

# Assessing Health-Related Quality of Life in Patients Receiving Home Enteral Nutrition with a Disease-Specific Tool (NutriQoL<sup>®</sup>): A Prospective Observational Study in Spain

Jose Antonio Irles-Rocamora<sup>1</sup>, Maria Nuria Virgili Casas<sup>2</sup>, Julia Álvarez-Hernández<sup>3</sup>, Estefanía Jiménez Licera<sup>1</sup>, Felisa Pilar Zarco Rodríguez<sup>1</sup>, Eva M García Raimundo<sup>2</sup>, Gloria Creus Costas<sup>2</sup>, Luis Lizán<sup>4</sup>, Mercedes Blanco Naveira<sup>5</sup>, Miguel Layola Brías<sup>5</sup>

<sup>1</sup>Departament of Endocrinology and Nutrition, Hospital Universitario Virgen de Valme, Sevilla, Spain; <sup>2</sup>Service of Endocrinology and Nutrition, Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Barcelona, Spain; <sup>3</sup>Service of Endocrinology and Nutrition, Hospital Universitario Príncipe de Asturias, Alcalá de Henares, Madrid, Spain; <sup>4</sup>Outcomes'IO, SLU, Castellón de la Plana, Castellón, Spain; <sup>5</sup>Medical Department, Nestlé Health Science, Barcelona, Spain

Correspondence: Jose Antonio Irles-Rocamora, Departament of Endocrinology and Nutrition, Hospital Universitario Virgen de Valme, Sevilla, 41014, Spain, Email irles@us.es

**Introduction:** Home enteral nutrition (HEN) is recommended for patients with nutritional requirements who can stay outside the hospital environment. HEN guidelines recommend assessing health-related quality of life (HRQoL) to evaluate the effect of the treatment. In this context, NutriQoL<sup>®</sup> is a specific questionnaire developed to assess HRQoL in patients receiving HEN and validated in Spanish population.

**Methods:** This was a prospective observational study was conducted in two Spanish hospitals to record and describe the evolution of HRQoL, in patients receiving HEN in routine clinical practice using NutriQoL<sup>®</sup>.

**Results:** Fifty-seven patients participated in the study, of whom 36 patients attended at least one visit during the 6-month follow-up period. Most of them were at risk or moderate malnutrition (61.1%) or showed severe malnutrition (27.8%) at baseline. The mean (SD) NutriQoL score obtained at baseline was 69.4 (12.6), which increased to 71.0 (14.6) and 71.8 (14.1) at 3 and 6 months of follow-up, respectively. Approximately 60% of patients had good HRQoL, while 25% had excellent HRQoL. At 6-months follow-up visit, 46.4% of patients had good HRQoL, and 32.1% excellent. Patients receiving oral HEN showed a higher score compared with those fed by a non-oral method/route. Proportion of patients at risk or with moderate malnutrition maintained at 6 months, and there were no patients with severe malnutrition, increasing the proportion of patients with normal nutrition to 38.5%. Additionally, physicians considered HRQoL evaluation useful for clinical practice. Limitations of the study include small sample size, and a loss follow-up after 6 months.

**Conclusion:** The assessment of HRQoL evolution using NutriQoL in patients receiving HEN appears valuable, as it provides valuable insights contributing to a more comprehensive nutritional evaluation and enhancing holistic patient care.

**Keywords:** malnutrition, home enteral nutrition, quality of life, NutriQoL, nutritional status, health status

## Introduction

Disease-related malnutrition (DMR) is a frequent condition among hospitalized patients, with a prevalence of 28% to 73%.<sup>1</sup> Nutritional status plays a significant role in the prognosis of the underlying disease, due to its impact on the immune function, increased infection rates, prolonged hospitalisation and increased mortality rates.<sup>2</sup> Therefore, DMR is a healthcare problem with serious consequences on clinical outcomes and patient's health-related quality of life (HRQoL)<sup>1,3</sup> and entails a high use of healthcare resources and associated costs.<sup>3,4</sup>

Patients with DRM who do not require hospitalisation, may benefit from home enteral nutrition (HEN), which is recommended for those who cannot meet their nutrition requirements by normal dietary intake but with functional gastrointestinal tract.<sup>5</sup> HEN facilitates the integration of patients into their social and familial environments, enabling the performance of daily activities and improving patient-reported outcomes (PROs) such as HRQoL, satisfaction, preferences, or adherence to treatment.<sup>6,7</sup>

Since HEN may have a considerable physical, social and psychological effect on the life of patients and their caregivers, the European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines recommend measuring HRQoL periodically in patients receiving HEN to evaluate the impact and effect of the treatment.<sup>5</sup> However, potential confounders such as underlying disease severity, comorbidities, and caregiver support may also influence HRQoL outcomes in patients receiving HEN.<sup>5,8,9</sup> NutriQoL<sup>®</sup> (Société des Produits Nestlé SA trademark) is a specific questionnaire designed to assess HRQoL in patients receiving HEN regardless of the underlying condition and the route of administration. It was developed and validated in Spanish population<sup>7,10,11</sup> and has been translated and adapted to French<sup>12</sup> and Italian<sup>13</sup> populations to support broader applicability. The questionnaire consists of 17 items, evaluating HRQoL in two dimensions (physical performance, daily life activities, and social aspects).<sup>7,10,11</sup> Additionally, the authors established the minimal clinically important difference (MCID) within a range between −4 and 4 points, indicating the smallest change in score deemed clinically relevant.<sup>10</sup>

Although recommended by guidelines, HRQoL is rarely assessed in patients receiving HEN, resulting in limited evidence on its evolution during HEN and true impact on patients' lives. Furthermore, HEN practices vary, as approaches to implementation and patient management differ across countries. To address this gap, the primary objective of our study was to evaluate the evolution of HRQoL in patients receiving HEN in routine clinical practice in Spain, using the NutriQoL<sup>®</sup> questionnaire. We also sought to characterize patients' sociodemographic and clinical profiles, assess their nutritional and disease status and treatment adherence, explore physicians' perceptions of the usefulness of HRQoL evaluation, and provide evidence for the minimal clinically important difference (MCID) in NutriQoL scores.

## Material and Methods

### Study Design

This was an observational, descriptive, prospective study carried out in ≥18 years old patients receiving HEN following routine clinical practice in two Spanish hospitals from November 2019 to July 2021. Patients were prospectively included in the study and followed-up during at least 6 months after inclusion. Data were collected by researchers from electronic health records and patient's questionnaires using an electronic case report form. Data were collected at the basal visit and after three and six months, as well as before HEN discontinuation if this happened before the final visit ([Supplementary Figure S1](#)).

Patients were recruited consecutively by physicians as they attended the consultation and met inclusion criteria, according to the usual clinical practice of each centre. Adult patients who met the following criteria were included in the study: receiving HEN for less than a month before starting the study, being able to answer the NutriQoL questionnaire (patients or caregivers), having an estimated survival over three months, and expectation of enteral nutrition lasting more than three months according to physicians' criteria. Written informed consent was obtained from all participating patients. Patients who needed a translated version of the NutriQoL and those who discontinued HEN before three months were excluded from the study.

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Bellvitge University Hospital (PR156/19). Written informed consent has been obtained from all subjects involved in the study.

### Sample Size

This is a pilot study, and the sample may not be fully representative of all HEN patients in Spain. Given the absence of prior long-term data on the use of this questionnaire, and considering that the registry was intended to describe the evolution of quality of life rather than to perform comparative analyses, we adopted a pilot-study framework in line with

published recommendations for sample estimation in this type of research.<sup>14</sup> For this reason, a sample size of approximately 10–40 patients per participating centre was established.

## Study Variables

Sociodemographic (age, sex) and clinical variables (weight, body mass index, nutritional status according to the SGA and GLIM, degree of dependency according to Barthel, Charlson's comorbidity index, HEN route of administration, patient's HRQoL and nutritional treatment adherence) were collected from all patients. Physicians reported their perspective regarding patients' health status, and the usefulness of HRQoL assessment. Standardized training and instructions were provided to all physicians to ensure consistency in completing the assessments.

## HRQoL Assessment

HRQoL was assessed in each visit using the NutriQoL questionnaire.<sup>9</sup> Briefly, this questionnaire evaluates the impact of HEN on HRQoL, which is classified into five categories defined according to the score obtained: 1) very poor: 0–20 points; 2) poor: 21–39 points; 3) acceptable: 40–60 points; 4) good: 61–80 points; 5) excellent: 81–100 points.

To provide evidence of the MCID, patients with a positive or negative difference of  $\geq 4$  points in the questionnaire were selected and classified into two subgroups.<sup>10</sup> For each subgroup, nutritional and health status evolution were described.

The usefulness of HRQoL evaluation for patient management was determined according to the physician's perception, responding on a scale from 0 (not useful at all) to 10 (very useful) to the following question: *How would you value the usefulness of HRQoL evaluation for patient management?*

## Nutritional Status Evolution

Patients receiving HEN were classified into three categories according to the subjective global assessment (SGA): 1) normal nutrition (category A); 2) risk or moderate malnutrition (B); 3) severe malnutrition (C). Additionally, patients were classified into two categories according to malnutrition severity following the Global Leadership Initiative on Malnutrition (GLIM) criteria:<sup>15</sup> 1) moderate malnutrition (grade 1); 2) severe malnutrition (grade 2).

## Health Status Evolution

Physicians evaluated the patient's health status on each visit responding on a scale from 0 (very bad) to 10 (very good) to the following question: *How do you consider patients' health status in relation to the underlying disease or main diagnose for which HEN is prescribed?* Incidences or interventions due to changes in the patient's health status as well as actions taken by the physicians were described.

## HEN Adherence

Patients were classified according to the categories in the previously validated HEN adherence questionnaire<sup>16</sup> into low (0–2 points), moderate (3–4 points), or high (5–6 points) adherence. The questionnaire is designed explicitly for HEN. This tool evaluates patient adherence through multiple dimensions of HEN management (eg, administration routines, handling of materials, and treatment follow-up) and has demonstrated adequate psychometric validity in terms of reliability and construct validity.<sup>16</sup>

## Statistical Analysis

Centrality and dispersion measures (mean, standard deviation [SD], minimum, P25, P50, P75, and maximum) were calculated for quantitative variables, while relative and absolute frequencies were obtained for the qualitative ones.

The analyses were performed in both the complete and the follow-up cohort using all valid data. Descriptive statistics were calculated according to valid data. Analysis was performed only with the data obtained. Missing data were reported for each case and were not considered for the analyses. Data imputation techniques were not used for any of the variables, as this approach is commonly avoided in small cohorts due to sample size sensitivity and the potential risk of bias.<sup>17</sup>

Data were analysed using the statistical package STATA version 14 and the statistical significance was set at  $p$ -value  $< 0.05$ .

## Results

### Sociodemographic and Clinical Characteristics at Baseline

A total of 57 patients met the inclusion criteria and were included in the study. Of these, 36 patients attended at least one follow-up visit during the 6-month follow-up period. These patients constituted the follow-up cohort, which limits the strength of the conclusions.

The mean age of the follow-up cohort was 53.8 years, being 47.2% women. More than half of the patients had an oncological comorbidity. Regarding the nutritional status at baseline of the follow-up cohort, 61.1% were at risk or with moderate malnutrition and 27.8% presented severe malnutrition according to the SGA. Additionally, 86.1% of the patients were moderately (67.7%) or severely (32.2%) malnourished according to GLIM criteria for malnutrition (Table 1).

**Table 1** Sociodemographic and Clinical Characteristics of the Follow-Up Cohort at Baseline

| Sociodemographic and Clinical Characteristics            | Follow-Up Cohort (N = 36) |
|----------------------------------------------------------|---------------------------|
| <b>Age</b> , years (mean [SD])                           | 53.8 (17.2)               |
| <b>Sex</b> (n [%])                                       |                           |
| Women                                                    | 17 (47.2)                 |
| Men                                                      | 19 (52.8)                 |
| <b>Usual weight</b> , kg (mean [SD])                     | 67.7 (16.4)               |
| <b>Basal weight</b> , kg (mean [SD])                     | 61.6 (14.2)               |
| <b>BMI</b> , kg/m <sup>2</sup> (mean [SD])               | 22.2 (4.3)                |
| <b>Nutritional status according to SGA</b> (n [%])       |                           |
| Normal nutrition                                         | 4 (11.1)                  |
| Risk or moderate malnutrition                            | 22 (61.1)                 |
| Severe malnutrition                                      | 10 (27.8)                 |
| <b>Nutritional status according to GLIM</b> (n [%])      |                           |
| Moderate malnutrition (grade 1)                          | 21 (67.7)                 |
| Severe malnutrition (grade 2)                            | 10 (32.3)                 |
| <b>Degree of dependency according to Barthel</b> (n [%]) |                           |
| Independence                                             | 23 (63.9)                 |
| Low dependency                                           | 6 (16.7)                  |
| Moderate dependency                                      | 3 (8.3)                   |
| Severe dependency                                        | 2 (5.6)                   |
| Full dependency                                          | 2 (5.6)                   |
| <b>Charlson's index</b> (mean [SD])                      | 3.0 (2.6)                 |
| <b>Motive for HEN prescription</b> (n [%])               |                           |
| Swallow or transit mechanic alterations                  | 16 (44.4)                 |
| Clinical situations involving severe malnutrition        | 10 (27.8)                 |
| Neuromotor disorders that prevent swallowing or transit  | 5 (13.9)                  |
| Special energy and/or nutrient requirements              | 4 (11.1)                  |
| Others                                                   | 1 (2.8)                   |
| <b>Route of HEN administration</b>                       |                           |
| Oral                                                     | 19 (52.8)                 |
| Nasojejunal tube                                         | 3 (8.3)                   |
| Nasogastric tube                                         | 5 (13.9)                  |
| Gastrostomy                                              | 8 (22.2)                  |
| Jejunostomy                                              | 1 (2.8)                   |

**Abbreviations:** BMI, body mass index; GLIM, Global Leadership Initiative on Malnutrition; SD, standard deviation; SGA, subjective global assessment.

Sociodemographic and clinical characteristics of complete cohorts are shown in [Supplementary Table S1](#).

## HEN Characteristics

At baseline, 16 (44.4%) and 10 (27.8%) patients in the follow-up cohort reported requiring HEN due to swallowing or transit mechanical alterations or clinical situations involving severe malnutrition, respectively. In relation to the route of administration, 19 (52.8%) and 17 (47.2%) patients were fed orally and by tube or ostomy, respectively ([Table 1](#)).

During the follow-up, six patients discontinued HEN due to improvements in their health state, transition to oral nutrition or pregnancy, while one patient discontinued because of disease progression.

HEN characteristics for the complete cohort are shown in [Supplementary Table S1](#).

## HRQoL Evaluation

Data on the evolution of the HRQoL during the study correspond to the 36 patients of the follow-up cohort.

The mean (SD) NutriQoL score obtained at baseline was 69.4 (12.6), which increased to 71.0 (14.6) and 71.8 (14.1) after three and six months of follow-up, respectively. As stated by the categories established by the NutriQoL questionnaire, approximately 60% of the patients had a good HRQoL at baseline, while 25% had an excellent HRQoL. At six-months follow-up visit, 46.4% of patients had a good HRQoL, while the percentage of patients with an excellent HRQoL increased to 32.1% ([Table 2](#)).

According to the route of administration, patients who received oral HEN showed a higher NutriQoL score compared with those fed by a non-oral method/route ([Table 2](#)).

At each visit, most of patients (84.4–90.3%) self-completed the NutriQoL; only 9.7–15.6% were responded by their caregivers.

## Minimal Clinically Important Difference

At the month 3 visit, 21 (67.7%) patients with available data showed improvements in HRQoL, with 15 (48.4%) patients reaching a clinically significant improvement ( $\geq 4$  points). However, seven (22.6%) patients significantly worsened their HRQoL ( $\leq -4$  points).

**Table 2** NutriQoL<sup>®</sup> Scores

|                                                                                | Follow-Up Cohort     |                     |                     |
|--------------------------------------------------------------------------------|----------------------|---------------------|---------------------|
|                                                                                | Baseline<br>(n = 36) | Month 3<br>(n = 31) | Month 6<br>(n = 28) |
| <b>NutriQoL<sup>®</sup> score, mean (SD)</b>                                   | 69.4 (12.6)          | 71.0 (14.6)         | 71.8 (14.1)         |
| <b>HRQoL category (n [%])</b>                                                  |                      |                     |                     |
| Very deficient                                                                 | 0 (0.0)              | 0 (0.0)             | 0 (0.0)             |
| Deficient                                                                      | 0 (0.0)              | 0 (0.0)             | 1 (3.6)             |
| Acceptable                                                                     | 5 (13.9)             | 8 (25.8)            | 5 (17.9)            |
| Good                                                                           | 22 (61.1)            | 12 (38.7)           | 13 (46.4)           |
| Excellent                                                                      | 9 (25.0)             | 11 (35.5)           | 9 (32.1)            |
| <b>NutriQoL<sup>®</sup> score according to administration route, mean (SD)</b> |                      |                     |                     |
| Oral                                                                           | 76.1 (11.1)          | 79.8 (7.8)          | 77.3 (11.4)         |
| Non-oral                                                                       | 61.9 (9.8)           | 57.0 (11.5)         | 61.9 (13.5)         |

**Abbreviations:** HRQoL, health-related quality of life; SD, standard deviation.

At six months, 15 (53.6%) of the 28 patients still receiving HEN and with available data showed HRQoL improvements from baseline (14 patients with a clinically significant improvement, and one an improvement between 0 and 4 points). Ten (35.7%) patients showed a significantly worse HRQoL (Table 3).

Overall, reporting of the MCID allowed us to capture both meaningful improvements and deteriorations in HRQoL. Notably, while a proportion of patients achieved clinically relevant improvements, others experienced worsening beyond the MCID threshold, highlighting the importance of interpreting changes in both directions.

## Usefulness of HRQoL Evaluation

Physicians reported that HRQoL evaluation was useful for patient management, with a mean (SD) score at month 3 and month 6 visits of 7.10 (1.42) and 7.13 (0.99), respectively.

## Nutritional Status Evaluation

The analysis of patients' nutritional status according to the SGA showed that 61.1% were at risk or with moderate malnutrition and 27.8% presented severe malnutrition at baseline. Even though the proportion of patients at risk or with moderate malnutrition maintained at six months, the percentage of patients with severe malnutrition decreased to 0.0%, increasing the proportion of patients with normal nutrition to 38.5% (Figure 1A).

In addition, the analysis of the 15 patients that significantly improved their HRQoL showed that all of them were, at least, at risk or suspicion of malnutrition. After three months, 40.0% of them showed normal nutrition and only 6.7% were severely malnourished (Figure 1B).

The nutritional evaluation following GLIM criteria showed that most ( $n = 31$ , 86.1%) patients were malnourished at baseline. Of these, 67.7% and 32.3% were classified with moderate and severe malnutrition, respectively. Sixteen patients met malnutrition criteria at six-months visit; 75% and 25% of them had moderate and severe malnutrition, respectively (Figure 2A).

Most (80–88.9%) of the patients with clinically significant HRQoL improvement after three months of follow-up showed moderate malnutrition at both basal and month 3 visits (Figure 2B). In addition, a reduction in the percentage of patients who met GLIM criteria for malnutrition was observed (Table 4).

## Health Status Evaluation

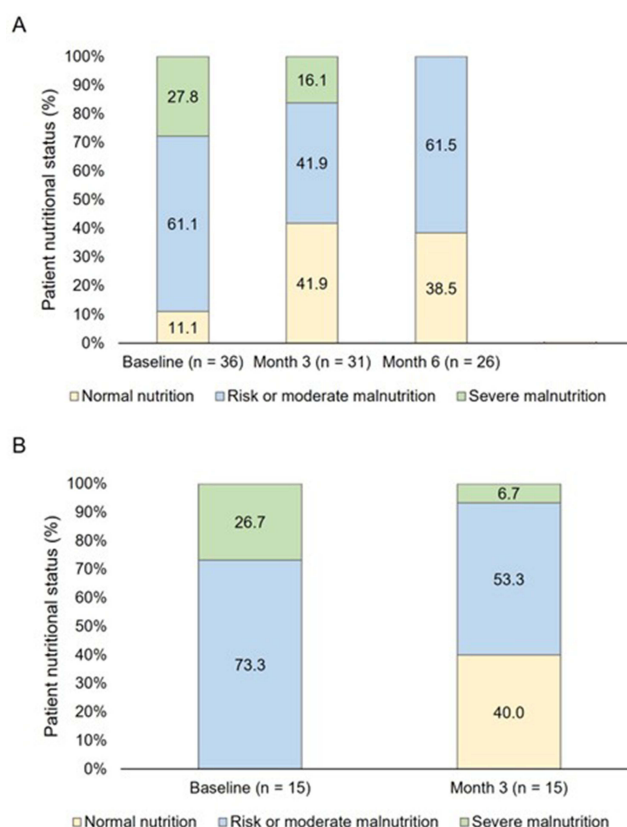
Physicians scored the health status of the patients with a mean (SD) value of 6.53 (1.73) at baseline. This value, and consequently, patients' health status, increased during the follow-up visits up to a mean (SD) score of 7.04 (1.69) at month 6.

**Table 3** Distribution of Patients According to the Difference in NutriQoL<sup>®</sup> Score Obtained in the Different Visits

|                                                      | Baseline-Month 3 | Month 3-Month 6 |
|------------------------------------------------------|------------------|-----------------|
| <b>Change in HRQoL</b>                               |                  |                 |
| Clinically significant improvement ( $\geq 4$ ), $n$ | 15               | 7               |
| Improvement ( $4 > \text{difference} > 0$ ), $n$     | 6                | 2               |
| No change (difference = 0), $n$                      | 0                | 2               |
| Worsening ( $0 > \text{difference} > -4$ ), $n$      | 3                | 3               |
| Clinically significant worsening ( $\leq -4$ ), $n$  | 7                | 9               |
| <b>HEN discontinuation*</b> , $n$                    | 0                | 7               |
| <b>Missing data</b> , $n$                            | 5                | 6               |
| <b>Total</b> , $n$                                   | 36               | 36              |

**Notes:** \*Discontinuation was due to improved health status, change to oral nutrition, gestation, disease progression, death, and loss to follow-up.

**Abbreviations:** HEN, home enteral nutrition; HRQoL, health-related quality of life.



**Figure 1** (A) Nutritional status evolution according to the subjective global assessment (SGA) in the follow-up cohort. Notably, no patients presented severe malnutrition at 6-month follow-up. (B) Nutritional status evolution according to the subjective global assessment (SGA) in patients with clinically significant health status improvement (n = 15). Almost half of the patients presented normal nutrition after 3 months. Interpretation of subgroup analyses is limited by small sample sizes.

## HEN Adherence

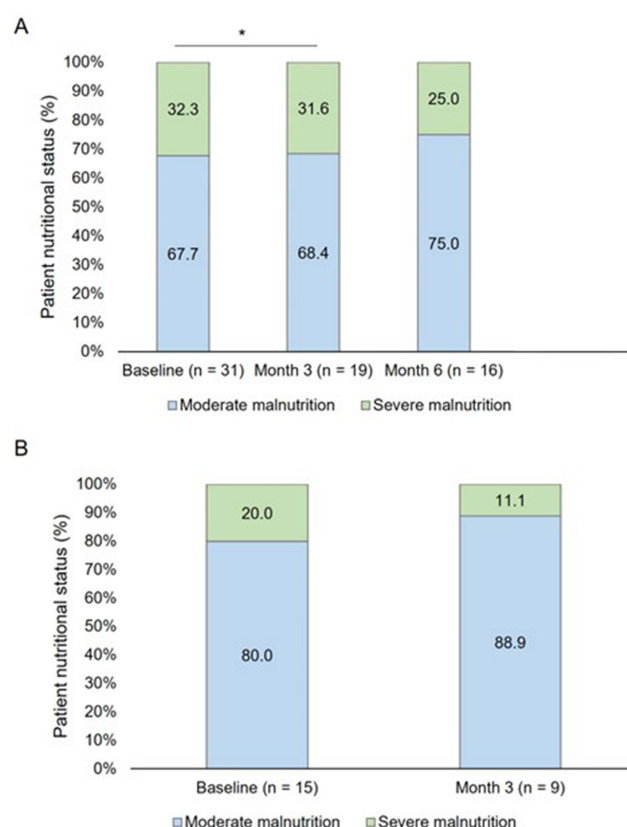
HEN adherence was moderate (58.1%) and high (41.9%) during the month 3 follow-up visit. The percentage of patients with moderate adherence decreased to 44.4% at month 6, while 11.1% of patients showed low adherence (Figure 3).

## Discussion

The evidence on HRQoL in patients receiving HEN is scarce and most of it is limited to data reported using a generic questionnaire.<sup>18,19</sup> The availability of detailed information on the HRQoL of patients receiving HEN is essential for optimizing patient care, since it provides valuable insights into how nutritional interventions impact on patients' daily living, beyond clinical measurements.<sup>20</sup>

In our study, we describe and register the evolution of the HRQoL during 6 months in patients receiving HEN in Spanish routine clinical practice using NutriQoL questionnaire. Patients included in the study reported a NutriQoL score of 69.4 points at baseline, which increased to 74.3 points at the end of the follow-up period, showing a good HRQoL at both visits. In this sense, the percentage of patients with a good HRQoL slightly increased after 6 months. However, it should be noted that a subset of patients experienced a clinically relevant worsening in HRQoL, highlighting the heterogeneity of responses, which may reflect unmet clinical or nutritional needs, treatment limitations, or insufficient support.<sup>9</sup>

The use of a specific questionnaire such as NutriQoL offers several advantages. First, it enables a comprehensive assessment of HRQoL, focusing on the challenges faced by patients undergoing HEN, including physical, social and emotional factors, which are accurately captured, leading to more reliable data for clinical decision-making. This approach enhances the ability to monitor patient progress, identify areas of concern, and adjusting nutritional treatment plans accordingly, ultimately contributing to improving patient outcomes and satisfaction.<sup>9,11</sup>



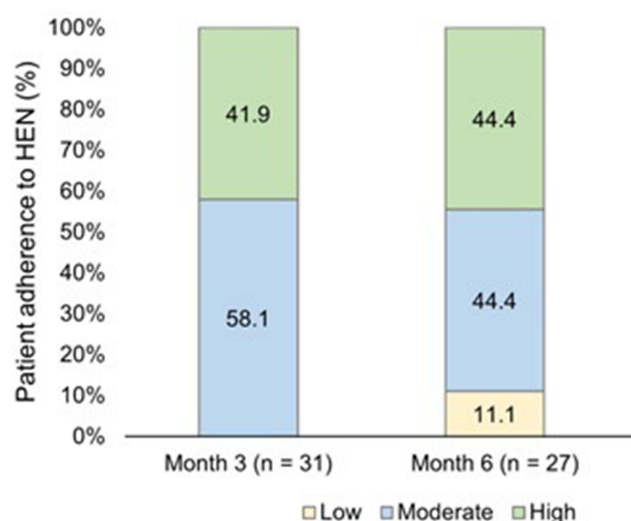
**Figure 2** Nutritional status evolution according to the Global Leadership Initiative on Malnutrition (GLIM) criteria in the follow-up cohort (**A**) and in patients with clinically significant health status improvement (n = 15) (**B**). \*p < 0.05. Interpretation of subgroup analyses is limited by small sample sizes.

The use of the NutriQoL also enabled the identification of patients with HRQoL changes reaching clinical significance, as defined by the MCID. Thus, at the month 3 follow-up visit, 15 patients showed a clinically significant improvement in their HRQoL. Their nutritional status improved at the first visit, with fewer patients reporting severe

**Table 4** Evolution of the GLIM Criteria for Malnutrition in Patients with Clinically Significant Health Status Improvement

|                                    | Basal Visit | Month 3  |
|------------------------------------|-------------|----------|
| <b>Phenotypic criteria (n [%])</b> |             |          |
| Weight loss                        | 8 (53.3)    | 3 (20.0) |
| Low BMI                            | 6 (40.0)    | 5 (33.3) |
| Muscle mass loss                   | 8 (53.3)    | 5 (33.3) |
| Others                             | 3 (20.0)    | 5 (33.3) |
| <b>Etiologic criteria (n [%])</b>  |             |          |
| Reduce intake or food assimilation | 7 (46.7)    | 4 (26.7) |
| Inflammation                       | 10 (66.7)   | 9 (60.0) |
| Others                             | 1 (6.7)     | 3 (20.0) |

**Abbreviation:** BMI, body mass index.



**Figure 3** Patient adherence to HEN in follow-up cohort at month 3 and 6.

malnutrition according to both the SGA and GLIM criteria. This reinforces the value of NutriQoL as a validated, disease-specific tool for monitoring patient-reported outcomes in HEN, complementing clinical and nutritional assessments.<sup>9</sup>

Regarding the HRQoL evaluation throughout the follow-up period, the results show that NutriQoL score increased over time, regardless of the route of administration, with patients receiving non-oral HEN showing a greater improvement after 6 months of follow-up. This is in line with previous findings demonstrating that HRQoL outcomes in HEN patients are consistent across administration routes.<sup>10,21</sup>

Data on the use of NutriQoL are still scarce and limited to the Spanish population, but our results are in line with those previously published using this questionnaire; these showed that patients receiving HEN had a good HRQoL according to the NutriQoL score, which was higher in those receiving oral HEN compared with non-oral HEN.<sup>9,11</sup> Zamanillo et al reported an increase in the NutriQoL score after two months in patients with oral HEN but not in those with non-oral HEN.<sup>11</sup> Possible explanations for the greater long-term gains observed in patients receiving non-oral HEN may relate to baseline disparities in nutritional status and treatment needs, such as patients who cannot maintain adequate oral intake and therefore require HEN, partly accounting for these differences.<sup>22</sup> We observed the same trend after three and six months of follow-up, showing that evaluating HRQoL for a longer period in patients receiving HEN is needed and should be included as an outcome variable in the studies. Overall, our results and those from previous studies show that NutriQoL is valid and reliable tool to evaluate HRQoL, detecting variations in health status in patients receiving HEN regardless of their underlying condition, route of administration, and who responds to the questionnaire.

In the follow-up cohort, the nutritional status improved by the end of the follow-up period, reporting fewer patients at risk of malnutrition or severe malnutrition in favour of normal nutritional status. The observed improved nutritional status could be related to the high proportion of patients with at least moderate treatment adherence.

It is important to highlight that more than half of the patients in our cohort were oncologic patients. Previous studies in the field have reported that these patients can benefit from HEN following surgery. For example, Wu et al showed that patients with oesophageal cancer receiving HEN improved their nutritional status and HRQoL after three months of HEN following esophagectomy.<sup>23</sup> In this regard, two systematic reviews showed that HEN prevented weight loss in patients with gastric cancer after the surgery.<sup>24,25</sup> In addition, the results of their meta-analysis revealed that these patients improved their physical function and fatigue dimension but did not significantly improve their global HRQoL.<sup>24,25</sup> Noteworthy, the reviewed studies used different HRQoL questionnaires thus, standardising HRQoL assessment in clinical practice would be of help for results comparison and evaluation.

Finally, according to physicians' evaluation, the evolution of patients' health status related to the underlying disease for which HEN was prescribed was favourable. This is of special interest as HRQoL improvement is probably related to the nutritional status evolution.<sup>18,26</sup> In addition, while physicians reported NutriQoL<sup>®</sup> as a useful tool, its integration into

real-world practice may face barriers such as time constraints or differences in clinical workflow, which should be considered when evaluating its broader implementation.<sup>27</sup>

Our study presents strengths and limitations. The study has a prospective design and a 6-month follow-up period. This design enables the capture of dynamic changes in both HRQoL and nutritional status over time, providing reliable data on the long-term impact of HEN. Moreover, following the ESPEN guidelines<sup>5</sup> recommendations, NutriQoL questionnaire was used to assess HRQoL reported by both patients and caregivers in patients with oral and tube HEN. The routine use of NutriQoL<sup>®</sup> may strengthen clinical practice by integrating HRQoL monitoring into nutritional management and adherence strategies, allowing clinicians to detect early signs of treatment burden, adapt interventions to patient needs, and ultimately improve long-term outcomes. Although we did not evaluate HRQoL using a generic questionnaire (due to its limitation to detect changes in HRQoL in patients with HEN), previous studies have shown a low correlation between generic questionnaires, such as EQ-5D, COOP/WONCA, and SF-12, and NutriQoL, which is more specific for patients with HEN.<sup>9,11</sup> On the other hand, the statistical power was not formally calculated, and therefore,  $n=57$  may be underpowered for subgroup analysis and potentially lead to false negatives. Furthermore, the reduced follow-up cohort (36 of 57 patients) represents an important limitation, as it may restrict the generalizability of our findings and introduce potential bias in the interpretation of long-term outcomes. Moreover, the study was developed during the COVID-19 pandemic, which hindered the recruitment capacity of the centres. Although further studies will be needed to confirm these results, the assessment of the clinical significance of NutriQoL scores showed an improvement in patients' HRQoL and nutritional and health status. Reflecting routine clinical practice, our study sample was heterogeneous, although with most subjects being oncological patients, who typically have a more deteriorated HRQoL and tend to be more engaged in their treatment and follow-up compared to patients with other conditions. This could have influenced the results obtained. The increased number of oncologic patients could also limit generalizability. In this context, further research including a high number of patients with different pathologies is needed to understand how HEN impacts their HRQoL according to their underlying disease and the degree of involvement of both patients and physicians in patient care. Furthermore, the evaluation of patients' health status by the physicians could be considered subjective and therefore, using a validated tool for that purpose would be more suitable. In line, none of the patients in the study underwent functional assessment, which could be an important component of both nutritional evaluation and HRQoL assessment.

## Conclusions

In conclusion, the results of our study highlight the significant impact of implementing HEN in malnourished patients, leading to improvements in both their nutritional and health status, as well as their HRQoL. Additionally, the assessment of HRQoL evolution using the NutriQoL in patients receiving HEN appears valuable in routine clinical practice, as it provides valuable insights that not only contribute to a more comprehensive nutritional evaluation but also enhance holistic patient care. Further research through larger, multicenter, and international studies is recommended to validate and expand upon our findings, ensuring their generalizability across diverse healthcare settings and patient populations.

## Data Sharing Statement

Data will be made available on reasonable request.

## Ethics Approval and Informed Consent

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Bellvitge University Hospital (PR156/19). Written informed consent has been obtained from all subjects involved in the study.

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## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

MBN and MLB work at Nestlé Health Science. MBN also reports a patent NutriQoL test licensed to Nestlé Health Science has the NutriQoL patent. LL works for an independent research entity, Outcomes'10, that received funding from Nestlé Health Science to conduct the project and for medical writing. The authors report no other conflicts of interest in this work.

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