


# Specific Quality of Life Assessment by the NutriQoL® Questionnaire Among Patients Receiving Home Enteral Nutrition

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## Abstract

**Background:** Home enteral nutrition (HEN), including tube feeding and oral supplementation, can improve or worsen quality of life (QoL). The specific assessment of factors affecting QoL may identify the inherent problems associated with HEN. The aim of this study was to evaluate whether the validated NutriQoL® questionnaire is useful for assessing the QoL and the factors influencing it in patients receiving HEN. **Methods:** A total of 78 patients receiving HEN completed both the NutriQoL and the SF-12 questionnaires during their routine visits to nutrition service at the hospital. **Results:** Ninety percent of patients receiving HEN had cancer, 58% received oral supplements, and 42% received tube feeding. At recruitment, the mean score  $\pm$  SD of the NutriQoL was  $66 \pm 14$ , whereas that of the SF-12 was  $40 \pm 9$ . A positive correlation between NutriQoL and SF-12 scores ( $\rho = 0.5$ ;  $P < .001$ ) was found. Multivariate analysis showed that HEN type (oral vs tube) (odds ratio [OR], 5.6; 95% CI 2.0–15.3;  $P = .001$ ) and the absence of secondary effects (OR, 3.0; 95% CI, 1.2–7.9;  $P = .024$ ) were both variables explaining NutriQoL results adjusted by sex and age. The SF-12 results did not show associations with nutrition factors. On visit 2, we observed significant improvements in NutriQoL results. **Conclusion:** The NutriQoL questionnaire identifies specific problems that affect the QoL of patients receiving HEN, whereas SF-12 does not. The route of entry and the occurrence of complications influence specific QoL. NutriQoL is a useful tool to identify the factors that worsen the QoL in patients receiving HEN. (*JPEN J Parenter Enteral Nutr.* 2021;45:490–498)

## Keywords

enteral nutrition; home nutrition support; NutriQoL; outcomes research/quality; quality of life; SF-12

## Clinical Relevancy Statement

Home enteral nutrition (HEN) is an effective nutrition intervention for patients with different diseases who have

increased nutrition requirements or swallowing difficulties. HEN is a medical treatment that impacts patients' quality of life (QoL). The NutriQoL® questionnaire evaluates the QoL of patients receiving HEN. NutriQoL has been

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recently released and validated; and the latest European Society for Clinical Nutrition and Metabolism (ESPEN) guideline on HEN proposed this questionnaire to measure specific QoL periodically in those patients. NutriQoL is a reliable tool independent of the route of entry (oral supplementation or tube nutrition), of the underlying cause for HEN, and of the person answering the questionnaire (caregiver or patient). This is the first study assessing QoL in a group of patients receiving HEN with the specific NutriQoL questionnaire to identify both the factors associated with QoL and the groups of risk that would need more clinical attention for HEN management.

## Introduction

Patients receiving home enteral nutrition (HEN) have specific difficulties that influence their quality of life (QoL), regardless of their cause and route of entry.<sup>1-3</sup> Recently, a specific questionnaire, named NutriQoL®,<sup>4</sup> has been developed to know the social and functional dimensions of daily life that are affected by HEN, including tube-fed and orally supplemented patients. This questionnaire, which can be completed by the patient or the caregiver, consists of only 17 items that can be answered during routine visits. The information that emerges from the questionnaire helps to make more accurate and focused decisions, specifically aimed at improving HEN, adherence to treatment, and the QoL of the patient.

The main objective of this study was to evaluate the QoL in patients receiving HEN, independent of their underlying disease and route of administration, through the validated NutriQoL questionnaire<sup>5</sup> to identify groups of risk whose QoL associated with HEN is more compromised, and, therefore, should receive special attention.

In addition, we also assessed the QoL through the SF-12 health questionnaire (version 2), a validated instrument for research on health outcomes and health services<sup>6-10</sup> so as to analyze the independence of the NutriQoL's results compared with the SF-12 ones and to assess the specificity of the NutriQoL questionnaire.

Finally, we studied the evolution of the QoL related to HEN that patients experienced during successive visits. This objective allowed us to describe changes over time in the results of the NutriQoL questionnaire, considering the usual periods between consultations that take place in the routine clinical practice of our hospital.

## Patients and Methods

### *Study Design and Participants*

It is a prospective study in which 78 patients receiving HEN were prospectively and consecutively invited to participate, between September 2018 and May 2019. Participants were eligible if they: (1) received HEN either orally or through a

tube, regardless not only of the underlying disease but also of whether they were chronic or new in the treatment with HEN; (2) were at least 18 years old; (3) could read Spanish or had a caregiver who could answer for them if they required it; (4) were in a physical and mental situation that allowed them to answer the questionnaires; and (5) were not participants in another research study simultaneously. This study was conducted in the Endocrinology and Nutrition Department of the Son Espases University Hospital (Palma de Mallorca, Balearic Islands, Spain).

### *Questionnaires and Variable Outcomes*

To achieve the main objective, the NutriQoL and the SF-12 questionnaires were distributed for the first time at recruitment, in case of chronic patients, or after 1 or 2 months following the start of HEN for new patients (Figure 1). Response options are Likert-type scales that evaluate the participant's level of agreement or disagreement and his or her intensity of feelings for a series of described states. A 0–100 scale is used to score all QoL results; the higher the score, the better the QoL.

To assess the evolution of the QoL, the NutriQoL questionnaire was also passed on the next successive visit 2 months after recruitment (Figure 1). All registered data were properly managed and transcribed from the questionnaires to the Data Collection Notebook (an Excel spreadsheet).

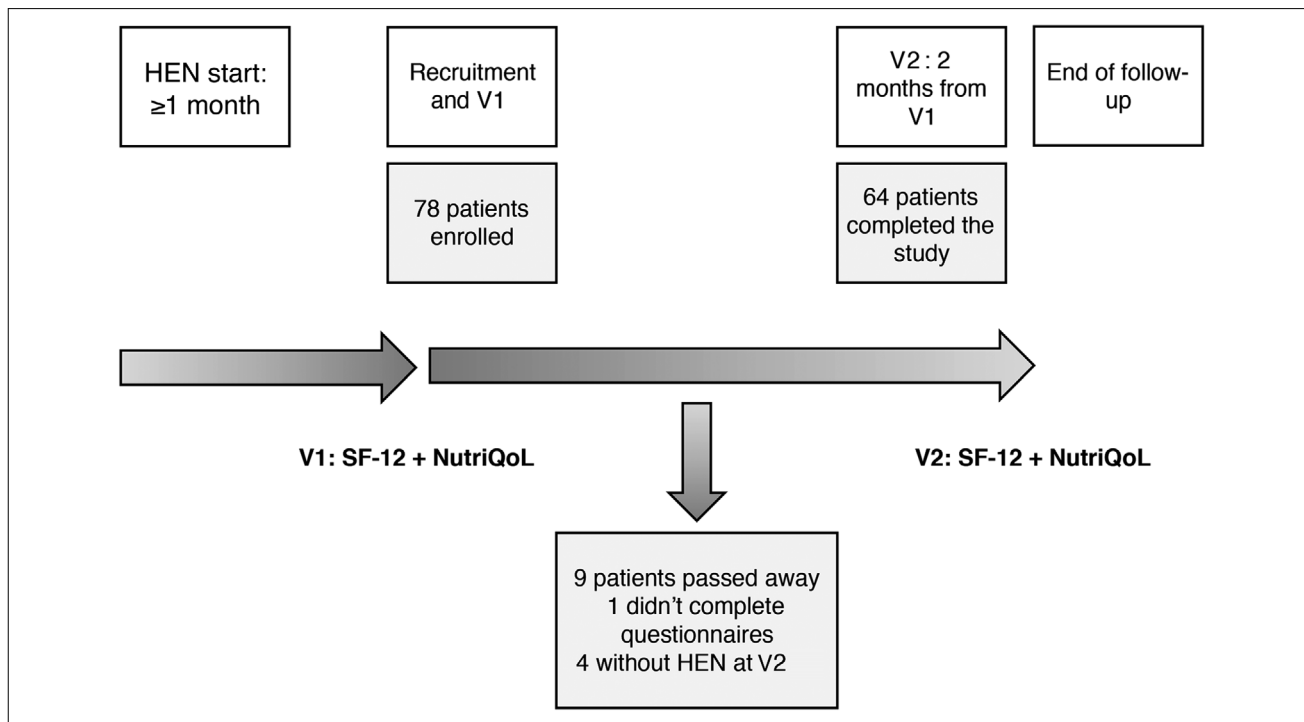
The NutriQoL questionnaire has 17 questions, each divided in 2 parts. The first part deals with the participant's frequency of feeling regarding some items related to HEN, to which they can answer “never,” “sometimes,” or “always.” The second part covers the importance the patient perceives of that item: not important at all, important, or very important.

The questionnaires dimensions were interpreted through resources provided by the developers of the questionnaire. The Nestlé Research Department provided an excel calculator for us to obtain not only the NutriQoL's total results but also the isolated results for both the “physical and daily activities” and the “social activities” dimensions.

In the case of the SF-12 (version 2), we obtained the results for the main dimensions of physical and mental status by using the available algorithms<sup>11</sup> and the Spanish reference body weights.<sup>7</sup>

Patients completed the NutriQoL and the SF-12 questionnaires while they were waiting for their appointments or during their routine visits with the dietitian-nutritionist (at baseline or on visit 1 and on visit 2).

Each patient also provided the following information: (1) demographic parameters, such as age and sex; (2) anthropometric parameters, such as weight (start and evolution with successive visits) and size; and (3) nutrition information, including duration of HEN, main disease causing HEN (cancer, neurodegenerative, digestive, or other), prescribed dose



**Figure 1.** Study design. HEN, home enteral nutrition; NutriQoL, NutriQoL questionnaire; SF-12, SF-12 questionnaire; V, visit.

of HEN and schedule, route of administration (oral or tube, including nasogastric, gastrostomy, or jejunostomy tubes), route changes during follow-up, method of administration by tube (gravity, syringe, or infusion per pump), need of help for tube feeding (autonomous vs dependent), HEN-related complications (psychological rejection, fullness, diarrhea, constipation, regurgitation, dumping, peristoma infection, dream disturbances, acidity, flavor disgust, or other adverse effects expressed by the patients themselves), and time since the first HEN or previous HEN experience.

### Ethical Aspects

The study was carried out based on the Declaration of Helsinki and in compliance with good clinical practices for research with humans. The Research Ethics Committee of the Balearic Islands (CEI-IB) approved the study in October 2018 with the code IB3772/18 PI. Written informed consent was obtained from all patients included in the study after reading the information document.

### Statistical Analysis

Data are presented as mean  $\pm$  SD (standard deviation) or frequencies (percentages). Intergroup comparisons on visit 1 were analyzed using the independent-samples *t*-test or the Mann-Whitney *U* test for continuous variables and the  $\chi^2$  test or Fisher exact test for categorical variables. Intragroup

(oral vs tube) differences (visit 2 vs visit 1) were evaluated using a Wilcoxon signed-rank paired test for continuous variables and the McNemar test for dichotomized variables. Intergroup comparisons on visit 2 were assessed using analysis of covariance (ANCOVA), with adjustment for changes according to the value of visit 1. Binary logistic regression was performed to estimate the odds ratios (ORs) (crudes and adjusted by age and sex) of the baseline variables using dichotomized NutriQoL (according to the median,  $\geq 66.7$ ) as a dependent variable. A 2-tailed *P*-value  $< .05$  was considered statistically significant. Statistical analyses were performed using SPSS version 23.0 (SPSS Inc, Chicago, IL, USA).

## Results

### Baseline Characteristics

A total of 78 patients (58 males and 20 females) completed the questionnaires during visit 1 (Figure 1). The mean  $\pm$  SD age was  $64.2 \pm 10.5$  years (Table 1). Overall, 89.7% of patients had cancer, whereas the remaining 10.3% presented neurological, digestive, or other kinds of illnesses. Functional status was independent for 89.7% of patients, whereas 10.3% were dependent for daily activities on visit 1. HEN was through oral support in 57.7% of patients and through tube feeding in the remaining 42.3% on visit 1. Also, 47.4%

**Table 1.** Patients' Characteristics.

	Visit 1	Visit 2
Overall	78 (100%)	64 (100%)
Gender		
Female	20 (25.6%)	18 (28.1%)
Male	58 (74.4%)	46 (71.9%)
Age, y	64.2 ± 10.5	64.3 ± 10.6
Underlying disease		
Cancer	70 (89.7%)	56 (87.5%)
Other	8 (10.3%)	8 (12.5%)
HEN experience		
Without any previous HEN experience	33 (42.3%)	25 (39.1%)
With some previous HEN experience	45 (57.7%)	39 (60.9%)
HEN type		
Oral	45 (57.7%)	37 (57.8%)
Tube	33 (42.3%)	27 (42.2%)
HEN dosage		
1-2 supplements	29 (37.2%)	28 (43.8%)
3-4 supplements	16 (20.5%)	9 (14.1%)
≤1300 mL	10 (12.8%)	12 (18.8%)
>1300 mL	23 (29.5%)	15 (23.4%)
Functional status		
Independent	70 (89.7%)	54 (84.4%)
Need of help	8 (10.3%)	10 (15.6%)
HEN schedule		
1 meal	11 (14.1%)	14 (21.9%)
2 meals	20 (25.6%)	20 (31.3%)
3 meals	22 (28.2%)	18 (28.1%)
4 meals	23 (29.5%)	11 (17.2%)
5 meals	2 (2.6%)	1 (1.6%)
Administration method		
Syringe	25 (32.1%)	18 (28.1%)
Pump infusion	2 (2.6%)	2 (3.1%)
Freefall	6 (7.7%)	8 (12.5%)
HEN complications		
Any	41 (52.6%)	36 (56.3%)
Some	37 (47.4%)	28 (43.8%)
Questionnaires answering		
Patient	49 (62.8%)	37 (57.8%)
Caregiver	29 (37.2%)	27 (42.2%)

HEN, home enteral nutrition.

of patients experienced some complications associated with HEN.

### Changes From Baseline to Visit 2

On visit 2, frequency results were very similar to visit 1, although 14 patients did not complete the study (Figure 1). Additionally, 4 patients experienced a change in HEN type from visit 1 to visit 2; another 2 of them changed from oral to tube feeding; and the other 2 changed from tube to oral feeding. Despite the fact that we expected this event to happen and that those patients still agreed with the inclusion criteria, we excluded them for the longitudinal analysis of QoL changes with time.

**Table 2.** Changes From Baseline to Visit 2 for Anthropometric Variables and Quality of Life Scores Assessed by Both NutriQoL and SF-12 Questionnaires.

	Visit 1 (n = 78)	Visit 2 (n = 64)
Body weight, kg	62.9 ± 13.5	62.1 ± 11.8
Height, cm	166.4 ± 8.7	165.7 ± 8.9
BMI	22.6 ± 4.0	22.5 ± 3.4
NutriQoL FF-AVD	55 ± 11.6	58.2 ± 11.7
NutriQoL VS	11.2 ± 4.0	10.6 ± 4.5
NutriQoL Total	66.2 ± 13.8	68.8 ± 14.4
MCS12	42.3 ± 13.4	44.4 ± 12.8
PCS12	37.8 ± 9.9	40.2 ± 10.4
SF-12	40 ± 8.5	42.3 ± 8.7*(n = 64)

BMI, Body Mass Index; NutriQoL-FFAV D, physical functioning and activities of daily living; NutriQoL VS, social life aspects; NutriQoL Total, quality of life associated to enteral nutrition; MCS12, Mental component summary scale from the SF12 questionnaire; PCS12, Physical component summary scale and SF-12, total score for general quality of life scale. Values are expressed as mean ± SD. Statistical analysis was performed by paired samples *t* test or Wilcoxon signed-rank test. \**p* < 0.05.

The anthropometric characteristics were also registered. On visit 1, mean body weight was 62.9 ± 13.5 kg, mean height was 166.4 ± 8.7 cm, and the calculated (kg/m<sup>2</sup>) mean body mass index (BMI) was 22.6 ± 4.0. On visit 2, the anthropometric results remained very similar (Table 2).

Differences between visits were not significant for any of the QoL results, with the exception of the SF-12's total score, which improved significantly from visit 1 to visit 2 (V1, 40.7 ± 8.5; V2, 42.3 ± 8.7; *P* = .032) for the 64 patients who completed the study.

We also observed that NutriQoL scored significantly better than SF-12 on both visits (V1, *P* < .001, *n* = 78; V2, *P* < .001, *n* = 64).

### Correlation Analysis

Correlation analysis showed significance for all the NutriQoL's dimensions with the social, physical, and total summary scores of the SF-12 questionnaire on visit 1 (Table 3). Only the mental dimension of the SF-12 did not reach statistical significance when compared with the social life aspects from the NutriQoL (*P* = .057). However, on visit 2, the mental dimension of the SF-12 did not correlate with any of the NutriQoL dimensions, suggesting that psychological issues are not related to HEN issues as much as physical aspects.

We did not observe significant correlations between QoL results with different variables, such as sex, age, and HEN experience, or with anthropometric parameters, such as body weight, calculated BMI, and the answerer of the questionnaires (patient or caregiver). However, the underlying disease, HEN type, and HEN complications were correlated

**Table 3.** Correlation Analysis Between NutriQoL Scores, SF-12 Scores, and Patients' Characteristics.

Correlation Factors ( $\rho$ )	Visit 1 (n = 78)			Visit 2 (n = 64)		
	NutriQoL					
	FF-AVD	VS	Total	FF-AVD	VS	Total
MCS12	.317**	.217	.322**	.156	.063	.154
PCS12	.336**	.271*	.359**	.290*	.214	.307*
SF-12	.474**	.396**	.503**	.270*	.162	.279*
Sex (male vs female)	-.095	-.005	-.094	.128	.033	.112
Age	-.121	-.044	-.113	-.057	-.181	-.086
Underlying disease (cancer vs other)	.251*	.016	.214	.276*	-.062	.216
HEN type (oral vs tube)	-.364**	-.495**	-.434**	-.578**	-.397**	-.596**
HEN experience (with vs without)	-.091	-.108	-.103	-.075	-.169	-.106
HEN complications (some vs any)	-.264*	-.219	-.281*	-.290*	-.072	-.275*
Body weight	-.041	-.042	-.061	-.034	.061	-.007
BMI	-.037	-.051	-.063	.015	.042	.036
Questionnaires answering (patient vs caregiver)	-.029	-.023	-.024	.054	-.118	.005

FF-AV D, physical functioning and activities of daily living; VS, social life aspects; Total, quality of life associated to enteral nutrition; MCS12, mental component summary scale from the SF12 questionnaire; PCS12, physical component summary scale and SF-12, total score for general quality of life scale; HEN, home enteral nutrition; BMI, Body Mass Index. Spearman's correlation test. \* $p < 0.05$ ; \*\* $p < 0.001$ .

with some or all the dimensions of the NutriQoL scale on both visit 1 and visit 2 (Table 3).

Patients with cancer, compared with those with other underlying diseases (such as neurological, digestive, or other) obtained worse QoL results for the physical functioning and activities of daily living aspects both on visit 1 ( $\rho = 0.251$ ;  $P = .027$ ) and on visit 2 ( $\rho = 0.276$ ;  $P = .027$ ). However, the number of patients between groups (cancer vs other) was not equally distributed (Table 1), so these results should be interpreted cautiously.

Regarding HEN type, in the NutriQoL questionnaire, we obtained negative and significant correlations for total and both physical and social dimensions of HEN QoL on both visit 1 and visit 2. Therefore, tube feeding obtained lower results on QoL than oral supplementation. Similar results happened with HEN complications, since patients presenting some sort of adverse effect to nutrition support showed lower results than the ones with no complications associated with enteral feeding.

General QoL measured by the SF-12 questionnaire did not correlate with any of the variables studied. Even though we expected this result for the nutrition variables, we did not expect the lack of correlation between general QoL with the underlying disease or with HEN complications. Considering this, we believe that the NutriQoL questionnaire is more accurate and specific than the generic SF-12 in terms of evaluating the QoL associated with HEN.

Finally, it is important to note that the person who answered the questionnaires (the patient or the caregiver) did not correlate with the results for both the NutriQoL (Table 3) and SF-12 questionnaires (data not shown). Then, the results were not different between the 2, regardless of

whether the questionnaires were answered by the patients or the caregiver.

### *Comparison Between Patients Receiving Oral Support and Tube Feeding*

Since HEN type (oral support vs tube feeding) was the variable showing the major associations with QoL results, we studied the differences between those groups (Mann-Whitney  $U$  and  $P$ -value) and the changes experienced from visit 1 to visit 2 (ANCOVA  $P$ -value) (Table 4). Quality of life was significantly better in oral-supplemented patients than in tube-fed patients for all the dimensions of the NutriQoL test (physical functioning and activities of daily living, social life aspects, and total QoL associated with HEN) on both visits (Figure 2). Moreover, oral-supplemented patients improved in physical functioning and in activities of daily living from visit 1 to visit 2 in comparison with tube-fed patients. Conversely, this improvement did not happen for the social life dimension; so, limited social life can be experienced differently depending on the HEN type, but with time, social life difficulties do not change for any of these groups. Thus, social life limitations related to HEN remain with time. In the case of the SF-12 results, none of the QoL dimensions or the total generic QoL presented differences depending on HEN type.

### *Factors Associated With NutriQoL Score*

Binary logistic regression was performed to determine the crude and adjusted OR of nutrition factors associated with the NutriQoL results, of which scores were above the



**Table 4.** Quality of Life and Anthropometrical Differences Between Oral-Support and Tube-Fed Patients.

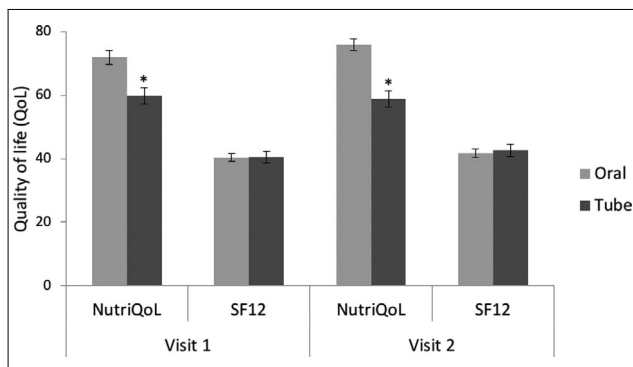
	Visit 1		Visit 2		Change	
	Oral n = 35	Tube n = 25	Oral n = 35	Tube n = 25	Oral n = 35	Tube n = 25
Body weight, kg	61.6 ± 12.9	62.5 ± 12.7	61.8 ± 11.9	62.7 ± 12.5	-0.1 ± 2.5	0.2 ± 1.4
BMI	22.3 ± 4.2	22.6 ± 3.4	22.4 ± 3.7	22.6 ± 3.3	-0.05 ± 0.9	0.1 ± 0.5
NutriQoL FF-AVD	58.7 ± 11.5	50.9 ± 10.4*	63.6 ± 9.1	50.4 ± 10.6**	5.0 ± 10.1	-0.5 ± 6.1**
NutriQoL VS	13.2 ± 3.1	8.9 ± 3.8**	12.2 ± 3.9	8.4 ± 4.8*	-1.0 ± 4.1	-0.5 ± 3.5
NutriQoL Total	71.9 ± 12.9	59.8 ± 12.7*	75.9 ± 11.2	58.8 ± 13.0**	4.0 ± 11.9	-0.9 ± 7.0*
MCS12	43.4 ± 11.9	42.1 ± 15.3	44.3 ± 12.4	44.1 ± 14.2	0.9 ± 13.9	2.9 ± 8.9
PCS12	37.3 ± 9.9	39.8 ± 8.2	39.0 ± 10.7	41.1 ± 10.0	1.7 ± 8.8	1.3 ± 9.4
SF-12	40.4 ± 7.9	40.5 ± 9.3	41.7 ± 7.7	42.6 ± 10.1	1.3 ± 7.0	2.1 ± 4.8

BMI, Body Mass Index; NutriQoL FF-AV D, physical functioning and activities of daily living; NutriQoL VS, social live aspects; NutriQoL Total, quality of life associated to enteral nutrition; MCS12, mental component summary scale from the SF12 questionnaire; PCS12, physical component summary scale and SF-12, total score for general quality of life scale. Values are expressed as mean ± SD. Intragroup comparisons (oral vs. tube) were analyzed by independent-sample *t*-test or the Mann-Whitney U test. Intergroup comparisons at visit 2 were analyzed by ANCOVA after adjusting by corresponding value at visit 1. \**p* < 0.05; \*\**p* < 0.001.

**Table 5.** Odds Ratio (OR) of Factors Associated With NutriQoL Scores Higher Than The Median.

	NutriQoL > 66.7 n = 78			
	Crude OR (95% CI for OR)	<i>P</i> -value	Age- and sex-adjusted OR (95% CI for OR)	<i>P</i> -value
Age, y	0.987 (0.945–1.03)	.548	— (—)	—
Sex (male vs female)	1.722 (0.613–4.837)	.302	— (—)	—
HEN type (oral vs tube)	5.333 (1.991–14.288)	.001	5.563 (2.022–15.303)	-.001
HEN complications (some vs any)	3.200 (1.266–8.086)	.014	3.019 (1.158–7.865)	-.024

HEN, home enteral nutrition.



**Figure 2.** Quality of life differences between oral-support and tube-fed patients. QoL scales range from 0 to 100. Values are expressed as means with error bars. Intragroup comparisons (oral vs. tube) were analyzed by independent-sample *t*-test or the Mann-Whitney U test \* *p* < 0.05

median (>66.7, Table 5). Our results showed that HEN type and associated complications adjusted for age and

sex were significant factors that explained the QoL results being higher than the median. This means that oral supplementation instead of tube feeding, along with the absence of HEN complications, were the 2 factors explaining the greater results.

## Discussion

### Summary of the Work

In this study, we evaluated the QoL of 78 patients who received HEN, including tube feeding and oral supplementation, and attended routine appointments with the dietitian-nutritionist at the hospital of reference in Mallorca. We registered the first data after 1–2 months from the beginning of HEN for the new patients and from different dates in chronic HEN patients. Oral supplementation and tube feeding were considered HEN. HEN by tube included different routes of administration, such as nasogastric, gastrostomy, and jejunostomy tubes. After the first appointment, we scheduled a second one 2 months after recruitment to assess

QoL changes with time, since we hypothesized that after a while, patients with HEN improve their feelings related to nutrition but not necessarily those related to their illness. For this reason, the specific NutriQoL and the general SF-12 QoL questionnaires were registered at both appointments. This study design allowed us to compare the QoL results, the factors influencing them between questionnaires, and the occurring changes between routine consultations. Moreover, this is the first study that has ever used the NutriQoL questionnaire to assess the QoL in patients receiving HEN. This questionnaire has been specifically designed to address problems related to this type of nutrition, including tube feeding and oral supplementation, and has been recently recommended by ESPEN in its last guideline on HEN.<sup>12</sup>

### *Generic Health-Related Quality of Life in HEN Patients*

The mean results of the SF-12 questionnaire were between 40 and 60 points, reflecting an acceptable health-related QoL (HRQoL) of the patient; however, half (50%) of the results was in the range below (21–39), meaning a poor HRQoL. SF-12 results obtained by other authors, in HEN patients, are not available. Nevertheless, a systematic review of the effects of enteral tube feeding on HRQoL has been recently published.<sup>13</sup> This review presents results from 7 studies about the effect of enteral tube feeding on QoL by using different-structured QoL questionnaires. Summarizing the results of the studies using generic QoL questionnaires,<sup>1,3,14–17</sup> the QoL of patients receiving HEN was poor—from 36 to 56, with 1 exception reaching 82.<sup>3</sup> As in our study, these were mainly patients with cancer, and their QoL improved in 5 of these studies, although 1 observed a decrease in QoL related to weight loss despite HEN.<sup>3</sup> We also observed an improvement on generic QoL between visits. Therefore, the SF-12 questionnaire is a short and easy-to-fill tool, with which we obtained QoL results similar to those previously published by other authors in HEN patients receiving tube formula (QoL, 36–56),<sup>1,3,14–17</sup> and it is useful to identify changes in HRQoL with time.

QoL has also been studied in patients who received oral supplementation,<sup>18,19</sup> which is considered part of HEN support. Yu et al compared QoL (QLQ-C30, quality of life of cancer patients) between patients with stent, ostomy, and nasogastric tube with patients with oral intake and found no statistical significance. Faruque et al showed that QoL (WHOQOL-BREF, World Health Organization quality of life shorted version) in HEN patients, of which 72% were patients with oral supplementation, was lower than that of the Australian reference population. Additionally, they did not find statistical differences in QoL between different clinical groups (neurology, head and neck cancer, upper gastrointestinal, gastroenterology, colorectal, respiratory, and other).

We found similar results in our study, since generic HRQoL was lower in HEN patients (SF-12 QoL, 40) than in the Spanish population (QoL, 75).<sup>20</sup> Moreover, neither the underlying disease, the route of entry of HEN, nor the number of complications made the SF-12 results any different. Thus, considering both the previous and present results, it seems that generic questionnaires are not suitable to address QoL related to HEN, including patients with oral supplementation.

### *Specific HEN-Related Quality of Life Assessment*

Mean results obtained in our study with NutriQoL are between 61 and 80 points, that being a good HRQoL according to the developers.<sup>5</sup> We also observed that NutriQoL results are explained only by HEN type (oral vs tube feeding) and the presence or lack of HEN complications. This is the first time that secondary effects related to HEN have been described as QoL determinants, since previously published data were not able to assess that because of the general QoL questionnaires used.<sup>21</sup> Here we also confirm that NutriQoL results depend on the route of administration, with oral support being better accepted than tube feeding, as the NutriQoL developers previously confirmed with 138 patients.<sup>5</sup> They also described significant differences due to the method of administration (gravity, pump, syringe bolus, or oral) and the HEN purpose (supplement or sole source of nutrition). However, as these variables depend on the route of administration, they disappear when they are included in a multivariable analysis. Therefore, after identifying the main nutrition factors influencing QoL related to HEN, we confirm that NutriQoL is a useful tool to assess QoL in patients receiving HEN, including tube feeding and oral supplementation. As we observed, the route of entry of HEN (oral support vs tube feeding) was the main factor influencing the NutriQoL results. Patients with oral supplementation not only had a better QoL than tube-fed patients at both visits and for all dimensions of the questionnaire, but they also improved their results for daily activities with time, whereas tube-fed patients did not. Then, physical performance improves in patients receiving oral support, but it remains unchangeable in tube-fed patients. Therefore, we suggest that an effort should be done with tube-fed patients, since they have the lower QoL results and need more help managing complications to improve their well-being progressively. Even patients receiving oral supplementation had better results for the social life dimension of the questionnaire than tube-fed patients; they did not improve it from visit 1 to visit 2. Therefore, HEN does not seem to influence the social life aspects, and thus an important part of the QoL of patients remains disregarded. However, more longitudinal studies are needed to support or reject these results.

### NutriQoL vs SF-12

Both specific and generic QoL are associated variables, as correlation analysis showed that about 8%–25% of the variance of general QoL is explained by specific QoL. However, only as much as 25% of the NutriQoL results can be explained by the health status that the SF-12 questionnaire evaluates. So, NutriQoL seems to address the QoL assessment mostly related to HEN and, consequently, it is a useful tool to manage HEN patients, regardless of their health status.

Furthermore, the little correlation factor found supports the difference observed in QoL between the NutriQoL and the SF-12 scores. NutriQoL results scored better than general QoL at both visits, suggesting that the general QoL is mostly influenced by health status rather than by the aspects related to EN, whereas HEN improves the QoL of patients who need it despite the difficulties inherent to their health status. Altogether, we show that NutriQoL is the tool of election when the QoL related to HEN needs to be assessed.

### Strengths and Limitations

The strengths of this study include the fact that the participants are representative of our HEN patients' population, and their characteristics are consistent with other HEN populations regarding age, type of HEN required, and primary diagnosis. Moreover, this is the first study evaluating QoL periodically with a specific questionnaire for HEN patients, following ESPEN's recommendation.<sup>12</sup> Some limitations of the study are that, even though we assumed we would lose 10% of patients when we calculated the sample size according to the study design, we lost 18% of patients recruited during follow-up. Also, the inclusion of both new and chronic patients and the fact that the questionnaires could be answered by either the patient or the caregiver are both confounding factors. However, none of these variables were associated with different results.

### Suggestions for Future Research

Future studies should assess specific QoL in HEN patients with the validated questionnaire NutriQoL to compare with our results and, also, to address each question from the questionnaire separately to achieve detailed concerns of patients, in addition to QoL results. It would be also of interest to compare the specific QoL of patients with a nasogastric tube and those with a gastrostomy tube to make informed decisions when choosing one or the other, since the general recommendation is still not clear for all patients and clinical situations.<sup>12</sup> Also, it would also be beneficial to study the QoL changes from the beginning of HEN to the next visits to evaluate how HEN improves or worsens with time. Time periods > 2 months should be considered, since

we did not observe changes in the NutriQoL results for this period.

### Conclusion

The results for the specific QoL of patients receiving HEN not only reflect differences between oral and tube feeding difficulties but also show that these are associated with patients experiencing HEN complications, whereas generic QoL does not. Then, by evaluating the patients' QoL with a tool specifically designed to address HEN difficulties, it is possible to pay more attention to those dimensions in which patients experience doubts or problems with HEN.

### Statement of Authorship

J. R. Urgelés, M. T. Colomar, and R. M. Ruiz equally contributed to the conception and design of the research; R. Zamanillo Campos contributed to the design of the research; R. Zamanillo Campos and M. P. Sanchís contributed to the acquisition and analysis of the data; R. Zamanillo Campos and J. R. Urgelés contributed to the interpretation of the data; and R. Zamanillo Campos drafted the manuscript. All authors critically revised the manuscript, agree to be fully accountable for ensuring the integrity and accuracy of the work, and read and approved the final manuscript. ® Registered Trademarks of Société des Produits Nestlé, S.A.

### Supplementary Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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