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Original

Nutritional orientation, knowledge and quality of diet in heart failure; randomized clinical trial

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Abstract

Background: **Non-pharmacological measures are recommended for heart failure patients. However, most studies evaluate low sodium diet, while little is known about the effects of interventions to improve adherence and knowledge of patients about diet content.**

Objective: **To evaluate if a global nutritional orientation could affect nutritional knowledge, adherence to food guidelines, anthropometrics and quality of life in heart failure patients.**

Methods: **Forty six patients were randomized to intervention or control group. Both groups received usual care with medical and nursing staff; the intervention group received additional nutritional guidance about diet and its relationship with disease, sources of nutrients, and reduction of dietary sodium and fats. Enforcement of the nutritional guidance was performed after 4 weeks. Both groups were evaluated at baseline, and after 6 weeks and 6 months. Evaluations included anthropometric parameters, sodium excretion in 24-hour urine, dietary recall, nutrition knowledge and quality of life questionnaires.**

Results: **Mean age of included patients was 58 ± 10 years and 70% were male. After 6 months of follow-up, the nutritional knowledge of intervention group increased compared to control ($p < 0.05$). Caloric, fat and sodium intake decreased in the intervention group compared to control ($p < 0.05$). No significant differences were seen in quality of life or anthropometric parameters.**

Conclusions: **Nutritional orientation was effective to modify 1) knowledge about food and nutrition, and 2) quality of diet in outpatients with heart failure. Further studies are necessary to evaluate the benefits on quality of life and prognosis.**

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ORIENTACIÓN NUTRICIONAL, CONOCIMIENTO Y CALIDAD DE LA DIETA EN LA INSUFICIENCIA CARDÍACA; ENSAYO ALEATORIZADO

Resumen

Introducción: **Medidas no farmacológicas se recomiendan en la insuficiencia cardíaca. Sin embargo, la mayoría de los estudios evalúa dietas restrictas en sodio, mientras que poco se sabe sobre el efecto de intervenciones para mejorar la adherencia y el conocimiento sobre dieta.**

Objetivo: **Evaluar si una orientación nutricional puede modificar la adherencia a la dieta, conocimiento nutricional, antropometría y calidad de la vida en pacientes con insuficiencia cardíaca.**

Métodos: **46 pacientes fueron aleatorizados al grupo control o intervención. Ambos recibieron el tratamiento habitual del equipo; el grupo intervención recibió además orientación sobre la dieta y su relación con la enfermedad, fuentes de alimentos y reducción de las grasas y sodio. Ambos los grupos fueron evaluados al principio del estudio, 6 semanas y 6 meses. Evaluaciones incluían antropometría, sodio en la orina de 24 h, el recordatorio alimenticio, y los cuestionarios de conocimiento nutricional y de la calidad de la vida.**

Resultados: **La media de edad fue de 58 ± 10 años y 70% eran hombres. Después de 6 meses, el conocimiento nutricional del grupo intervención aumentó en comparación al grupo control ($p < 0,05$). La ingestión calórica, de grasa y del sodio reducirán en grupo intervención, comparado con el grupo control ($p < 0,05$). No hubo diferencias significativas en la calidad de vida y antropometría.**

Conclusiones: **La orientación nutricional fue efectiva en la modificación de 1) conocimiento nutricional, y 2) calidad de la dieta en pacientes con insuficiencia cardiaca. Más estudios que evalúan los beneficios en la calidad de la vida y pronóstico son necesarios.**

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Palabras clave: *Insuficiencia cardíaca. Dieta. Cooperación del paciente. Conocimiento.*

Abbreviations

NYHA: New York Heart Association.
BMI: Body Mass Index.
WHO: World Health Organization.
WC: Waist circumference.
AC: Arm circumference.
MLHFQ: Minnesota Living with Heart Failure questionnaire.
QL: Quality of Life.
NK: Nutritional Knowledge.

Introduction

Non-pharmacologic management strategies are recommended for heart failure patients, to maintain stability, avoid hospital readmission[1] and decrease mortality.[2] These measures include a low sodium balanced diet, weight control and water intake.[3] The American Heart Association recommends a sodium intake of no more than 2-3 g/day to control heart failure, but advertise that the recommendations should be individualized according to disease severity.[4]

Studies have show an inadequacy in heart failure patients diet, high in sodium consumption and poor in vitamins, mineral and fiber.[5] Moreover, the high prevalence of coronary artery disease as a cause of heart failure[6] makes it necessary to restrict saturated fat, cholesterol and simple carbohydrate ingestion in the diet of this patients.[7]

The adherence to the orientations provided by health professionals is usually lower then expected and that may be a precipitating factor for hospital readmissions.[2,8] Moreover, adherence to dietetic guidelines is often lower than to medications,[9] it seems to improve when patients receive appropriate education[10,11] and by a multidisciplinary staff.[12] However, studies attempting to assess nutritional interventions have focused on the reduction of sodium intake and its effects,[13-14] not evaluating other aspects of diet quality (fat content, carbohydrate, protein).

The objective of this study was evaluate if a global nutritional orientation improve adherence to food guidelines (salt restriction and diet quality), nutritional knowledge, anthropometric measures and quality of life in heart failure patients.

Methods and materials

Patients

This randomized clinical trial included forty-six outpatients recruited from a tertiary university hospital in Brazil. The sample size was based in available literature, by using the change in sodium intake found by Arcand et al.[15] The inclusion criteria were: 18 years or older, of both gender, confirmed diagnosis of heart failure, functional class I to III according the New York Heart Association (NYHA). Candidates were excluded if they were already receiving orientation by a nutritionist or if they could not read the educational material. This study was approved in the Ethics Committee of Hospital de Clínicas de Porto Alegre and all patients were informed about the study purpose and signed an Informed Consent. This clinical trial was registered in Clinicaltrals.gov identified as NCT00957814.

Protocol

Participants were randomized by a computer-generated code for intervention group or control group as they attended routine visits in the heart failure clinic. The follow-up was initially planned for 3 months and then added one more moment in 6 months.

Both groups (intervention and control) received usual treatment with medical and nurse staff. In the first meeting were realized by a nutritionist: anthropometric evaluation, quality of life and nutritional knowledge questionnaires application and 24-hour dietary recall with delivery of the 24-hour urine collection. The intervention group received additional orientations (for one hour) about diet and its relationship with heart failure that include: food groups (sources of macro, micronutrients and dietary fiber), water intake, reduction of dietary sources of sodium, cholesterol and triglycerides, all based in recommendations in the literature.[16,17] As an education strategy, graphic material as a calendar created specifically for this purpose was used in the orientation and delivered to patient use at home. Based on the detection of possible abnormal eating behavior in agreement with the patient, goals were set to improve adherence to the diet and motivation. After one month, intensification was made when an inappropriate behavior was detected.

Main outcomes included variation in scores of questionnaires of nutritional knowledge and quality of life, diet content and anthropometric measures. All variables were analyzed in three moments in both groups: baseline, in six weeks and in six months.

Anthropometric measures

Weight was measured with the patient positioned upright in the center of the electronic balance *(Filizola®)* up to 150 kg with a range of 100 g, wearing little clothing as possible. For measurement of height was used vertical anthropometer fixed in wall. Body Mass Index (BMI) was calculated as current weight (kg) divided by height square (m) and classified according to World Health Organization (WHO).[18] The waist circumference (WC) was measured after expiration, with tape not extensible at the midpoint between the

tenth rib and the iliac crest, with cutoff points of 102 and 88 cm for men and women, respectively.[19] The arm circumference (AC) was measured using a tape around the midpoint between the acromion and olecanon on the posterior surface of the nondominant arm flexed at a 90° angle.

Food consumption

Dietary intake was assessed through a 24-hour recall and calculation was performed on nutrition software (Nutwin, 1.5 Version, 2002). Assessment of the reability of food records was performed by estimating the protein intake obtained by food records and compared with the excretion of urea nitrogen of 24-hours,[20] obtained by the following formula: urea (mg) x 0.46 + 4 x 6.25.[21]

Confidence interval of 95% of the log ratio of reported intake and urinary nitrogen excretion was calculated to identify the correlation between methods; recalls outside this range were excluded (five recalls met this criterion and were not included in the analysis). Along with the recall, 24-hour urinary sodium excretion was measured, a direct method that allows more accurate assessment of sodium intake[22]. In the calculation of the software was not considered the sodium added in diet due to the difficulty to measure it.

Quality of life and nutritional knowledge questionnaires

The Minnesota Living with Heart Failure questionnaire (MLHFQ) was used to evaluate the quality of life (QL).[23] MLHFQ consists of 21 questions relating to restrictions associated with how much the heart failure limits the patients to live as they like. The scale of responses to each question ranges from 0 (no limitations) to 5 (maximum limitation).

A scale of knowledge based in National Health Interview Survey Cancer Epidemiology, previously adapted and translate to portuguese, was used to assess nutritional knowledge (NK).[24] Seven of twelve original questions were maintained and eight more have been created with the purpose of directly assess knowledge related to heart failure. This range was previously tested in a pilot study to perform a discriminatory validation. The questionnaire has objective and discursive questions with standardized score and 19 points are the maximum score.

Clinical variables

Ejection fraction, comorbidities, functional class, etiology and medications were obtained from medical records. Urea nitrogen and sodium were obtained from 24-h urine collection.

Table I
Baseline characteristics of patients

	Total (n = 46)	*Control (n = 23)*	*Intervention (n = 23)*	*p**
Male	32 (70%)	14 (61%)	18 (78%)	0.200
Age	58 ± 10	61 ± 9	55 ± 10	0.035
Incomplete Elementary School	23 (55%)	12 (60%)	11 (50%)	0.813
Clínics:				
Ischemic etiology	17 (37%)	8 (35%)	9 (39%)	0.818
Functional class I e II	36 (78%)	19 (83%)	17 (74%)	0.497
Ejection fraction (%)	33 ± 10	36 ± 9	31 ± 11	0.100
Comorbidities:				
Hypertension	30 (65%)	18 (78%)	12 (52%)	0.063
Diabetes mellitus	16 (35%)	3 (13%)	6 (26%)	0.265
Anthropometrics:				
BMI (kg/m^2)	29.2 ± 5.7	28.0 ± 5.1	30.4 ± 6.1	0.151
Arm circunference (cm)	30.6 ± 4.3	29.6 ± 3.2	31.5 ± 5.0	0.137
Waist circunference (cm)	99.5 ± 13.8	94.6 ± 12.3	104.4 ± 13.8	0.015
Questionnaires:				
Nutritional Knowledge	12.2 ± 2.6	12 ± 2.7	12.4 ± 2.5	0.571
Quality of live	29.5 ± 16.2	29.9 ± 18.5	29.1 ± 14	0.879
Bioquimic:				
Urinary sodium (mg/24 h)	5017 ± 1919	4558 ± 1841	5476 ± 1925	0.105
Urea (g/24 h)	21.7 ± 8.7	20.3 ± 8.4	23.1 ± 8.9	0.288
Medication:				
β-Blocker	39 (85%)	20 (87%)	19 (83%)	0.681
ACEI ou ARB	44 (96%)	21 (91%)	23 (100%)	0.148
Diuretics	44 (96%)	23 (100%)	21 (91%)	0.148

Continuous variables expressed as mean ± standard deviation and categorical variables as n (%).
*p-value represent comparison between groups with Student *t* Test or Chi-square.

Statistical analysis

Data are reported as mean and standard deviation for quantitative variables and frequencies and percentages for categorical variable. Student's *t* Test and Chi-square were used for comparison of baseline variables between groups. The analysis of variance over time and between groups was performed by Repeated Measures ANOVA Test. The Pearson correlation coefficient was used to analyze the correlation between urinary sodium and reported consumption. The level of significance lower then 5% was considered significant and analyses were done at the Statistical Package for Social Sciences (18.0 version, SPSS Inc., Chicago, IL).

Results

Forty-six patients were included, 23 in the intervention group and 23 in the control group. The mean age of patients was 58 ± 10 years and 70% were male (table I). Approximately 55% have not completed primary school. According to BMI classification, 45% of patients were obese and 50% had increased cardiovascular risk according to waist circumference. Patients of intervention group were younger and had higher values of waist circumference. However, when separated by gender, the values of these measure were not statistically different between groups (p = 0.213 for men and p = 0.080 for women). The baseline nutrient intake was generally similar between the two groups, and only sodium intake was higher in the intervention group (table II).

During follow-up, there was one death and a dropout, both in the intervention group. After six months of follow-up, the nutritional knowledge score was higher in the intervention group, demonstrating that learning intervention remained over the first 6 months (fig. 1). Regarding to food intake, nutritional orientation resulted in reduction in calorie intake (p = 0.034), increase in the percentage of carbohydrate intake and reduction in fat, both percentage of kilocalories and grams (p = 0.014) (fig. 2). Also, there was a significant reduction in reported sodium intake by 24-hour recall in the intervention group (p = 0.017). However, there was no significant difference in urinary sodium excretion. It is important to note that the sodium intake measured by recall method was calculated only as the

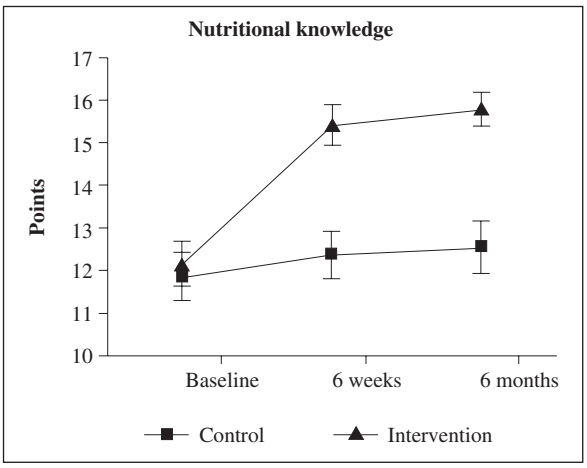

Fig. 1.—Variation of the questionnaire score of nutritional knowledge over time (mean and standard deviation). Comparison between groups performed by repeated measures ANOVA was statistically significant (p = 0.007).

Table II
Basal food intake obtained by the 24-hours recall

	Total (n = 46)	*Control (n = 23)*	*Intervention (n = 23)*	*p**
Kilocalories (kcal)	1,573 ± 550	1,494 ± 520	1,653 ± 579	0.333
Carbohydrate (g)	210 ± 83	204 ± 90	216 ± 78	0.615
Carbohydrate (%)	52.5 ± 9.1	53.4 ± 10.3	51.7 ± 7.9	0.546
Proteín (g)	67.4 ± 25.5	67.7 ± 24.8	67.0 ± 26.8	0.929
Proteín (%)	17.7 ± 5.5	18.5 ± 5.0	17 ± 6.0	0.357
Lipíds (g)	54.9 ± 27.9	48.4 ± 25.0	61.3 ± 29.7	0.120
Lipíds (%)	30.2 ± 8.3	28.1 ± 8.8	32.2 ± 7.5	0.090
Saturated (%)	29.6 ± 7.7	30.4 ± 8.7	28.8 ± 6.7	0.498
Polyunsaturated (%)	19.4 ± 9.1	20.2 ± 9.4	18.5 ± 8.9	0.531
Monounsaturated (%)	29.6 ± 6.5	29.5 ± 6.0	29.8 ± 7.2	0.922
Cholesterol (mg)	162 ± 98	156.5 ± 96.6	168.5 ± 100.4	0.681
Fibers (g)	16.5 ± 10.5	17.1 ± 11.8	15.8 ± 9.2	0.658
Sodium (mg)	1,485 ± 1033	1,133 ± 673	1,966 ± 1207	0.014

Data expressed as mean ± standard deviation.
*p-value represent comparison between groups with Student *t* Test.

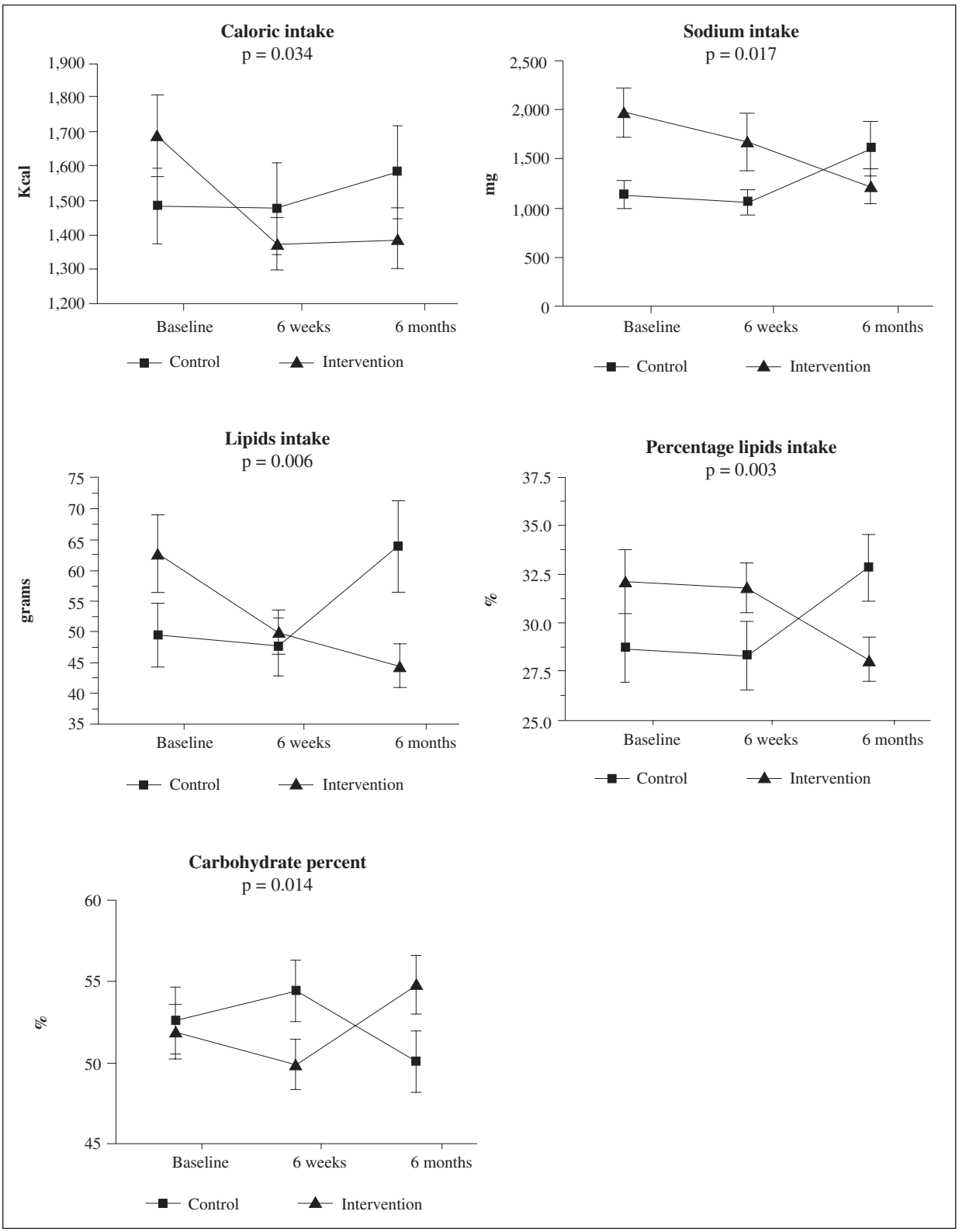

Fig. 2.—Variation in food consumption over time (mean and standard deviation). Comparison between groups performed by repeated measures ANOVA. Levels of significance are shown in figure.

intrinsic of food and not added salt. Furthermore, there was no correlation between urinary sodium and sodium reported in 24-hour recall (r = 0.047; p = 0.762).

Variation in anthropometric and clinical parameters are presented in table III. Nutritional intervention did not result in significant changes on anthropometric

Table III
Analysis of variance of anthropometric and clinical variables over time

	Baseline		*6 weeks*		*6 months*		
	Control	*Intervention*	*Control*	*Intervention*	*Control*	*Intervention*	*p**
Weight (kg)	72.4 ± 13.6	85.0 ± 19.4	72.8 ± 13.6	84.1 ± 18.5	72.7 ± 14.7	84.0 ± 18.0	0.390
BMI (kg/m^2)	28.1 ± 5.2	30.0 ± 6.3	28.1 ± 5.1	29.8 ± 6.0	28.1 ± 5.4	29.7 ± 6.0	0.421
AC (cm)	29.6 ± 3.3	31.5 ± 5.3	30.0 ± 3.1	30.8 ± 4.4	29.4 ± 3.4	30.7 ± 4.2	0.221
WC (cm)	94.6 ± 12.6	102.6 ± 13.1	94.5 ± 12.6	100.7 ± 12.8	95.4 ± 12.0	100.4 ± 12.2	0.544
QL	29.8 ± 18.9	29.4 ± 14.7	27.3 ± 18.1	23.5 ± 17.8	29.2 ± 14.9	21.1 ± 17.1	0.736
Na (mg/24 h)	4,315 ± 1,880	5,632 ± 2,071	4,192 ± 1,789	4,678 ± 2,433	4,101 ± 1,649	5,027 ± 3,271	0.831
Urea (g/24 h)	19 ± 8	23 ± 9	17 ± 7	20 ± 8	18 ± 7	24 ± 10	0.368

BMI: Body mass index; AC: Arm circumference; WC: Waist circumference; NK: Nutritional knowledge questionnaire; QL: Quality of live questionnaire; Na: Urinary sodium. Data adjusted for age and waist circumference and expressed as mean ± standard deviation.
*p-value represent the comparison between the three periods with Repeated Measures ANOVA Test.

parameters. Despite the reduction of numerical score MLHFQ in the intervention group, which may indicate an improvement in quality of life, this effect was not significant.

Discussion

This study shows that a comprehensive nutritional orientation given to stable patients with heart failure resulted in 1) an increased knowledge about a healthy diet, 2) a higher compliance with food guidelines, and 3) lower sodium intake. No significant effects were seen on anthropometric parameters and quality of life. Previous studies have shown that, by knowing about their disease and the benefits of treatment and lifestyle changes, patients may have less episodes of decompensation and hospital readmissions.[25] Education is a necessary process that allow patients to understand basic health information and thus make appropriate lifestyle changes.[26] Therefore, an initial step to improve patient's adherence to treatment could be focused in increasing knowledge about what is considered a healthy diet in heart failure. Moreover, it seems that multidisciplinary teams play a fundamental role in the education process, allowing heart failure patients to have an adequate understanding of their condition.[27]

Quality of diet

By using the 24-hour recall we demonstrated a reduction in lipid consumption, increase in carbohydrate percent and caloric reduction. Lipid changes may result in long term benefits including a better lipid profile, as well as possible reductions in the inflammatory state and oxidative stress in these patients.[28,29] The observed increase in percent carbohydrate consumption might be explained by the lipid reduction (grams), altering the proportion of macronutrients. Regarding caloric reduction, experimental studies using animal models show that caloric restriction leads, besides the change in body composition, to the reduction in oxidative damage, reduction in cardiac functional decline, improvement of insulin sensitivity and neuroendocrine function.[30] Taken together, those changes might result in long-term benefits to heart failure patients. However, those theoretical benefits must be evaluated in properly conducted trials.

Sodium intake

Reduction in sodium intake may help to prevent hospitalizations for decompensated heart failure[31]. In the present study, using a general food orientation, we found a significant reduction in reported sodium consumption in the intervention group. In our patients, baseline urine sodium values were higher than those recommended in the literature, showing low adherence to the recommendations of sodium restriction.[3] The observed low adherence reinforces the intervention and its potential role in these patients. In a previous randomized clinical trial limited to examine the effects of guidance of sodium for patients with heart failure, there was also a significant reduction in reported consumption of sodium three months after intervention.[15] While that study shows that it is possible to modify sodium consumption, it did not approach other important dietetic aspects.

Furthermore, we found no correlation between calculated 24-hour recall sodium and values of urine excretion. In fact, 24-hours urine sodium excretion is widely used as a marker of sodium intake; however a recent study by Arcand et al showed that 24-hour urine sodium excretion does not agree with food records in

heart failure patients who are taking loop diuretics.[32] Since over 90% of our sample was on diuretics, that may explain the lack of correlation we found between the two measures.

Anthropometric parameters and quality of life

In the present study, there was no significant modification in anthropometric parameters and quality of life with food orientation. Ramirez et al, in a similar study, found no significant differences between the anthropometric and biochemical parameters comparing dietary intervention and control groups, but there was improvement in quality of life and urinary sodium excretion.[33] In that study, the intervention was performed by prescribing specific diet plans, while we provided general information on what is a healthy diet for patients with heart failure, as well as educational materials.

Nutritional management in heart failure

Outcomes related to diet are notoriously difficult to measure accurately. Furthermore, the sensitivity to change should be considered in the implementation of nutritional intervention. Some subjects are less sensitive to change than others, especially in an intervention of short duration and with fewer repetitions. Thus, attention should focus on changes that subjects find it more difficult to do, rather than the concept of healthy eating as a whole.[34] Therefore it was not surprising that significant difference were detected for some but not for all outcomes studied. Perhaps dietary prescription combined with general guidelines could result in a structured dietary guide to facilitate choices. In fact, the nutritional management should ideally be individualized, taking into account drug therapy, multiple comorbidities and potential needs of nutritional supplements, admissions, retention and salt, voluntary versus involuntary weight loss, and other issues relevant to the population in the age group that comprises the majority of patients with heart failure.[35]

This study should be interpreted taking into account some limitations. We observed a trend for better quality of life with our intervention, and that benefit might be statistically confirmed with a larger number of patients. Also, the 24-hour recall may not accurately describe the dietary habits of the patient. In order to minimize that, after the interviews we asked if the day was atypical. In that case, urine collection and recall were repetead on another day. Finally, we need more clinical trials that establish the relationship of diet quality with clinical improvement in patients with heart failure.

In conclusion, this randomized clinical trial showed that a nutritional orientation, as a tool to help in non-pharmacological treatment in heart failure, was an alternative to improve the level of knowledge about nutrition, as well as diet quality. Further clinical studies are needed to assess the impact of these changes on laboratory profile and disease progression.

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