Adaptation and Applicability of a Diuretic Algorithm for Patients with Heart Failure

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Abstract

Background: Congestive states can be identified and managed through algorithms such as the Diuretic Treatment Algorithm (DTA) to adjust the diuretic over the telephone, focused on the clinical evaluation. However, the DTA is currently available only in English.

Objective: To adapt the DTA and test its applicability for Brazil in outpatients with heart failure.

Methods: The stages of translation, synthesis, back-translation, review by an expert committee, and pre-test (clinical applicability by means of a random clinical trial) were followed. The Brazilian version of the DTA was called algoritmo de ajuste de diurético (AAD; as per its acronym in Portuguese, standing for diuretic adjustment algorithm). Patients were randomized to the intervention group (IG) – diuretic adjustment according to the AAD – or control group (CG) – conventional adjustment. The clinical congestion score (CCS) and weight values were obtained for both groups.

Results: A total of 12 changes were made to the DTA. Thirty-four patients were included. For those with congestion, the increase in the diuretic as guided by the AAD solved their condition, reducing the CCS by two points for 50% of the sample −2 (−3.5; −1.0), while the median for the CG was 0 (−1.25; −1.0), (P < 0.001). The median for weight variation was greater in IG −1.4 (−1.7; −0.5) compared to the CG 0.1 (1.2; −0.6), P = 0.001.

Conclusions: The AAD proved applicable in clinical practice after adaption and appears to result in better congestion management in patients with heart failure. The clinical effectiveness of the tool should be tested in a larger patient sample aiming at validating the instrument for Brazil (Universal Trial Number: U1111-1130-5749) (Arq Bras Cardiol. 2013;100(6):553-560).

Keywords: Heart Failure / therapy; Diuretics / administration & dosage; Algorithms.

Introduction

In heart failure (HF), the leading cause of decompensation and subsequent visits to emergency rooms and hospital readmission is congestion, most often characterized by fatigue, edema and activity intolerance[1]. The identification of early signs and symptoms interrupts progressive exacerbation of the condition, with a direct impact on reduced costs, hospitalizations and mortality. One of the strategies that has already been proven to prevent exacerbation is intensive and systematic monitoring through telephone and home visits. These programs have been successful, especially with clinical evaluation and identification of congestive conditions, enabling decision-making through individualized care[2].

In light of this, the Diuretic Treatment Algorithm (DTA) was developed for adjustment of diuretics conducted by telephone by North-American nurses, with a focus on non-pharmacological and pharmacological evaluation and home management of patients with HF. This algorithm has proven to be an effective tool in preventing decompensation, significantly decreasing the rates of readmissions and 50% of hospitalizations related to HF at 30 days[3]. The implementation of a diuretic protocol can contribute to immediate action before early signs of congestion become apparent, through intensive follow-up during the adjustment period, with more autonomy for the nurse and a guarantee of maintenance of safety for patients by means of telephone monitoring[2-4]. Even if utilized by nurses, the tool is not restricted to these professionals, since it has to do with an algorithm governing diuretic dose titration associated with non-pharmacological management based on clinical evaluation face-to-face and by telephone, through the report of signs and symptoms of congestion. Thus, the health care team, especially doctors and nurses, have an objective instrument available to them to guide possible treatment adjustments in their daily practice. However, before evaluating its use and set up,

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this tool must be translated and validated in the Portuguese language. Moreover, because it is an algorithm that involves specific interventions according to various clinical scenarios, its applicability and usefulness must be assessed in clinical practice. Thus, this study seeks: 1) to conduct a cross-cultural adaptation of the DTA, and 2) to evaluate its clinical applicability through a randomized clinical trial.

Methods

Type of study and patients

This methodological study[5] was developed to cross-culturally adapt and test the clinical applicability of the Diabetic Treatment Algorithm (DTA) through a randomized clinical trial conducted in an HF clinic of a university hospital in southern Brazil. The study was conducted from March to December 2011. Patients of both genders were included, aged ≥ 18 years, diagnosed with systolic HF, able to monitor body weight at home, using furosemide and who, at the time of the evaluation, required adjustment of diuretics. Those who were not able to make return visits or participate in telephone contact, and those on renal replacement therapy, were excluded. This study was approved by the institution's Research Ethics Committee.

Instrument used - Diuretic Treatment Algorithm (DTA)

The DTA encompasses assessment steps, diagnosis and treatment for decompensated HF, according to the patient's clinical presentation. It is used as a step-by-step method for the investigation of signs and symptoms that suggest decompensation that can be detected through telephone contact with a nurse[3]. The initial stage provides guidance to the patient regarding the recognition of the signs and symptoms of worsening of his clinical condition. To accomplish this, a daily evaluation of body weight is necessary, with reevaluation in 24 hours. The client must be available for telephone consultation, in which the nurse shall perform an oral evaluation of the clinical manifestations reported by the patients. Situations of hypovolemia are identified through the client's report of experiencing dizziness, weakness and a decrease in body weight. In these cases, the underlying causes are investigated, such as the occurrence of diarrhea or anorexia, before the diuretic dosage is changed. When the patient returns to his/her normal weight, the medication must be restarted at its previous dosage, if necessary. In cases where there is weight gain with no symptoms, or weight gain in patients with symptoms of decompensation, the approach must prioritize the investigation of other possible causes, such as excessive intake of sodium, non-adherence to the treatment and/or other diseases or conditions. In these situations, the client may be asked to make a physical appointment within 48 hours to perform a clinical examination, collect blood samples and have medications reviewed.

At the beginning of the early stages of this study, the DTA author's permission for adaptation of the tool and its use in Brazil was obtained. Following acceptance, in accordance with the literature, the following methodological stages were performed to adapt the instrument: translation, synthesis, back-translation, composing an expert committee, pre-testing and applicability of the final version[6].

After the stages of translation, synthesis, back-translation and formation of an expert committee were achieved, clinical applicability was tested by means of a randomized clinical trial, which consisted of a pre-test stage. This study was planned to support applicability in practice at a clinic for patients who were allocated into the intervention group (increase of diuretic by the DTA), if, as a primary outcome, it achieved reduction in the clinical score of congestion greater than or equal to two points.

Cross-cultural adaptation

The initial translation of the DTA into Brazilian Portuguese was performed by two independent translators, native Brazilians with different knowledge levels regarding the study (one knew the details of the study, the other did not). Afterward, synthesis of the two translations was performed when the two translators and researchers came together to produce a version without concessions. The version was subsequently subjected to back translation (Portuguese-English)[6]. This stage was performed by two different translators who were natives of English-speaking countries, who did not know the concepts explored in the study and were not health care professionals. The next step involved the formation of an expert committee, which is essential to obtain an instrument that includes all the features of the original instrument and is adapted to the culture in which it is being inserted. The translators, four nurses, one physician and a linguistic professional were part of the committee. The committee evaluated all instrument items for semantic, idiomatic, experimental and conceptual equivalence. Afterwards, the versions were sent to the author for his knowledge and approval.

The final version was called *algoritmo de ajuste de diurético* (DTA; as per its acronym in Portuguese, standing for *diuretic adjustment algorithm*) and was applied as a pre-test to 34 outpatients. According to the theoretical referential adopted, the pre-test sample should include 30-40 research subjects[6].

Randomization

Patients who met the inclusion criteria, agreed to participate in the study and signed an informed consent form were randomly allocated to the intervention group (IG) or control group (CG). Randomization was performed immediately after the indication of the need for a change in the diuretic dose by the physician using the software found at http://www.randomization.com. All interventions were performed by the investigator (nurse); however, the initial and final assessments were conducted by a blind professional as to allocation to CG or IG.

Study protocol and intervention

The intervention study was conducted by the nurse in a systematic way. In the IG calls were made (median duration of 15 minutes) at 48 h, 96 h, 10 days, 14 days, 21 days and

28 days. On occasion there were investigational signs and symptoms of congestion; when this occurred, medications were revised, non-pharmacological guidance was provided and the educational aspect was individually strengthened. According to the AAD, changes in weight of ± 1 kg were indicative of the need for a change in the diuretic dose, with the addition or reduction of a single tablet of furosemide. In the CG, the patients received no phone calls and diuretic doses were adjusted at the discretion of the physician during the initial consultation. After 30 days, all patients returned for a final evaluation. For both groups the degree of congestion was identified through auscultation of the chest auscultation, presence of a third heart sound, jugular venous distention, lower limb edema, orthopnea, hepatojugular reflux and functional class, allowing a determination of the clinical congestion score (CCS). Scores ≥ 5 indicate the presence of congestion[2].

Data collected and variables measured

Demographic and clinical data were obtained from all patients. Clinical data collected included: information regarding previous hospitalizations, comorbidities, medications being used, echocardiographic data and laboratory values (potassium, sodium, urea and creatinine levels) at the time of study inclusion and at the final assessment at 30 days when available. For the initial and final clinical evaluation CCS was used, which includes lung auscultation, cardiac auscultation, assessment of jugular vein distension, hepatojugular reflux, lower limb edema, orthopnea or paroxysmal nocturnal dyspnea and functional class. The weight was also recorded and evaluated.

Statistical Analysis

Continuous variables were described as mean and standard deviation for those with normal distribution, or median and interquartile range for those with asymmetric distribution. Categorical variables were described with absolute numbers and relative frequencies. As for the distribution of data, the baseline characteristics of the groups and the effects of the interventions were compared by Student's t test, Mann-Whitney and chi-square tests. The Student *t* test and Mann-Whitney test were used for the variation of the CCS and the weight of both groups from baseline to 30 days. The p-value < 0.05 was considered as statistically significant.

Results

Cross-cultural adaptation of the DTA

We performed a total of 12 modifications of the instrument to adapt it to our culture. Tables 1, 2 and 3 show the adjustments made and the reasons for each change.

Research subjects - pre-test stage

Of a total of 1,440 eligible patients, 1,406 were excluded for not meeting the inclusion criteria or for other reasons described below. Seventeen patients were randomized to IG and 17 to CG. After one month of follow up, 17 patients from IG and 14 from CG were analyzed (Figure 1).

The study included 34 patients with a mean age of 65.3 (± 10.6) years, predominantly male (23 [67.6%]) and white (25 [73.5%]). The etiology of HF of highest predominance was ischemic (44.1%), followed by hypertension (32.4%), and left ventricular ejection fraction was 31.4 ± 8.8. More than half of the patients (64.7%) had been hospitalized one or more times. The median number of previous admissions was 1 (1-2) and 2 (1-3) for IG and CG, respectively, and 15 (44.1) had been hospitalized at least once in the last year. The laboratory variables were similar between the two groups, except for creatinine, which was higher in the CG (Table 4).

Variation in CCS and body weight

When the CCS was assessed at baseline and at 30 days for both groups, it a significant reduction in the need to increase diuretics guided by the AAD (6.3 ± 2.4 and 3.6 ± 1.1) was observed in IG when compared with CG, which showed an increase in diuretic use from the baseline period to 30 days (6.9 ± 3.7 and 5.2 ± 3.0). The other groups that reduced the use of diuretics with or without use of the AAD did not present significant scores. In the IG with reduced diuretic use guided by the AAD, the CCS was 2.3 ± 1.1 and 3.3 ± 2.5, compared to the CG, which also decreased diuretic use (3.8 ± 1.6 and 4.2 ± 0.8) from baseline to final analysis, respectively.

The median variation of the CCS final to baseline scores was higher in IG in terms of increasing diuretics -2 (-3.5, -1.0) when compared to CG with increased diuretic 0 (-1.25, -1.0), p < 0.001. Similarly, the median of the variation of body weight in the comparison of these groups was also significantly higher in the IG – 1.4 (-1.7; -0.5) in relation to CG 0.1 (-1.2; -0.6), p = 0.001. These variations can be seen in Figure 2.

Discussion

This is the first study to perform the cross-cultural adaptation of an adjustment algorithm for diuretic use in Brazil in HF patients, through a randomized clinical trial conducted by nurses. Besides the cross-cultural adaptation, the randomized clinical trial allowed us to evaluate the applicability of this algorithm, and its use seems to be superior to conventional outpatient methods for controlling and reversing clinical congestion.

In the cross-cultural adaptation process 12 items that make up the algorithm were modified. Among the biggest changes are the assessments of treatment adherence (non-pharmacological), increasing the amount of phone calls (from three to six) and the inclusion of consultation and sample collection for patients with symptoms that persist in the presence of two diuretic dose increases. These modifications were necessary and were identified by the committee of experts aiming to ensure client safety from afar[7,8].

The IG-driven AAD showed a significant reduction in the value of CCS within 30 days (p < 0.001). Likewise, body weight was also reduced significantly in this period (p = 0.001). In a study that adopted titration of diuretics as a tool to decrease morbidity and mortality in outpatient subjects, the guidance was for participants to weigh themselves daily; however, the authors did not present variation results. A critique relevant to this study concerns the lack of a specialized nursing assessment and the only intervention is the change in dose of diuretic, if deemed necessary[9].

Table 1 - Cross-cultural adaptation of the DTA

Original and adapted version for Brazil's Diuretic Treatment Algorithm (DTA)		
Original Version	**Adapted version**	**Justification**
Weight increased beyond parameters	**Weight increase ≥ 1 kg**	**Increase of 1 kg for modification**
Call patient to evaluate weight gain: − Diet sodium restriction, eating out, fluids intake − Provide education	Evaluate; − Diet: salt restriction, fluid intake, food − Provide orientation	Expression "eating out" adapted to "feed". Expression "Provide education" adapted to "provide direction" with a broader sense.
	− Rate poor adherence − Resume doses and strengthen guidelines	New item to assess adherence and strengthen guidance before extra dose of diuretic for those who are not responding due to lack of proper monitoring of targeted measures.
Extra dose of diuretic for one day − I needed KCL	Extra dose of diuretic for 2 days (inc 1 tablet)	The expert committee opted for more conservative stance on increasing diuretic dose (1 tablet more). Excluding the item to KCl administration.
	Connection at 48 h	Added link to 48 h after the enforcement of the guidelines.
Rapid weight gain equal too if weight gain greater than 2 pounds/day	Rapid weight gain = 1 kg/ day	Rapid weight gain ≥ 1 kg/ day
If no weight change in 24-48 hours: − Double dose of loop diuretic / KCL × 2d − Considerer aldactone, triamterene, Diamox − Provide education	If no change in weight at 48 h: − Extra dose of diuretic for 2 days − Provide orientation	The expert committee opted for more conservative stance on increasing diuretic dose (1 tablet more). For be unusual to use Triamterene, the item was not inserted.
	Connection at 48 h	Included connection in 48 h after furosemide increase and patient education.
If at maximum diuretic dose with no weight decrease or with symptoms − Clinic appointment within 2 days − Considerer addition of thiazide with blood chemistry − Considerer Lasix IVP or Lasix drip − Considerer inotrope infusions	If, with a maximum dose of diuretic, there is a decrease in weight or symptoms: − Medical consultation in two days − Collection of laboratory tests (urea, sodium, potassium and creatinine) − Consider adding thiazide diuretic in the medical consultation − Consider intravenous infusion of furosemide − Consider infusions of inotropes	− Included the possibility of adding a thiazide diuretic by the physician during the extra consultation. − Maintained the indication in the use of furosemide and intravenous inotropes in conditions requiring the referral of the patient to the emergency room.

Table 2 - DTA cross-cultural adaptation - adjusting for weight higher than expected

Original and adapted version for Brazil of Diuretic Treatment Algorithm (DTA)		
Original Version	**Adapted version**	**Justification**
Weight Within range	**Weight as expected**	**Modification of <900 g body weight**
Extra dose of diuretic for one day − KCL if needed	Extra dose of diuretic for 2 days (inc 1 tablet)	The expert committee opted for more conservative stance on increasing diuretic dose (1 tablet more). Excluding the item to KCL administration.
	Connection at 48 h	Included connection in 48 h after furosemide increase and patient education.
If Symptoms persist beyond 24-48 hours: − Double dose of loop diuretic − Considerer aldactone, triamterene, Diamox	If symptoms persist for 48 h: − Extra dose of diuretic for 2 days − Provide orientation − Collection for exams: urea, sodium, potassium, creatinine	The expert committee opted for more conservative stance on increasing diuretic dose (1 tablet more). Because it is unusual to use Triamterene, the item was not inserted. For security reasons, it was included laboratory exams collection for those who changed even after the dose of diuretic for 48 h showed no improvement

In clinical practice, the greatest proportion of adjustment of diuretics occurs in cases of congestion. As to fluctuations in weight within a short period of time, this is also used as a parameter to assess fluid overload in HF[2,10-12]. There is evidence that these changes are correlated with symptoms and an increase in hemodynamic parameters, such as pressure within the jugular vein[2]. A recent study has shown that patients with HF, when compared with healthy individuals, present with gradual weight gain in the month previous to hospital admission. When followed for a period of 18 months, using the strategy of home weight monitoring, it was identified that the most important changes occurred in the seven days prior to admission. The authors concluded that, for the majority of cases, admissions due to HF are preceded by weight gain[13].

Table 3 - DTA cross-cultural adaptation - adjusting for weight lower than expected

Original and adapted version for Brazil of Diuretic Treatment Algorithm (DTA)		
Original Version	**Adapted version**	**Justification**
Decreased Weight: beyond set parameters	**Decreased weight ≤ 1 kg**	**Reduction of 1 kg body weight**
	Weight loss with improvement in symptoms of HF (orthopnea, dyspnea, edema, fatigue)	Included item to evaluate patients who reduced their weight and benefited from improved symptoms of HF. The program remains.
	Connection at 24 h	Included link for patients with symptoms such as dizziness, vertigo and fatigue.
Continue program	Continue the program Restart with one less tablet	In the absence of symptoms, continue the program and restart with 1 less tablet.

Table 4 - Demographic and clinical characterization of patients with heart failure

Characteristics (n = 34)	**Total (n = 34)**	**Intervention Group (n = 17)**	**Control Group (n = 17)**	**p**
Age (years)	65.3 ± 10.6	67.1 ± 8.4	63.8 ± 12.2	0.40
Gender (male) †	23 (67.6)	13 (76.5)	10 (58.8)	0.46
Ethnicity (white) †	25 (73.5)	14 (82.4)	11 (64.7)	0.54
HF etiology †				
Ischemic	15 (44.1)	7 (41.2)	8 (47.1)	0.40
Hypertensive	11 (32.4)	7 (41.2)	4 (23.5)	0.40
LVEF (%)*	31.4 ± 8.9	33.5 ± 9.1	29.1 ± 8.3	0.16
Current medications † in use				
Beta blockers	24 (72.7)	13 (81.3)	11 (64.7)	0.44
Digoxin	20 (60.6)	12 (75)	8 (47.1)	0.20
ACE inhibitors	19 (57.6)	9 (56.3)	10 (58.8)	< 0.99
NYHA (baseline) †				
II	24 (70.6)	13 (76.5)	11 (64.7)	
III	6 (17.6)	2 (11.8)	4 (23.5)	
NYHA (30 days) †				
I	5 (16.1)	3 (17.6)	2 (14.3)	0.73
II	23 (74.7)	13 (76.5)	10 (71.4)	
Laboratory Tests				
Sodium (baseline)	140.7 ± 3.2	141.8 ± 2.8	139.5 ± 3.1	0.34
Sodium (30 days)	138.9 ± 3.1	139.3 ± 3.1	138. ± 3.4	0.91
Urea (baseline) ‡	63 (46-96.5)	58.5 (40-77.2)	180 (48-122)	0.10
Urea (30 days) ‡	83 (57-144)	81.5 (31.75-100)	180 (81-245)	0.13
Potassium (baseline)*	4.6 ± 0.6	4.6 ± 0.5	4.7 ± 0.6	0.68
Potassium (30 days)	4.5 ± 0.55	4.66 ± 0.24	4.4 ± 0.8	0.09
Creatinine (baseline)*	1.4 ± 0.6	1.3 ± 0.4	1.5 ± 0.8	0.16
Creatinine (30 days)*	1.9 ± 0.8	1.5 ± 0.42	2.3 ± 1.0	0.02

*HE: Heart Failure; LVEF: left ventricular ejection fraction; ASA: acetylsalicylic acid; ACE inhibitor: angiotensin-converting-enzyme inhibitor; NYHA: New York Heart Association. *Variable expressed as average ± standard deviation and independent t-test; †n (%) and Pearson's chi-square; ‡Median interval interquartile, Mann-Whitney test.*

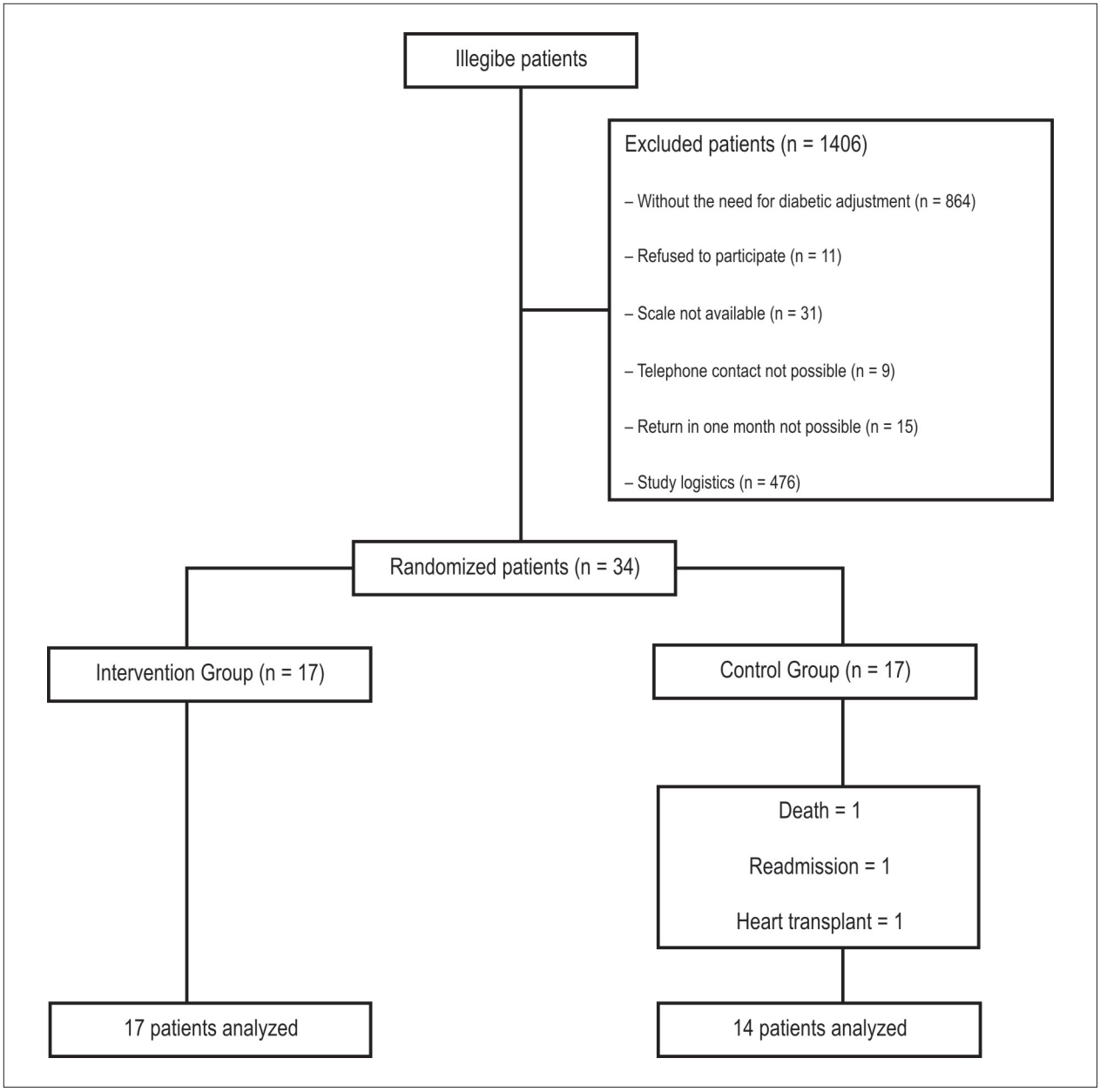

Figure 1 – *Flow diagram of patients allocated in the intervention and control groups.*

Currently, there are two similar algorithms discussed in the literature that were used to evaluate outcomes of readmissions and deaths due to HF in a sample of outpatients in a randomized clinical trial. The first, which used the strategy of diuretic adjustment, included 123 patients and primarily took into account the change in weight over other variables that typically indicate congestion. Telephone contact was also utilized as a way to reinforce the initial teaching provided. The results were favorable, as evidenced by a reduction in mortality and hospitalization for the intervention group, as well as an improvement in self-care. The second study included 62 outpatients who received identical guidance regarding HF and were provided with a guideline manual, a scale and a diary to record their weight. Only patients in the intervention group were provided with instructions on how to perform auto-adjustment of their diuretic. In terms of follow-up, patients were contacted within 72 hours, and after two, four, eight and 12 weeks for the evaluation of the readmission outcome. Although the authors of these studies have not performed comparisons between congestion and weight at the beginning and end of the study, it is emphasized that the strategy to adjust diuretics contributed to the clinical stability of the patients[9,14].

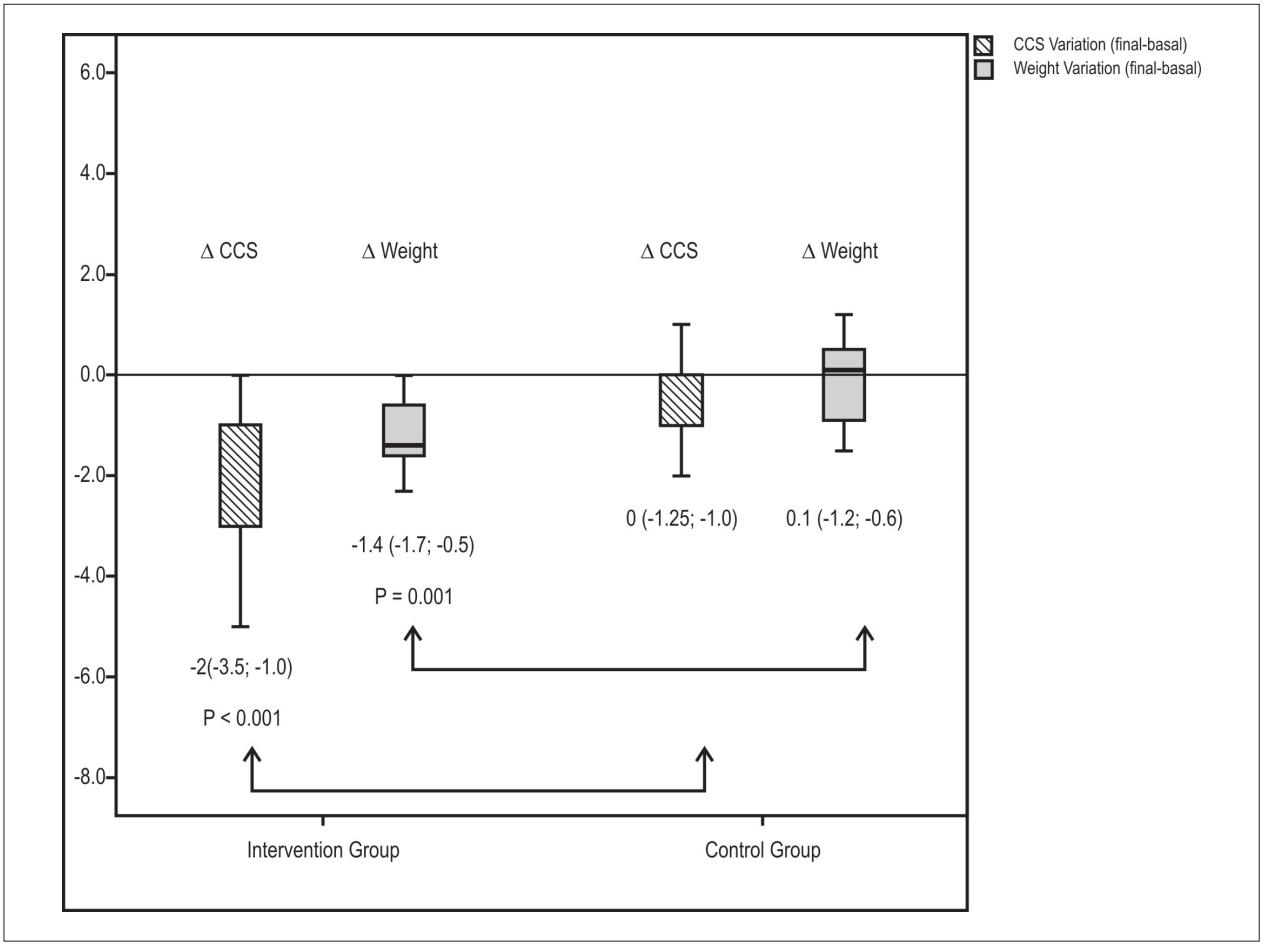

Figure 2 – *Variation of the congestion clinical score for the intervention and control groups. Comparison of the variables in the baseline period and at 30 days. Mann-Whitney test.*

The AAD is the only algorithm available for adjustment of diuretic based on the current clinical condition of the patient not taking a previously established dose. The AAD is not only restricted to the pharmacological approach, but includes overall attention to non-pharmacological treatments and adherence to treatment. In addition, it provides systematic guidance at least weekly. Added to this, the link established between practitioner and patient, involving family and support networks in the process of self-care, is undeniable. Questions remain to be answered, especially regarding the relationship between treatment adherence and the interventions carried out. In this study, the results cannot be judged solely by the effectiveness of the use of AAD via telephone contact, but also by the strengthening of educational components whenever the patients revealed a need for teaching.

A potential limitation of the study is the occasional difficulty encountered in making telephone contact, whether due to difficulty in verbalizing signs and symptoms by the patient, by hearing impairment or even by the patient's understanding of the guidance relayed by the health care professional.

Conclusions

The results demonstrate that the adapted version of the AAD maintained the semantic, idiomatic, experimental and conceptual equivalence of the original tool, according to the evaluation committee of experts. The AAD demonstrated, through the pre-test in the form of a randomized clinical trial, to be more effective than conventional management in reducing CCS and weight for patients who required an increased dose of diuretic. For this tool to be recommended in clinical practice, its effectiveness should be tested in larger studies with the evaluation of appropriate clinical outcomes, such as the prevention of hospitalizations.

Author contributions

Conception and design of the research, Analysis and interpretation of the data, Statistical analysis, Writing of the manuscript and Critical revision of the manuscript for intellectual content: Feijó MKEF, Biolo A, Rabelo-Silva ER; Acquisition of data: Feijó MKEF.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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