SYSTEMATIC FLUID ASSESSMENT IN HAEMODIALYSIS: DEVELOPMENT AND VALIDATION OF A DECISION AID

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SUMMARY

Background: About a third of patients undergoing haemodialysis have poorly controlled fluid status, which may affect survival. Clinical assessment is subjective and imprecise, which has led to the increasing use of devices based on bioimpedance spectroscopy (BIS). However, BIS cannot provide a simple target applicable to all patients. Our aim was to develop and validate a decision aid combining clinical assessment of fluid status with information from BIS in target weight determination.

Methods: The decision aid was based on empirical experience and a literature review identifying physiological parameters already used in the clinical assessment of fluid status. Content validity was established by patient representatives, interdisciplinary stakeholders and external experts, who assessed item relevance and comprehensiveness. Reliability was assessed by inter-rater agreement analysis between nurses assessing typical patient cases.

Results: The decision aid for Recognition and Correction of Volume Alterations (RECOVA) consists of three parts (1) a scoring system; (2) thresholds and triggers; (3) a decision aid algorithm. Agreement between raters in the assessment of symptoms was almost perfect, with Intraclass Correlation Coefficient > 0.90. Agreement in clinical response was only fair, but increased to moderate, with training and self-reported confidence.

Conclusion: RECOVA may enable systematic clinical assessment of fluid status, facilitating early recognition of fluid alterations, and incorporation of bioimpedance into target weight management. However, implementation into clinical practice will require training of staff. Clinical intervention studies are required to evaluate if RECOVA facilitates response to and correction of recognised fluid alterations.

KEY WORDS Bioimpedance • Fluid management • Haemodialysis • Overhydration • Validation

BIODATA

Jenny Stenberg *is a registered nurse working in the haemodialysis unit of Uppsala University Hospital, who is in her last year of a PhD study at Uppsala University. Her interest lies in improving the health outcomes for patients with chronic kidney disease, with focus on fluid management, and her PhD project investigates methods for fluid management and the usefulness of bioimpedance spectroscopy in dry weight determination.*

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INTRODUCTION

Overhydration is a risk factor for mortality and morbidity in haemodialysis patients (Zoccali *et al.* 2017), but fluid depletion is also a risk factor, associated with reduced quality of life and end-organ injury, including myocardial stunning and loss of residual renal function (Assimon *et al.* 2016; Chou *et al.* 2017; van der Sande *et al.* 2018). About a third of patients have poorly controlled fluid status (Moissl *et al.* 2013) and even minor deviations from normal fluid status may affect survival (Dekker & Kooman 2018).

Current fluid management in haemodialysis is mainly based on clinical assessment, such as weight gain between dialysis sessions, pre- and post-dialysis blood pressure (BP) and patient-reported symptoms (Lindley *et al.* 2011; Chou & Kalantar-Zadeh 2017). However, it is not always straightforward. For example, large inter-dialytic weight gains (IDWG) require higher ultrafiltration rates (UFR) to achieve target weight within fixed haemodialysis treatment times, but when UFR exceeds capillary refilling rate, a rapid reduction in intravascular volume results in intradialytic hypotension (IDH), even if extracellular volume is normal or increased (Flythe *et al.* 2013).

Since clinical assessment of fluid status is subjective and imprecise there is increasing use of devices based on bioimpedance spectroscopy (BIS) technology (Stenberg *et al.* 2016; Ekinci *et al.* 2018). Evidence of the impact of BIS-guided fluid management on survival is still lacking (Covic *et al.* 2017) and one limitation of the current adoption of this technology is the use of it in isolation rather than as a part of clinical assessment. It is important to recognise BIS is adding information to an already complex decision-making process, rather than providing a simple target applicable to all patients (Scotland *et al.* 2018; Tabinor & Davies 2018). Clinical guidelines for target weight determination are lacking (Hecking *et al.* 2015; Dasgupta *et al.* 2016), and there is a need for the development of a decision aid that helps clinicians incorporate the information from BIS when setting target weights (Weiner *et al.* 2014; Tabinor & Davies 2018).

It has been recognised that the clinical response to acutely ill patients could be substantially improved by the routine embedding of simple early warning systems, i.e. the New early warning systems (NEWS), which is based on two key requirements: (i) a systematic method to measure and record simple physiological parameters in all patients, to allow early recognition of those presenting with acute illness or who are deteriorating, (ii) a clear definition of the appropriate urgency and scale of the clinical response required, tailored to the level of acute-illness severity (Royal College of Physicians 2017).

Our aim was to develop and validate a decision aid which, in similarity to the NEWS, standardises the process of recording, scoring and responding to changes in routinely measured physiological parameters. The purpose is to allow early recognition and response to fluid status alterations in haemodialysis patients by combining clinical assessment of fluid status with information from BIS in target weight determination.

METHODS AND MATERIALS

Ethical approval to conduct the study was obtained from the Swedish Ethical Review Authority (Dnr: 2019-00011). The study complied with the Declaration of Helsinki, and informed consent was obtained from all study participants.

DEVELOPMENT OF THE DECISION AID

A core group made up of nurses and physicians conducted a series of meetings to develop the decision aid, which was based on empirical experience and a literature review identifying and appraising physiological parameters routinely measured in haemodialysis care for assessment of fluid status (Wizemann & Schilling 1995; Kraemer 2006; Lindley *et al.* 2011; Chou & Kalantar-Zadeh 2017). For review and evaluation of the content and comprehensiveness, the tool was then circulated to a larger group of interdisciplinary stakeholders, and experts in the use of BIS, including clinical scientists, dieticians, physiotherapists and physicians, and also to patients' representatives. This face-validity process eventually led to an updated version of the draft tool.

TESTING OF THE DECISION AID

In order to test the reliability of the tool we subsequently constructed four fictional patient cases with a range of clinical presentations and BIS results that could be observed in a typical HD unit (Supplementary Material 1). Haemodialysis nurses were recruited to test the decision aid by scoring the cases' symptoms and suggesting clinical response—choosing one of four options in the decision aid algorithm. All nurses assessed the same four cases individually and responded via a multiple-choice

Scoring system and Thresholds and triggers
1. What is Elsa's total symptom score?
2. What is the appropriate response to Elsa's symptom score according to the Thresholds and triggers?
3. Does Elsa mainly have symptoms of hypovolemia or of hypervolemia according to the symptom score?
Decision aid algorithm
1. Which direction (A, B, C or D) in the Decision Aid algorithm should you choose from the occurrence of symptoms and BCM measurement?
2. What is the suggested goal (1, 2, 3, 4, 5 or 6) if you follow the decision aid algorithm?
3. Elsa's prescribed dry weight is currently 70.5 kg. What would be a reasonable dry weight goal for Elsa according to RECOVA?

Table 1: Main questions of the reliability test, linked to Case # 1. All answers were multiple-choice.

questionnaire (Supplementary Material 1), main questions presented in Table 1. Then the nurses' agreement was measured with inter-rater reliability (IRR) analysis. The nurses were also asked to rate their perceived confidence in using BIS in fluid management, on a 6-graded (0-5) Likert-scale. The data from confident raters (rating 5) and less confident raters (rating 0-4) were analysed as separate groups. After a pilot test with five nurses, the questionnaire was slightly revised for clarity and 30 minutes of training was added to the introduction of the tool.

Existing professional networks were used to address managers of three haemodialysis units across Sweden and four British haemodialysis (main and satellite) units belonging to one main renal unit, and the managers were asked to recruit haemodialysis nurses to participate in the study. Prior to enrolment, the nurses received written information about the purpose of the study and that participation was voluntary. The first author introduced the tool to the Swedish study participants by visiting the dialysis units: one university unit treating approximately 140 patients, one county unit (45 patients) and one satellite unit (20 patients). In the UK the decision aid was introduced by the second author. The British nurses represented one home haemodialysis unit (23 patients) and three satellite units (40, 40 and 78 patients respectively).

STATISTICAL ANALYSIS

IBM SPSS Statistics Version 25 was used for statistical analyses. IRR was assessed using a two-way random, consistency, average-measures Intraclass Correlation Coefficient (ICC) (Landers 2015) to assess the degree that coders provided consistency in their ratings of symptom score across subjects. Fleiss' κ was used for assessment of multiple raters of discrete variables (Miles & Huckabee 2013), i.e. the nurses' choice of clinical response. Agreement was categorised as poor (<0), slight (0.00–0.20), fair (0.21–0.40), moderate (0.41–0.60), substantial (0.61–0.80) or almost perfect (0.81–1.00) (Landis & Koch 1977). Values are presented with 95% confidence interval (CI).

RESULTS

The decision aid was named the Recognition and Correction of Volume Alterations (RECOVA) tool and consist of three parts:

1. A symptom scoring system, Figure 1.
2. Thresholds and triggers for action, Figure 2.
3. A decision aid algorithm, Figure 3.

SYMPTOM SCORING SYSTEM

The scoring system for assessment of fluid status was based on physiological parameters routinely measured in haemodialysis care. In the content-validation process, consensus was reached upon the inclusion of seven parameters: dyspnoea at rest, pretibial oedema, symptoms of fluid overload between dialysis sessions, BP increase, muscle cramps (calf), symptomatic IDH, and symptoms of fluid depletion between dialysis sessions (Figure 1). The rationale for inclusion and cut-off values were verified in a review of published literature, detailed in the discussions section.

THRESHOLDS AND TRIGGERS

The RECOVA tool also incorporates triggers for target weight evaluation (Figure 2). The Thresholds and Triggers component is based on the patient's total symptom score, i.e. the sum of fluid depletion symptoms (left side of the scoring system) and fluid overload symptoms (right side). The total score gives suggestions for response and continued treatment.

DECISION AID ALGORITHM

The decision aid was constructed as an algorithm based on two primary assessments: (i) predominant symptoms according to the symptom score system and (ii) fluid status according to BIS. The algorithm is hence based on four possible scenarios (Figure 3):

Direction A. Symptoms of fluid overload, *but* BIS measured overhydration will be below or equal to 0 after planned ultrafiltration (Fictional Case 3)

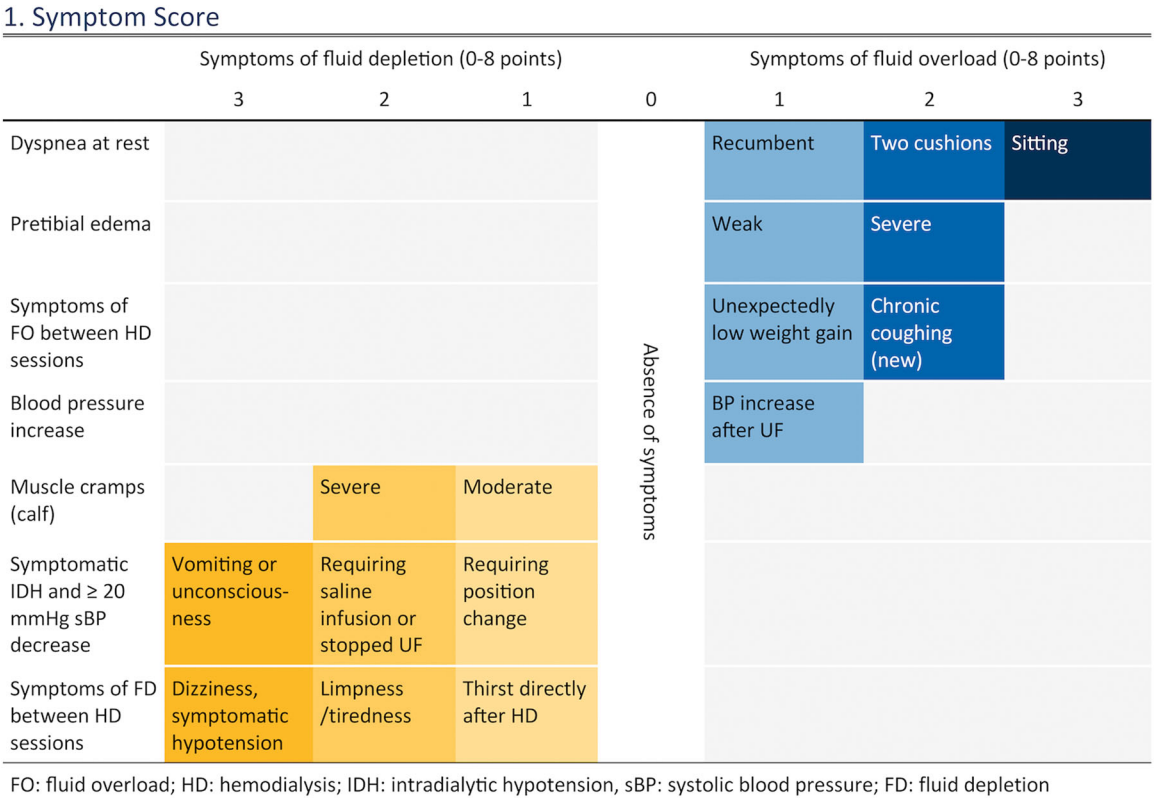


Figure 1: The scoring system, for detection and assessment of clinical symptoms of altered hydration status. Symptom Score can generate between 0 and 16 points. If several symptoms occur within a parameter, the symptoms that generate the highest score should be selected [Color figure can be viewed at wileyonlinelibrary.com]

Direction B. Symptoms of fluid overload, *and* BIS measured overhydration will remain after planned ultrafiltration (Fictional Case 1)

Direction C. Symptoms of fluid depletion or absence of symptoms, *but* BIS measured overhydration will remain after planned ultrafiltration (Fictional Case 2)

Direction D. Symptoms of fluid depletion, *and* BIS measured overhydration will be below or equal to 0 after planned ultrafiltration (Fictional Case 4)

Depending on which criteria are fulfilled, the caregiver is directed along different paths in the decision aid algorithm leading to different target weights to aim for. Correction of target weight is advised to be altered slowly, with 0.5–1 kg per week and attention is paid to the preservation of residual renal function. If clinical assessment and BIS-measurement are contradictory, the caregiver is advised to consider if there are patient-related barriers for adopting the BIS-reading, as specified in directions A and C. The advice is then to aim for either a target weight slightly lower or higher than normohydration according to BIS. If none of the conditions apply the caregiver is advised to consider possible treatment-related causes of symptoms, e.g. dosing and timing of antihypertensive agents and UFR.

VALIDATION

Nineteen nurses tested decision aid. However, one questionnaire was not complete and was hence excluded from IRR analysis. Ten nurses rated themselves confident in using the BIS and eight nurses rated themselves less-confident. All confident raters had more than five years' experience from haemodialysis care and had performed more than 20 BIS measurements, Table 2.

The degree that confident raters provided consistency in their ratings of symptoms across subjects was ICC = 0.96 (CI: 0.87–1.0) indicating almost perfect agreement. Table 3 shows

2. Thresholds and triggers

SVS Score	Response	Action
0	Evaluation of target weight (DW) every second week	Bioimpedance measurement 2 – 4 times/year for assessment of hydration status and nutritional status
1 – 4	Target weight should be questioned	Inform registered nurse, who must assess the patient, and decide whether initiation of DW change is required or if symptoms may be explained by other known conditions (such as heart failure or advanced chronic obstructive pulmonary disease). Perform Bioimpedance measurement and evaluate according to decision aid. Repeat measurement at three occasions or until target weight is achieved.
5-6 or 3 in a single parameter	Target weight should be adjusted	Inform clinician for assessment. Perform Bioimpedance measurement without delay and evaluate according to decision aid. Repeat on three occasions or until achievement of target weight goal.
7 or more	Immediate need for evaluation of hydration status and target weight adjustment	Registered nurse to immediately inform the clinician

Figure 2: The thresholds and triggers for action, a simple track-and-trigger system guiding the caregiver in deciding when and how to respond to the clinical symptoms. It is based on the patient's total symptom score, i.e. the sum of symptoms of both fluid depletion and hypervolemia [Color figure can be viewed at wileyonlinelibrary.com]

the overall percentage agreement in suggested clinical response was 75% (range 60–100%). In the patient cases where symptoms and fluid status according to BIS were consistent (case 1 and case 4) the confident raters were consistent in suggested clinical response 90% and 100% respectively. However, in cases where symptoms and BIS readings were inconsistent (case 2 and case 3) the overall agreement was only 60%. The overall mean κ value for IRR was $\kappa = 0.53$ (CI: 0.46–0.61), indicating moderate agreement above chance.

	Total (n = 18)	Confident raters (n = 10)	Less confident raters (n = 8)
Years of experience in haemodialysis			
0–1	2	0	2
1–5	1	0	1
5–20	11	6	5
>20	4	4	0
Number of performed BIS measurements			
<5	3	0	3
5–20	0	0	0
>20	15	10	5
Self-reported confidence in use of BIS			
2	1	0	1
3	4	0	4
4	4	0	3
5	10	10	0

Table 2: Descriptive statistics of nurses participating in inter-rater reliability test

The degree that less confident raters provided consistency in their ratings of symptoms across subjects was ICC = 0.95 (CI: 0.82–1.0), again indicating almost perfect agreement. The overall percentage agreement in suggested clinical response for less confident raters was 56% (range 44–67%) (Table 3). In this group, there was no difference in agreement depending on if the cases' symptoms and the BIS reading was consistent or not, and the overall mean κ value for IRR was only $\kappa = 0.26$ (CI: 0.17–0.36), indicating fair agreement above chance.

DISCUSSION

Achieving optimal management of fluid status is a key objective in haemodialysis. To the best of our knowledge RECOVA is the first tool that aims to systematically combine clinical assessment of fluid status and BIS-measured overhydration, to guide fluid management in haemodialysis. Content validity was established by patient representatives, interdisciplinary stakeholders and external experts. Reliability was assessed by inter-rater agreement analysis.

			Confident raters (n = 10)					Less confident raters (n = 9)				
	Symp	BIS	A	B	C	D	% agreement	A	B	C	D	% agreement
Case 1	FO	OH	1	9	0	0	90	3	5	1	0	56
Case 2	FD	OH	1	0	6	3	60	0	2	6	1	67
Case 3	FO	NH	6	3	0	1	60	4	5	0	0	44
Case 4	FD	UH	0	0	0	10	100	0	1	2	5	56
Mean agreement							75					56

Table 3: Raw agreement data in the analysis of the application of the decision aid algorithm. Letter A–D corresponds to a direction in the decision aid algorithm. Expected answers are highlighted.

BIS: bioimpedance spectroscopy, FD: Fluid depletion, FO: fluid overload, NH: normal hydration, OH: overhydration, UH: underhydration; Symp: symptoms.

SYMPTOM SCORING SYSTEM

For this tool to work in diverse haemodialysis care settings, it must be simple to implement. RECOVA was therefore based on seven physiological parameters already used in the clinical assessment of fluid status (Figure 1). However, clinical assessment of fluid status is not always straightforward. For example, oedema is independently linked to left ventricular hypertrophy and indirectly to systolic hypertension and widened pulse pressure (Agarwal *et al.* 2008) while dyspnoea is associated with pulmonary congestion and IDWG (Elsayed & Stack 2015). Still, many patients with fluid overload do not show obvious signs of oedema or breathing difficulties, while chest infections or anaemia can cause breathlessness to complicating their use as markers of fluid overload. There is an association between IDWG and fluid overload, but conversely, unexpectedly low weight gain between dialysis sessions could indicate inferior nutritional intake in patients with severe fluid overload, which is independently associated with mortality (Hecking *et al.* 2013, 2018).

Pre- and post-dialysis BP were not included in the scoring system as they have been shown to be rather poor at predicting fluid status. Patients who are normally hydrated, or even dehydrated, pre-dialysis can have high BP and patients who are fluid overloaded may have low BP, for example, in heart failure (Biesen *et al.* 2011; Lindley *et al.* 2011). However, we did include intradialytic hypertension (a paradoxical increase in BP during dialysis), which has been linked to fluid overload (Nongnuch *et al.* 2015; Buren & Inrig 2017), and IDH was defined as BP decreased by more than 20 mmHg accompanied by clinical symptoms of hypovolemia requiring nursing intervention (the National Kidney Foundation KDOQI guidelines 2005; Kooman *et al.* 2007).

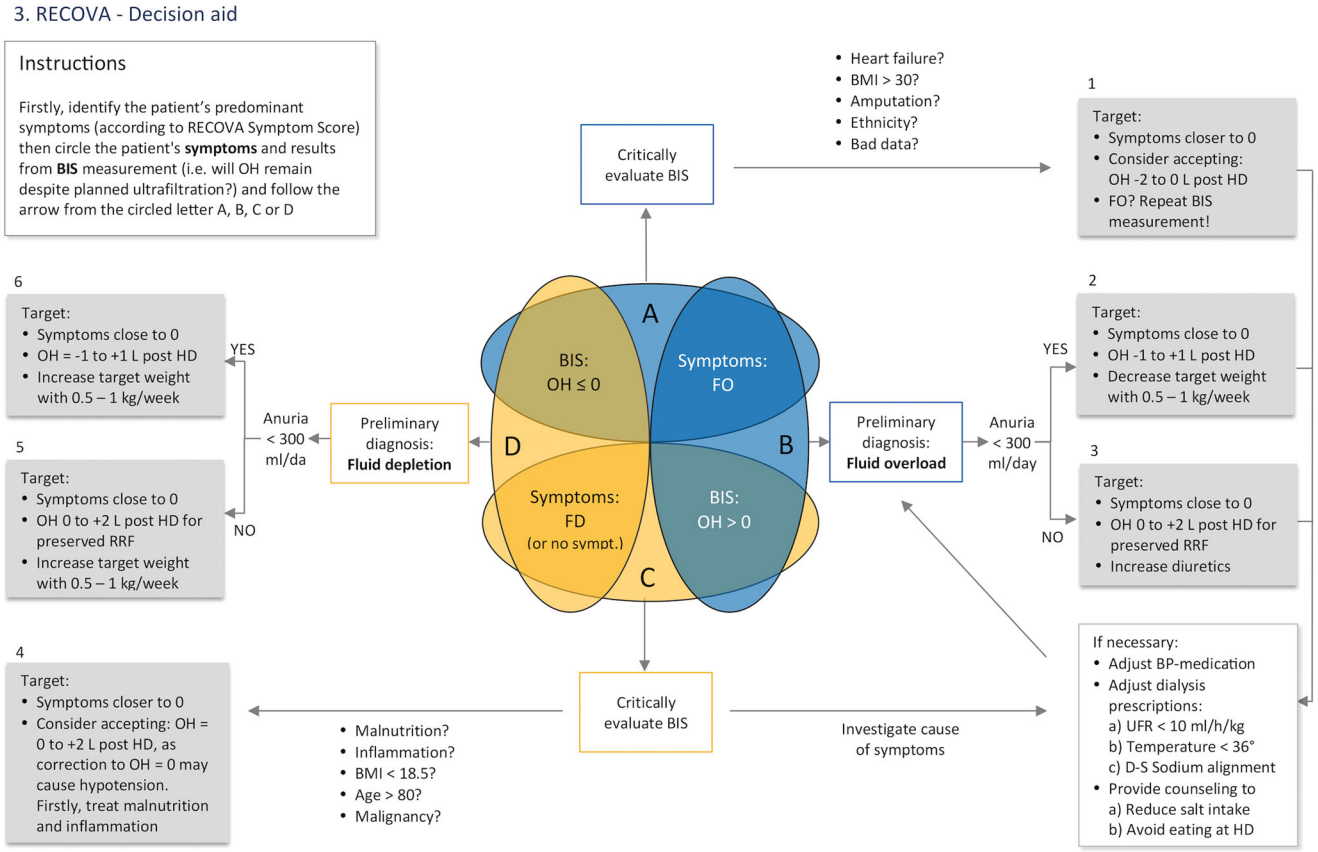
Muscle cramps affect 25–50% of all dialysis patients during haemodialysis treatment or at home following dialysis (Mastnardo *et al.* 2016). It can be related to fluid depletion, but it is worth noting, that just like IDH, increased thirst and dizziness it may also be related to the rapid removal of fluid (Chou *et al.* 2017).

THRESHOLDS AND TRIGGERS

The complexity of fluid management is challenging (Weiner *et al.* 2014; Hecking *et al.* 2015; Dasgupta *et al.* 2016; Dekker & Kooman 2018; Tabinor & Davies 2018). For fluid management interventions to be successful they must be considered as part of a multidisciplinary team. Although target weight determination is usually the responsibility of the nephrologist, fluid status is often assessed by nurses (Dasgupta *et al.* 2016). Having a protocol that specifies how often to assess target weight is associated with a lower risk of all-cause and cardiovascular mortality (Dasgupta *et al.* 2019). By providing a systematic approach to fluid assessment, and guidance in deciding when and how to respond to clinical symptoms, as in the track-and-trigger system (Figure 2) similar to the NEWS (Royal College of Physicians 2017), our aim was not only to facilitate recognitions of symptoms of fluid alterations, but also contribute to improved interdisciplinary communication, and thereby prevent delay of action.

DECISION AID ALGORITHM

Intra- and post-dialytic complications can make fluid removal difficult even in patients with significant overhydration (Antlanger *et al.* 2017). This is reflected in direction B in the decision aid algorithm (Figure 3), and it is suggested that target weight reduction should not be reinforced rapidly. Normohydration range for BIS is between −1.1 L and +1.1 L (Wabel *et al.* 2008), but removal of excessive fluid in an attempt to achieve a euvolemic state can also lead to poor patient outcomes, by provoking IDH, which may lead to loss of residual renal function, myocardial stunning and other organ ischaemia. For preservation of residual renal function, many patients would likely benefit from some fluid



BIS: bioimpedance spectroscopy, BMI: body mass index, BP: blood pressure, D-S Sodium alignment: Prescribed dialysate sodium concentration should be equivalent to serum sodium concentration; DW: dry weight; HD: hemodialysis, FD: fluid depletion, FO: Fluid overload, OH: overhydration, RRF: residual renal function; UFR: ultrafiltration rate, UFV: ultrafiltration

Figure 3: The decision aid is an algorithm based on four possible scenarios combining the information from bioimpedance spectroscopy (BIS) with clinical symptoms when setting the target weight [Color figure can be viewed at wileyonlinelibrary.com]

reserve (Hur *et al.* 2013; Huang *et al.* 2015), which is reflected both in directions B and D.

As highlighted in direction C, pre-dialysis overhydration is associated with higher levels of CRP indicating inflammation (Dekker *et al.* 2017). Furthermore, overhydration is inversely associated with body mass index and serum albumin, and slightly elevated BIS-measured overhydration appears to be common in elderly subjects. This may be explained by changes in the composition of adipose tissue and the effects of malnutrition may not be possible to isolate from sarcopenia (Antlanger *et al.* 2013; Keane *et al.* 2017). Thus, there is a general need for caution when reducing target weight in elderly and vulnerable patients, and in these cases, the RECOVA tool advises consideration of a target weight above normohydration according to BIS.

In direction A the inverse relationship between overhydration and obesity in haemodialysis patients (Antlanger *et al.* 2013) is highlighted. Pre-dialysis BIS measured underhydration is associated with increased mortality, but post-dialysis underhydration is associated with a lower mortality-risk, suggesting that the window of optimal fluid status is narrow (Dekker *et al.* 2017). This may motivate a target weight below normohydration according to BIS in patients experiencing symptoms of fluid overload, although underhydrated according to BIS.

Choice of BIS device is important and validation and applicability to patients with kidney failure should be checked. Some BIS devices are validated in healthy Caucasian controls, but also in the haemodialysis population (Wabel *et al.* 2008). In our opinion, different ethnicities are not barriers to performing BIS measurement. In occurrence of bad data, fluid assessment

should be guided by clinical assessment until a valid BIS measurement is obtained, and if conflicting results are found in BIS-measurement of haemodialysis patients, fluid assessment should always be guided by clinical assessment primarily, since evidence on the benefit of BIS is still scarce (Covic *et al.* 2017; Ekinci *et al.* 2018).

Although an individual may have symptoms of fluid depletion, such as IDH, this may be related to antihypertensive medication use and dialysis prescription rather than fluid depletion per se. When target weight is decreased, it is usually necessary to gradually and continuously adjust BP-medication, alter dialysis prescriptions and provide dietary counselling, in order to prevent symptoms of fluid depletion. Dietary counselling should emphasise sodium reduction (Weiner *et al.* 2014; Sinha & Agarwal 2017; Wong *et al.* 2017; Raimann *et al.* 2018), and high dialysate sodium concentration should be avoided. Dialysate to serum sodium alignment has been shown to reduce IDWG, as lowering or individualising dialysate sodium reduces thirst. Also reduced dialysate temperature could be considered to prevent IDH (Jefferies *et al.* 2011; Mustafa *et al.* 2016), and UFR is recomended to be kept below 10 ml/h/kg as higher rates are associated with all-cause mortality (Assimon et al. 2016).

VALIDATION

In validating the RECOVA tool, we considered IRR of the scoring system and the suggested clinical response separately. The ICC of the symptom scoring showed almost perfect agreement (Landis & Koch, 1977), ICC = 0.95–0.96, suggesting that raters scored clinical symptoms of altered fluid status similarly. The high ICC suggests that a minimal amount of measurement error was introduced by the independent nurses. However, the application of the decision aid algorithm in guidance of clinical response showed only fair agreement between raters. One possible explanation for the low IRR may be due to poorly trained coders (Hallgren, 2012). After first conducting a pilot test, we found agreement increased with training, and thus conclude the implementation of the tool will not be successful without education and training of staff. This finding was supported by the results showing that more confident and more experienced users were more likely to have a higher agreement, as illustrated in Table 3.

LIMITATIONS OF THE STUDY

In IRR analysis, raters achieved less agreement when assessing patients where clinical symptoms and BIS conflicted (direction A or C). Poor knowledge of the limitations of BIS, as discussed above, may be one explanation for the limited implementation of BIS in clinical practice (Dasgupta *et al.* 2016; Stenberg *et al.* 2016, 2018). Although we aimed for the RECOVA tool to be simple, we acknowledge that nurses found it difficult to comprehend the algorithm of the decision aid—reflecting the complexity of target weight determination—and this may be considered a limitation of the tool. Another weakness may be the challenge in deciding which symptoms to include or exclude and what cut-off values to use in the clinical assessment of fluid status. However, we believe there is sound evidence for the parameters included.

There is the potential for bias in this study given the relatively small number and non-random selection of nurses participating in the study, although our selection of raters included a variety of experience and confidence in the use of BIS across two countries with different healthcare systems. A selection of only confident raters might have increased IRR but would have reduced generalisability.

IMPLICATIONS FOR PRACTICE

Implementation of RECOVA in clinical practice will require training of staff. Clinical intervention studies are required to evaluate if the tool facilitates response to and correction of recognised fluid alterations and hence has an impact on patient outcomes.

CONCLUSION

We have developed a decision aid for early recognition and correction of volume alterations in haemodialysis patients, the RECOVA tool. The tool combines a systematic clinical assessment of fluid status with BIS measurement. Validation showed agreement between raters in the assessment of symptoms was almost perfect. In applying the algorithm for clinical response, however, agreement was only fair but increased with training.

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CONFLICT OF INTEREST

No disclosures or conflicts of interest for all authors. The results presented in this article have not been published previously in whole or part, except in abstract format.

AUTHOR CONTRIBUTIONS

The final version of the manuscript has been read and approved by all authors and all authors agree to the submission of the manuscript to the Journal of Renal Care. All authors fulfill the ICMJE requirements for authorship, they all contributed to the study conception and study design. JS and DK were responsible for data collection and JS performed the data analysis in collaboration with ML and HF. JS was also responsible for drafting the manuscript, and DK, ML, and HF made critical revisions for important intellectual content.

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