

ORIGINAL ARTICLE

Nutritional Intervention in Malnourished Hospitalized Patients with Heart Failure

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Background and Aims. Hospitalized patients with heart failure who are malnourished present a worse prognosis than those with an adequate nutritional status. We undertook this study to assess whether a nutritional intervention in malnourished hospitalized patients with heart failure benefits morbidity and mortality.

Methods. A multicenter, randomized, controlled clinical trial was conducted. A total of 120 malnourished hospitalized patients due to acute heart failure were randomised to conventional heart failure treatment or conventional heart failure treatment combined with an individualized nutritional intervention. The primary endpoint of this study was a composite of all-cause death or readmission for worsening of HF, with a maximum follow-up of 12 months. Analysis was by intention to treat.

Results. Recruitment was stopped early according to the study protocol after completing the follow-up of the first 120 patients enrolled (59 in the intervention group and 61 in the control group). Both groups were homogeneous in baseline characteristics. At 12 months, the primary outcome occurred in 27.1% of patients in the intervention group and in 60.7% of patients in the control group (hazard ratio 0.45; 95% confidence interval [CI], 0.19–0.62, p = 0.0004). In total, 20.3% of patients died in the intervention group and 47.5% in the control group (hazard ratio 0.37, 95% CI, 0.19–0.72, p = 0.003). Readmission due to heart failure was also lower in the intervention group (10.2 vs. 36.1%, p = 0.001).

Conclusion. Nutritional intervention in malnourished hospitalized patients with heart failure reduces the risk of death from any cause and the risk of readmission for worsening of heart failure (ClinicalTrial.gov NCT01472237). © 2016 IMSS. Published by Elsevier Inc.

Key Words: Heart failure, Malnutrition, Nutritional intervention, Clinical trial, Outcomes.

Introduction

Malnutrition is a prevalent disorder that affects up to 25% of patients hospitalized with heart failure (1). These patients show a worse prognosis than those with an adequate

nutritional status; thus, malnutrition is associated with higher mortality (2) and with an increased risk of readmission due to heart failure (3), as well as being an independent predictor of mortality (1,2). Despite the clinical relevance of malnutrition in these patients, it is unknown whether a nutritional intervention can modify their prognosis. Only a few studies published to date have assessed the effect of nutritional intervention in patients with heart failure, and those studies have assessed the effect on general series

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Table 1. Characteristics of the patients at baseline

| | Total cohort $(n = 120)$ | Control $(n = 61)$ | Intervention $(n = 59)$ | р |
|---|--------------------------|--------------------|-------------------------|------|
| Age (years) | 79.2 ± 7 | 79.8 ± 7 | 78.6 ± 7.1 | 0.38 |
| Female (%) | 62.5 | 60.7 | 64.4 | 0.67 |
| Decompensated chronic HF (%) | 65 | 65.6 | 64.4 | 0.89 |
| Previous hospitalization for HF (%) | 34.2 | 35 | 33.9 | 0.9 |
| LVEF (%) | 48.5 ± 17.3 | 48.2 ± 17.5 | 48.8 ± 17.2 | 0.97 |
| LVEF < 50% (%) | 43.3 | 44.3 | 42.4 | 0.84 |
| Ischemic etiology of HF (%) | 40 | 39.3 | 40.7 | 0.94 |
| Hypertension (%) | 75 | 80.3 | 69.5 | 0.17 |
| Hyperlipidemia (%) | 29.2 | 26.2 | 32.2 | 0.47 |
| Diabetes (%) | 48.3 | 49.2 | 47.5 | 0.85 |
| COPD (%) | 15 | 11.5 | 18.6 | 0.27 |
| Heart rate (beats/min) | 79.6 ± 12.3 | 80.3 ± 19.9 | 78.8 ± 14.3 | 0.63 |
| Systolic blood pressure (mmHg) | 130.9 ± 26.2 | 131 ± 28.1 | 130.8 ± 24.5 | 0.96 |
| GFR $(mL/min/1.73 m^2)$ | 58.8 ± 29.8 | 58 ± 32.9 | 59.5 ± 26.4 | 0.78 |
| GFR $<60 \text{ mL/min}/1.73 \text{ m}^2$ (%) | 58.3 | 59 | 57.6 | 0.9 |
| Hemoglobin (g/dL) | 11.9 ± 1.8 | 12 ± 1.9 | 11.8 ± 1.7 | 0.42 |
| Serum sodium (mEq/L) | 140.2 ± 3.8 | 140.2 ± 4.2 | 140.1 ± 3.4 | 0.96 |
| NTproBNP (pg/mL) | 10285 ± 9231 | 10786 ± 10301 | 9783 ± 8079 | 0.87 |
| Charlson index | 3.9 ± 2.1 | 4 ± 2.2 | 3.8 ± 2 | 0.63 |
| Serum albumin (g/dL) | 3.44 ± 0.49 | 3.42 ± 0.54 | 3.46 ± 0.44 | 0.62 |
| Serum albumin ≤ 3.4 g/dL (%) | 49.2 | 50.8 | 47.5 | 0.71 |
| Serum prealbumin (mg/dL) | 15.5 ± 6 | 15.9 ± 5.8 | 15.1 ± 6.1 | 0.51 |
| Serum transferrin (mg/dL) | 240.7 ± 63.4 | 232.5 ± 70.7 | 248.5 ± 55 | 0.2 |
| Total cholesterol (mg/dL) | 139.1 ± 39.5 | 135.14 ± 37.5 | 143 ± 41.4 | 0.28 |
| Lymphocytes/µL | 1314 ± 1010 | 1466 ± 1294 | 1160 ± 569 | 0.18 |
| Body mass index (kg/m ²) | 25.2 ± 5.2 | 24.7 ± 5.1 | 25.5 ± 5.4 | 0.41 |
| Tricipital skinfold thickness (mm) | 14.6 ± 7.4 | 13.9 ± 7.4 | 15.3 ± 7.4 | 0.3 |
| Arm muscle circumference (cm) | 19.6 ± 2.4 | 19.8 ± 2.5 | 19.3 ± 2.3 | 0.31 |
| MNA score | 14.3 ± 2.4 | 14.1 ± 2.6 | 14.4 ± 2.3 | 0.41 |
| Heart failure drugs at baseline (%) | | | | |
| Intravenous inotropic support | 12.5 | 13.1 | 11.9 | 0.84 |
| Intravenous loop diuretic | 99.2 | 98.8 | 100 | 0.32 |
| Intravenous nitrates | 3.3 | 3.3 | 3.4 | 0.97 |
| ACEI/ARB-II | 73.3 | 73.8 | 72.9 | 0.84 |
| Beta-blocker | 61.7 | 60.6 | 62.7 | 0.77 |
| Treatment at discharge (%) | | | | |
| Diuretic | 97.5 | 96.4 | 98.3 | 0.53 |
| Beta-blocker | 68.3 | 67.3 | 69.5 | 0.8 |
| ACEI/ARB-II | 85 | 83.6 | 86.4 | 0.67 |
| Mineralocorticoid antagonist | 34.2 | 34.5 | 33.9 | 0.94 |

ACEI/ARB-II, angiotensin converting enzyme inhibitors/angiotensin II receptor blockers; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; HF, heart failure; LVEF, left ventricle ejection fraction; MNA, Mini Nutritional Assessment.

regardless of the baseline nutritional status of the patient, with modest aims and without assessing the effect on survival or hospital admission (4-6). The proposals and results were similar in patients with cardiac cachexia (7).

The main aim of the PICNIC study (Nutritional Intervention Program in Hospitalised Patients with Heart Failure who are Malnourished) was to assess whether a nutritional intervention in malnourished hospitalized patients with heart failure provides benefits in terms of morbidity and mortality.

Patients and Methods

The study design has been previously published (8). PICNIC is a multicenter, randomized controlled clinical trial in which patients > 18 years old hospitalized for acute heart failure, either decompensated chronic heart failure or new onset heart failure, also presenting malnutrition, were randomly assigned to a conventional treatment for heart failure or a conventional treatment for heart failure combined with a more individualized nutritional intervention. The investigation conforms with the principles outlined in the Declaration of Helsinki. The research protocol was approved by the ethics committees of each of the participating centers and all patients signed informed consent. The recruitment began in March 2012.

Diagnosis of Malnutrition

The diagnosis of malnutrition was established according to the Mini-Nutritional Assessment (MNA) score. This survey, Download English Version:

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