the control / ADHF groups respectively. Exclusion criteria included development of cardiogenic shock, admission SBP < 90mmHg, admission creatinine > 3mg/dl and those who died during the admission.
Design	• Prospective observational study. • BIA measure obtained on admission and at discharge (expressed M/P ratio for ECW). • Clinical response measured throughout admission to therapy – BNP / IVC diameter / echocardiographic data. • Follow up for 6 months.
Results	• Of those admitted, 6.2% were intubated, 6.2% required NIPPV, 35.4% had IV infusion of furosemide, 6.9% had GTN infusion, 23.8% had dobutamine and 12.3% had milrinone. • In follow up period, 37% events noted – 35 of these were admissions for acute heart failure and 2 were cases of sudden death. • On Kaplan-Meier analysis, M/P ECW > 1 at discharge significantly associated with 6-month event rate (HR 5.28, 95%CI 2.2-12.6, p < 0.001). • Univariate predictors of ADHF readmission and cardiac death included prior admission for ADHF, eGFR, BNP, IVC diameter, iVC respiratory change and M/P ECW.
MVA	• Cox analysis of variables at discharge which predict 6 month event. • Prior ADHF admission and M/P ECW > 1.0 predictive of event, independent of other factors.
Strengths	• MVA of predictors of outcome provided. • Clear inclusion and exclusion criteria. • Treatments given allows us to gauge severity of HF presenting in study.
Weaknesses	• Could have included deaths in hospital*

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

2055+2056

Objective	To determine the prognostic effect of markers of malnutrition on a dialysis population in Romania.
Sampling	2055 and 2056 are from the same cohort of Romanian HD patients (single centre, Dr CI Pahon University Hospital) – 2056 having a longer follow up. In total, from the final 2056 cohort, there were 149 prevalent HD patients included, of which 55% were male, the mean age was 55.1years, 14.77% were diabetic and 15.44% had heart failure. Exclusion criteria included recent acute illness, recent major cardiovascular event, recent major surgery, CRP > 6 and refusal to participate. Prevalent cohort in 2006 for both studies; 2056 had longer follow up (see below).
Design	• Prospective observational study. • Follow up 13.5months in 2055, 63 months in 2056. • Post HD BIA used in each study.
Results	• 7.4% death rate during follow up in 2055, 28.85% death rate in 2056. • In final analysis (from paper 2056) - Age > 65 / DM / HF / dialysis vintage > 2years associated with reduced survival. • In Kaplan Meier analysis, BMI / SGA / nPNA / PA < 5.58 all predicted mortality.
MVA	• Cox MVA adjusted for age, vintage, gender, DM, HF, BMI > 25, numerous nutritional indices (x6), Albumin and PA<5.58°. • PA < 5.58° was an independent predictor of mortality (RR 2.15, 95%CI 1.16,3.99, p = 0.014).
Strengths	• Adjusted for common covariates.
Weaknesses	• Post HD BIA. • Did not state causes of death in outcome analysis.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)					
SP	SA	PFM	OM	SC	SAR

2178 +2179

Objective	To determine the prognostic value of extravascular lung water (derived from lung ultrasound) / echocardiographic combined with bioimpedance spectroscopy in determining survival in HD patients.
Sampling	From final cohort (study 2179), 173 HD patients from a single secondary care centre (Dr CI Pahon University Hospital) in Romania. Of this cohort, the mean age was 57.9 years, the mean dialysis vintage was 48.9 months, 49.1% were male and 20.8% were diabetic. Patients with amputations, decompensated cirrhosis, cardiac pacemakers / stents and those without informed consent were excluded. Recruitment period May 2011-October 2012 for both studies.
Design	• Prospective observational study. • Median follow up time 21.3 months (for study 2179). • Pre-dialysis BIA measured, post dialysis echocardiographic evidence and lung ultrasound was performed. BIA expressed as relative fluid overload (RFO).
Results	• 31 deaths (17.9%) during total follow up period. • Significant differences in diabetic status, DBP and NHYA classification between survivors and non-survivors on Univariate analysis. • Additionally, on Univariate analysis, no significant differences were noted between survivors and non survivors with respect to US-B line scores, whereas significant differences noted in RFO (relative fluid overload) and echocardiographic data (specifically left atrial dimensions).
MVA	• Cox model, adjusted for NHYA severity, diabetes, CRP levels and LVMI. • Using two separate analyses, Ultrasound Lung comet scores (>22 compared with ≤ 22, HR 2.72, 95%CI 1.19-6.16,) and RFO (>6.68L compared with ≤6.68L, HR 2.93, 95%CI 1.30-6.58) were significant independent predictors of all cause mortality. • Of note, in 2178, Hyperhydration was not a significant predictor of mortality – however this was an earlier study from the same cohort (only 13 patients died in this study).
Strengths	• Compares different fluid balance assessment modalities.
Weaknesses	• Does not characterise endpoints according to aetiology. • Does not specify attrition endpoints (r.e. number of transplants / transfers etc) • Small number of endpoints for large covariate number in MVA • Heterogeneity of definition regarding measurement time (echocardiography was post dialysis / BIA was pre dialysis)

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

2546

Objective	To investigate and quantify a possible link between hydration state and risk of death in chronic HD patients.
Sampling	269 HD patients from a secondary care centre in Poland. Mean age was 65, 28% were diabetics, 35% had CVD, average vintage was 41.2 months. Patients with amputations and pacemakers were excluded.
Design	• Prospective observational study. • Pre dialysis BIA measured and stratified into hyperhydrated groups (58 patients) and normohydrated (211 patients) groups (defined as OH >15%). • Follow up period was 3.5 years.
Results	• There were ?86 endpoints with an overall mortality of 32%. 41% of the hyperhydrated group died, while 30 % of the normohydrated group died. • There were significant differences between the two groups in BMI, vintage post dialysis bp and relative fat %. • Survival benefit of normohydration group shown in kaplan meier survival analysis.
MVA	• Cox analysis adjusted for age, gender, diabetes, CVD conditions, peripheral vascular disease, vintage, BP, albumin, haematocrit, pth, phosphate, creatinine kt/v. • Overhydration >15% demonstrated as significant predictor of mortality in HD patients (HR=2.102, 90%CI 1.389,3.179, P=0.003).
Strengths	• Adjusted for a large number of covariates. • Good description of baseline characteristics.
Weaknesses	• Does not describe primary renal disease • Unclear number of endpoints as gives percentage mortality. • Unclear significance of Kaplan Meier analysis.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

2703

Objective	To evaluate the use of BIA measurements in HD patients for predicting outcomes.
Sampling	344 HD patients from a single centre in Korea. 252 patients were grouped into an initial overhydrated group and initial normohydration group. Then 240 patients were selected on the basis of age and gender matching to be included into the study, the mean age was 65.6 and 65.7 and 28.1% and 33.8% had cardiovascular disease for the initial overhydrated group and initial normohydration group respectively.
Design	• Prospective observational study. • Post dialysis BIA measured and stratified into groups, overhydration defined as OH/ECW >15% on BIA measurements. When BIA measurement was delayed (i.e. greater than 1 day post HD), body weight adjusted for dry weight to estimate overhydration index (accounting for ECW rises post HD). • Median follow up 24 months. • Dry weight and presence of peripheral oedema significant differences between groups.
Results	• 43 patients in the overhydration group and 7 patients form the normohydrated groups died. • Most common causes of death included infection (13), CVD (6), malignancy (5), cerebral vascular disease (2) and other (4). • Overhydrated patients had significantly increased risk of death on Kaplan-Meier survival analysis HR=4.768 95%CI 1.841, 12.351 p=0.023. • There was no significant difference in all cause admission between the two groups or for disease specific admission.
MVA	• Cox analysis adjusting for age, gender, diabetes, cardiovascular disease, cerebral vascular disease, albumin, haematocrit, PTH (parathyroid hormone), phosphate and creatinine showed that only age and overhydration were significant predictors of mortality.
Strengths	• Number of variables significantly different in a selected cohort.
Weaknesses	• Low numbers of endpoints for MVA • Don't include numbers of diabetics.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

2704

Objective	To evaluate how BIA analysis can predict mortality in MHD patients.
Sampling	697 HD patients, from 34 dialysis (NephroCare) centres in Portugal. Median age 67years, 43.5% were female, 35.6% were diabetic. Doesn't state exclusion criteria.
Design	• Prospective observational study. • HD provided was all high flux, three times weekly. • BIA (OH/ECW) before midweek HD session. OH/ECW was directly derived from BIA machine (Fresenius BCM). • Follow up of 1 year.
Results	• 66 patients died during follow up, 23 were transplanted and 15 were transferred to another centre. • Comparing the "dead" and "alive" patient groups, significant between group differences were found age, diabetic status, dry weight, albumin levels, BMI and bioimpedance parameters. • Kaplan Meir survival analysis showed cumulative survival in patients with OH/ECW>15% was significantly less than <15% (Log Rank 11.44, p<0.001).
MVA	• Cox proportional hazards model for mortality; transplanted and transferred patients were censored. • Adjusted for age, gender, vintage, DM, BMI (x2 groups), Albumin, OH/ECW>15% and Low FTI. • OH/ECW>15% independent predictor of mortality in this cohort.
Strengths	• Large cohort, with clear delineation of attrition. • Adds known confounders to the MVA.
Weaknesses	• Unclear endpoint aetiology. • Unclear reference range for BCM data.

QUIPS (Prognostic study methodological assessment) – Green (low risk of bias) / Yellow (moderate) / Red (high)

SP	SA	PFM	OM	SC	SAR

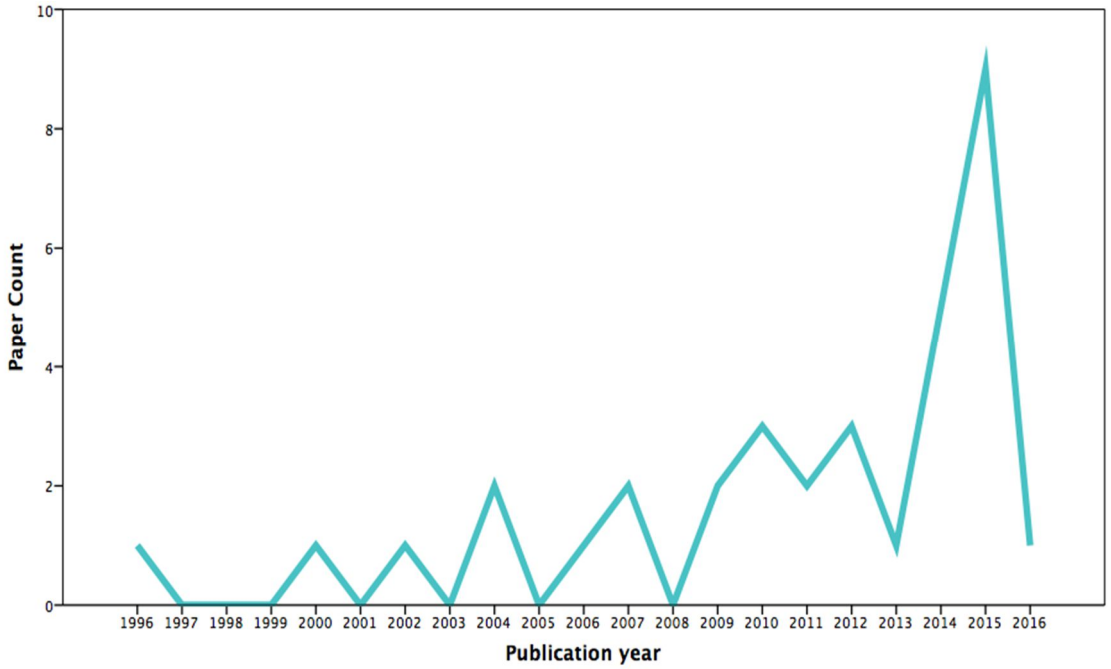
Timeline of included studies.

There are a fairly large number of studies in the literature that help to answer our research question. There also appears to be a significant increase in the number of studies published addressing this question over recent years. With 15 papers in the last 3 calendar years compared to 7 pre-2009 (figure 4.3 and 4.4).

Figure 4.3 - Tabular representation of year of published papers included in study

Numbers of studies	
2016	1
2015	9
2014	5
2013	1
2012	3
2011	2
2010	3
2009	2
<2009	7

figure 4.4 - Graphical representation of year of published papers included in study.



Risk assessment of bias in included studies.

A number of the studies we have determined are fairly high risk of bias as they include at least one domain with a high risk of bias. However, with the exception of a few studies the trend in quality of the research appears to be improving since 2009, with more studies only having low or moderate only risk of bias (figure 4.5).

Figure 4.5 - tabular representation of assessment of bias of papers included in study ordered by recency.

Paper ID	Year of publication	N	QUIPS criteria / domain (Red = high risk of bias / Yellow = moderate risk / Green = Low risk)					
			SP	SA	PFM	OM	SC	SAR
2704	2016	1						
946+948	2015	9						
1021								
1527								
1745								
1814								
1928								
1994								
2179+2178								
2703								
194	2014	5						
195								
1692								
1742			Randomised Controlled Trial (RCT) – QUIPS not validated					
2056+2055								
574	2013	1						
371	2012	3						
401								
486								
10	2011	2						
1230								
140+766	2010	3						
670								
1777								
790	2009	2						
2546								
370	2007	2						
407								
141	2006	1						
635	2004	2						
1860								
768	2002	1						
422	2000	1						
1459	1996	1						

Note: Combined studies are amalgamated for purposes of QUIPS – publication date is based on the most recent study.

Discussion

This work demonstrates a strong narrative that bioimpedance defined overhydration is an independent predictor of mortality in end stage renal disease. As shown earlier there has been an increasing trend in the numbers of papers that have shown that this is the case.

We have found a wide range of variables that studies adjusted for across the different studies in their multivariate analysis. This shows that there are unlikely to be any confounding factors and that bioimpedance defined overhydration is likely to be a true independent risk factor of mortality even when studies adjusted for a large number of co-morbidities or a co-morbidity index. For example, 6 studies adjusted for a co-morbidity index and all found that BIA was an independent predictor of mortality. Other studies decided to adjust for range of known factors that affect mortality, common co-morbidities in the population and other potential markers of prognosis or disease burden. The factors that each study adjusted for in each multivariate analysis are summarised in the table in appendix 3

Importantly co-morbidities adjusted for include markers of nutrition including BMI and subjective global assessment, this demonstrates that bioimpedance defined overhydrataion is likely to be an independent factor and not a surrogate marker of lean body mass wasting.

Our subsequent published paper from this study has further expanded on this work - providing a more up to date literature search and also a sub-group meta-analysis. (89) This has clearly confirmed the narrative this work has also tried to demonstrate with the meta-analysis. It shows that bioimpedance is an independent risk factor when included with a number of co-morbidities including nutritional markers.

There are a number of strengths to our research from the use of independent reviewers for study selection and bias risk assessment. The structured and systematic way studies were identified and the selection of a common and frequently used tool to assess the studies for bias. However, our research also has some limitations.

There are a large number of different indices used to express overhydration defined by bioimpedance. This makes it extremely difficult to compare results of each study to see if similar outcomes are found. It also makes it more difficult to perform meta-analysis of the data - due to the limited amount of homogenous data, which as mentioned earlier was performed at a later date. However, from the perspective of this review there are also positives to be found as bioimpedance is shown to be an independent predictor in almost all studies despite the use of different indices of measurement.

It should be noted that there are a number of arguments that could be put forward with regards to which measure of BIA should be used, however there appears to be no consensus in the scientific community with regards to which to use. There also appears to be very little justification behind the choice of measure that authors are using in their study and in most cases it appears to be personal preference. It does appear however that traditionally Phase angle has been the most popular measure, however overhydration indices are becoming increasingly popular (Figure 5.1)

Figure 5.1 Bioimpedance measurement methods

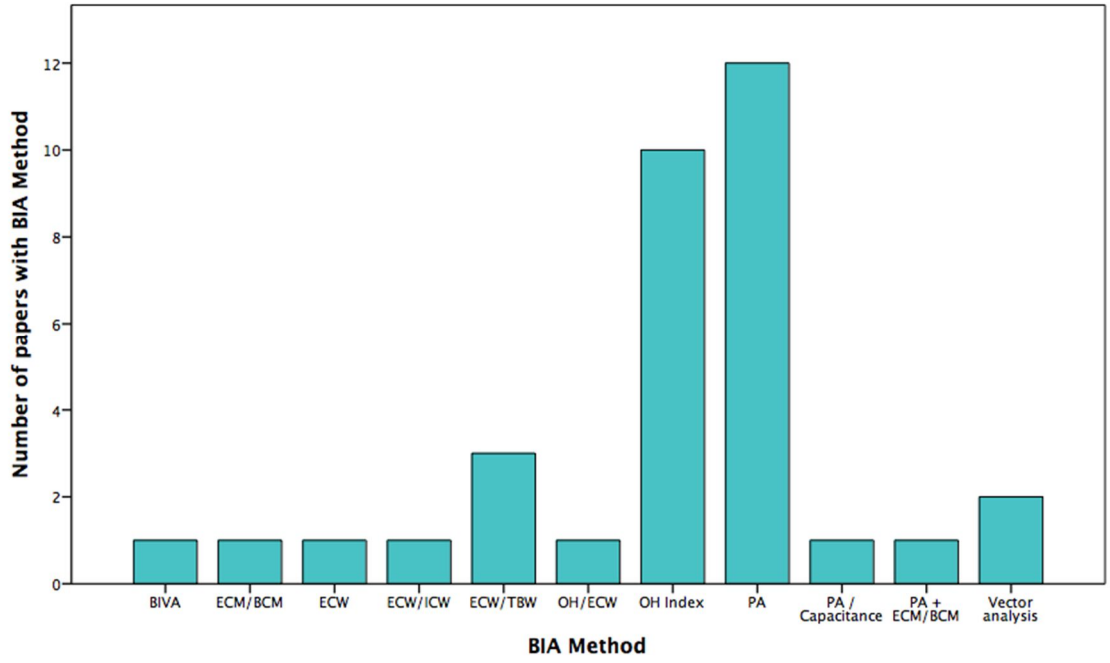


Figure 5.1 Graphical representation of bioimpedance measurement indices used in included studies.

Other limitations of our study include the risk of bias in our included studies. We feel that we have been very thorough in our quality appraisal of each study. We found a number of studies with a high risk of bias in at least one domain. While it is reassuring that the overall outcomes of each study appear to reaffirm the same conclusion, In fact the only study that did not support that BIA is an independent predictor of Mortality was study 422, which was not answering our research question directly and despite this study having a large sample we also felt that in two domains it was high risk in terms of bias.

However, there are common themes identified in the studies risk assessment for bias that cloud the overall generalisability of the results such as lack of transparency in information about their cohorts demographics and/or co-morbidities (10, 422,768,790,946, 1454, 1527, 1860).

The study also looked into HF cohorts and tried to answer if again bioimpedance defined overhydration was an independent risk factor for mortality in this patient group. The evidence for this hypothesis is a lot weaker, with only 5 studies identified which show this. However, of note study 370 is of a higher risk of bias and study 370+ 670 performed no multivariate analysis.

The other outcome that we were trying to show also was the effect on hospitalisation however there appears to be too little research done into this area to make a strong conclusion with only study 195 addressing this question for renal patients. 1745 in heart failure patients with a multivariate analysis and 790 in a univariate analysis. However, this evidence does point that this is likely to be the case when considering the increased mortality shown in this research.

Overall, there appears to be a large number of studies that determine that BIA is an independent predictor of mortality in renal failure. These appear variable in quality however are

largely very supportive of this conclusion. Unfortunately, due to the heterogeneity of the studies in terms of BIA measurement indices and variations in multivariate analysis design it was difficult to develop a meta-analysis of the data at that stage. There appears to be less strong but nevertheless suggestive evidence for heart failure the finding would be replicated and this could possibly be true for other conditions where fluid accumulation is prevalent.

With regards to moving forwards with this area of research, there appears to be a growing trend in the research whereby BIA is being used as an interventional tool to guide management of patients and whether this improves outcomes in clinical practice. This seems to be a natural evolution of the research if we conclude that BIA defined fluid overload is an independent predictor of mortality.

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Appendix 2 – Studies considered for systematic review

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Appendix 3 – Summary table of co-variates used in multivariate analysis by each identified study

Number	Co-variates selected																											
	age	ethnicity	gender	BMI	Dialysis modality	Dialysis vintage	DM	CVD	comorbidity	cholesterol	CRP	HIV	Renal failure	NYHA class	BP	EF	ECHO	BNP	troponin	HBA	KT/V	albumin	phosphate	D/p c r	Nutritional markers	RRF	BIA	Hospital stay
10	Y		Y						Y																			
141	Y	Y	Y				Y																					
194	Y					Y	Y	Y																				
195	Y		Y			Y	Y		Y												Y					Y		
370	N/A	N/	N/A	N/	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
371	Y												Y	Y		Y						Y						
401	Y		Y			Y	Y															Y						
407			Y						Y												Y	Y			Y		Y	
422	Y	Y	Y				Y			Y										Y	Y	Y					Y	
486	Y						Y													Y								
574	Y				Y						Y				Y													
635									Y											Y		Y					Y	Y
670	N/A	N/	N/A	N/	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
140	Y	Y	Y			Y	Y					Y															Y	
766	Y	Y	Y			Y	Y					Y															Y	
768	N/A	N/	N/A	N/	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
790	Y		Y			Y	Y																					
946 +948	Y		Y				Y		Y		Y				Y						Y	Y		Y			Y	
1021							Y			Y						Y						Y					Y	
1230	Y		Y			Y	Y								Y						Y	Y	Y				Y	
1459	Y																								Y		Y	
1527				Y																					Y			
1692	Y	Y	Y			Y	Y		Y		Y											Y						
1742	Y		Y	Y		Y	Y	Y																				
1745	Y		Y			Y	Y	Y							Y	Y												
1777	Y		Y		Y	Y	Y				Y							Y	Y			Y					Y	
1814	Y	Y	Y			Y	Y																		Y		Y	
1860	Y	Y	Y			Y	Y													Y		Y					Y	
1928	Y		Y				Y														Y	Y					Y	
1994	Y															Y		Y			Y						Y	
2055+2056	Y		Y	Y		Y	Y															Y			Y		Y	
2178	Y					Y					Y					Y	Y					Y					Y	
2179							Y				Y			Y			Y											
2546	Y	Y	Y			Y	Y	Y							Y						Y	Y	Y					
2703	Y		Y				Y	Y														Y	Y					
2704	Y		Y			Y	Y															Y			Y		Y	

Index of abbreviations for appendix 3 : BMI = body mass index, DM = diabetes mellitus, CVD = cardiovascular disease, comorbidity = validated scores of comorbidity, CRP = C reactive protein, HIV = Human immunodeficiency virus infection, NYHA class = New York heart association class, BP = Blood pressure, EF = ejection fraction, ECHO = echocardiographical measurements other than ejection fraction, BNP = brain naturietic peptide, HBA = glycated haemoglobin levels, KT/v = standardised measure of dialysis, D/pcr = dialysate to plasma creatinine ratio, nutritional markers = biochemical or non-biochemical validated methods of measuring nutrition, RRF = modality of renal replacement therapy other than non-specified haemodialsysis or peritoneal dialysis, BIA = other bioimpedance measurements other than a representation of over hydration, hospital stay = duration spent in hospital.