



Trabajo Original

Nutrición artificial

The NutriQoL[®] questionnaire for assessing health-related quality of life (HRQoL) in patients with home enteral nutrition (HEN): validation and first results *Cuestionario NutriQoL[®] para la evaluación de la calidad de vida relacionada con la salud (CVRS) en pacientes con nutrición enteral domiciliaria (NED): validación y primeros resultados*

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Abstract

Introduction: Health-related quality of life (HRQoL) provides a global view of the state of health of a patient receiving home enteral nutrition (HEN).

Objective: To evaluate the HRQoL of patients receiving HEN using the NutriQoL[®] questionnaire, a specific instrument regardless of the underlying disease and route of administration.

Materials and methods: Observational, prospective and multicentre study conducted in the context of the validation and assessment of the NutriQoL[®] questionnaire's psychometric properties.

Results: One-hundred-and-forty individuals [disease: cancer (58.6%), malabsorption and other (27.1%), neurological (13.6%); HEN: supplement (61.4%), sole source of nutrition (35.7%); administration route: oral (54.3%), ostomy (31.4%), nasogastric tube (12.1%)] participated. NutriQoL[®] was reliable [ICC: 0.88 (95%CI: 0.80-0.93); Cronbach's α : 0.77 (1st visit) and 0.83 (2nd visit)], valid (significant Rho), lowly sensitive to changes (effect size 0.23), can be completed by either patients or caregivers (ICC: 0.82). The mean HRQoL (SD) with NutriQoL[®] was 14.98 (14.86), EQ-5D tariff: 53(0.25), EQ-5D VAS: 54.15(20.64) and COOP/WONCA charts: 23.32(5.66). HRQoL with NutriQoL[®] was better ($p < 0.05$) for oral HEN [19.54(13.23)], than nasogastric tube [14(11.71)], ostomy [7.02 (15.48)]; administered orally [19.54 (13.23)], than by gravity [10.97 (14.46)], pump [8.5 (19.78)] or syringe bolus [7 (11.40)]; as a supplement [19.33 (13.73)] instead of sole source of nutrition [8.18 (14.23)].

Conclusions: NutriQoL[®] is valid, reliable, even if lowly sensitive to change, and useful to measure HRQoL in this population. More studies are needed to know HRQoL in routine practice.

Key words:

Home enteral nutrition. Health-related quality of life. Questionnaire. NutriQoL[®].

Resumen

Introducción: la calidad de vida relacionada con la salud (CVRS) permite disponer de una visión global del estado de salud del paciente que recibe nutrición enteral domiciliaria (NED).

Objetivo: evaluar la CVRS de pacientes con NED usando el cuestionario NutriQoL[®], herramienta específica para pacientes con NED independientemente de la patología subyacente y vía de administración.

Materiales y métodos: estudio observacional, prospectivo, multicéntrico, en el contexto de la validación y evaluación de las propiedades psicométricas del cuestionario NutriQoL[®].

Resultados: se incluyeron 140 individuos [patologías: oncológica (58,6%), malabsorción y otros (27,1%), neurológica (13,6%); NED: complemento a la alimentación (64,4%), única nutrición (35,7%); vía de administración: oral (54,3%), ostomía (31,4%) y sonda naso-entérica (12,1%)]. El NutriQoL[®] resultó fiable [CCI: 0,88 (IC95%: 0,80-0,93); α de Cronbach: 0,77 (1ª visita) y 0,83 (2ª visita)], válido (Rho significativas), aunque poco sensible a los cambios (tamaño del efecto: 0,23), pudiendo ser cumplimentado por el paciente o su cuidador (CCI: 0,82). La CVRS media (DE) con NutriQoL[®] fue 14,98(14,86), con la tarifa EQ-5D: 53(0,25), EVA EQ-5D: 54,15(20,64) y viñetas COOP/WONCA: 23,32(5,66). La CVRS medida con NutriQoL[®] fue mejor ($p < 0,05$) en pacientes con NED por vía oral [19,54(13,23)] que con sonda naso-entérica [14(11,71)] u ostomía [7,02(15,48)]; administrada por vía oral [19,54(13,23)] que por gravedad [10,97(14,46)], bomba [8,5(19,78)] o bolo con jeringa [7(11,40)]; como complemento [19,33(13,73)] que como única alimentación [8,18(14,23)].

Conclusiones: NutriQoL[®] es un cuestionario válido, fiable, aunque poco sensible a los cambios y útil para medir la CVRS en pacientes con NED. Son necesarios más estudios para conocer la CVRS de estos pacientes en la práctica habitual.

Palabras clave:

Nutrición enteral domiciliaria. Calidad de vida relacionada con la salud. Cuestionario. NutriQoL[®].

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INTRODUCTION

Home enteral nutrition (HEN) is a treatment used to restore or maintain nutritional status in the patient's home (1). It involves the administration of necessary nutrients through the digestive tract using different administration routes and methods in people who cannot eat food normally due to a particular clinical situation (mechanical disturbance of swallowing or transit, neuromotor disorders, special energy or nutrient requirements or severely malnourished patients) (2). HEN facilitates the patients' integration in their social and family environment, enabling them to perform daily activities and improving patient-reported variables such as health-related quality of life (HRQoL), satisfaction, preferences or adherence to treatment (3).

The variables perceived and reported by patients provide information from the patient's viewpoint and are an extremely useful addition to traditional clinical variables (4,5). HEN calls for instruments that can assess HRQoL irrespective of the diseases leading to this type of nutritional treatment and the route of administration, and which are also able to distinguish the impact of HEN on HRQoL as an essential outcome variable. It seems safe to say that a global view of a patient's health status can only be obtained using information drawn from clinical parameters, practitioners' observations and patient perceived and reported variables (5). There are several definitions of HRQoL. However, possibly the most appropriate for assessing it in the context of HEN is that HRQoL evaluates the subjective impact of the patient's health status and healthcare on individual capacity to achieve and maintain a level of functioning that makes it possible to attain life goals and which is reflected in general wellbeing (6).

HRQoL is measured by generic or specific questionnaires. Generic questionnaires can be used to measure the impact of any disease on a given population and compare HRQoL in different groups (5). However, the generic instruments available lack the sensitivity to investigate the influence of the specifics of any disease or therapy, and in this case the features of HEN in patients receiving this therapy (7,8). At present, there are a limited number of specific and validated questionnaires available to measure and evaluate the effect of nutritional status or nutritional treatments on HRQoL. They include the nutritional status-related quality of life questionnaire (caVEN) which identifies the impact of nutritional status on HRQoL, the Quality-of-life questionnaire for head and neck cancer patients with Enteral Feeding tubes (QoL-EF) questionnaire, which is specifically for assessing the impact of enteral nutrition tubes on patients with head and neck cancer, and the Home Parenteral Nutrition-related Quality of Life questionnaire (HPN-QoL), which assesses the effect of parenteral nutrition on HRQoL (9). However, none of these questionnaires is generalizable to both heterogeneous underlying conditions and different routes of administration neither they assess specifically HRQoL related to HEN. Therefore, we developed a specific questionnaire to fill this need, the NutriQoL[®] questionnaire (10).

The main aim of this study is to evaluate the HRQoL of patients receiving HEN in the context of the validation study of the NutriQoL[®] questionnaire, a specific tool to measure HRQoL in patients receiving HEN regardless of the underlying disease and the route of administration.

MATERIALS AND METHODS

STUDY DESIGN

Observational, prospective and multicentre study conducted in the context of the validation and assessment of the NutriQoL[®] questionnaire's psychometric properties (11-14).

SAMPLE DESCRIPTION

Two cohorts of patients were enrolled in the study. The first cohort (reliability cohort) included 54 participants (38 patients and 16 caregivers) (95% confidence, 80% power and 0.3 effect size), who had initiated and maintained HEN between 3 and 6 months prior to their inclusion into the study. Patients belonging to this cohort had to be in a stable health status, for this reason they were required to have experienced HEN for at least 3-6 months. The results of this cohort were used for the reliability analysis (internal consistency and intra-observer reliability) (11).

The second cohort of participants (responsiveness cohort) included a sample of 86 subjects (80 patients and 6 caregivers) (95% confidence and power and 0.5 effect size). The results from this cohort were used in the testing for responsiveness. Patients who had started HEN in the previous month were included (13). In this case, the objective was to confirm that the questionnaire was able to detect the changes in patients' health status related to HEN initiation, so patients were required to have started HEN recently (the previous month). In addition, 35 patients in the responsiveness cohort had a caregiver who met the selection criteria. In this case, caregivers were also asked to complete the NutriQoL[®] questionnaire from the point of view of the patient in their charge at baseline. The results of these patients and their caregivers were used to test inter-observer reliability (12).

The results of the first visit of both cohorts were used to estimate criterion validity by performing a correlation matrix between the NutriQoL[®] questionnaire and EuroQoL-5D-3L question (EQ-5D) and the COOP/WONCA charts (14). The patients' HRQoL data were those obtained on the first visit of both cohorts.

In all cases were included patients seen in nine Spanish public health centres aged over 18 who were physically and intellectually able to complete the questionnaire from the point of view of the researcher. If patients did not comply with the inclusion criteria, the caregiver was invited to respond from the patient's point of view (11-14).

HRQoL MEASUREMENT TOOLS

NutriQoL[®] questionnaire

The NutriQoL[®] questionnaire is a specific tool to measure HRQoL in patients receiving HEN regardless of the underlying disease and the route of administration. It consists of 17 items grouped in two dimensions, which assess physical functioning,

and activities of daily living and aspects of social life (10) (Table I). In turn each item is divided into two parts (SEIQoL Method) (15). Part "a" includes questions about the frequency with which the patients perceive certain HEN-related situations. Part "b" contains questions about how important these situations are for the patients. The study design was divided into two phases.

Phase 1 consisted of a literature review, focus groups with experts, semi-structured interviews with patients and caregivers, assessing face validity and feasibility, as well as the application of Rasch analysis in a pilot study. The pilot study with 165 subjects was conducted to perform Rasch analysis and differential item functioning (DIF). The Rasch analysis ensured that all the items in the NutriQoL[®] questionnaire work in the same way for all the individuals that complete them, while the DIF made it possible to eliminate items that worked differently in groups of people where the route of administration of HEN and the patient's underlying disease were different. The overall score in the NutriQoL[®] questionnaire ranges from -51 to 51, which are worse and better HRQoL respectively. This score has been adapted to a range of

0 to 100 for ease of interpretation (Table II) but results showed in this paper are reported in the original scale (from -51 to 51).

Phase 2 included the validation or evaluation of the psychometric properties of the questionnaire. During this phase we tested for reliability (internal consistency, intra-observer reliability or test-retest and inter-observer reliability), responsiveness, minimal

Table II. Turning the NutriQoL[®] score into the scale from 0 to 100

Original score	New score	Health-Related Quality of Life (HRQoL)
-51 to -30	0 to 20	Very poor
-29 to -11	21 to 39	Poor
-10 to 10	40 to 60	Acceptable
11 to 31	61 to 80	Good
32 to 51	81 to 100	Excellent

Table I. Questionnaire items and response options

N ^o Ítem	Nunca – a veces - siempre	Nada importante – algo importante – muy importante
1*	Con la NED mantengo mis horarios habituales para comer (ejemplo: desayuno, almuerzo, merienda y cena)	Mantener mis horarios habituales para comer, para mí es:
2*	La NED se adapta a mis preferencias por las características de la alimentación (ejemplo: textura, color, olor, temperatura, sabor)	Que la NED se adapte a mis preferencias por las características de la alimentación, para mí es:
3*	Desde que tomo la NED me es más fácil moverme, me siento más ágil	Que me sea más fácil moverme, sentirme más ágil, para mí es:
4*	Con la NED puedo seguir haciendo mis tareas cotidianas (ej. leer el periódico, cocinar, lavar el coche, limpiar, ver la TV)	Poder seguir haciendo mis tareas cotidianas, para mí es:
5*	Desde que tomo la NED veo que mi aspecto físico va mejorando (ejemplo: me veo más saludable)	Que mi aspecto físico vaya mejorando, para mí es:
6*	Conseguir los preparados de la NED es sencillo (ej. está disponible en las farmacias, obtengo la receta fácilmente)	Que sea sencillo conseguir los preparados de la NED, para mí es:
7*	Con la NED confío en que estoy bien nutrido	Confiar en que estoy bien nutrido, para mí es:
8*	Con la NED he recuperado peso	Recuperar peso, para mí es:
9**	La NED me permite poder salir con mis amigos	Poder salir con mis amigos, para mí es:
10*	La NED daña mi piel (ejemplo: sequedad, irritación, infecciones)	Que mi piel se dañe, para mí es:
11*	La NED me impide dormir bien	Dormir bien, para mí es:
12*	Me preocupa que mi cuerpo se adapte a la NED y no pueda volver a alimentarme como antes	Que mi cuerpo se adapte a la NED y no pueda volver a alimentarme como antes, para mí es:
13*	Con la NED echo de menos masticar y saborear alimentos	Masticar y saborear alimentos, para mí es:
14*	Con la NED tengo molestias físicas por la alimentación (ej. pesadez de estómago, ardores, sequedad de boca, regurgitaciones)	Tener molestias físicas por la alimentación, para mí es:
15*	Con la NED mi familia vigila más mi alimentación	Que mi familia vigile más mi alimentación, para mí es:
16**	Con la NED limito las actividades con mis amigos a aquellas que no estén relacionadas con la comida	Limitar las actividades con mis amigos a aquellas que no estén relacionadas con la comida, para mí es:
17**	Desde que tomo la NED estoy más preocupado por mi salud	Estar más preocupado por mi salud, para mí es:

*Physical functioning and activities of daily living dimension; **Social life aspects dimension.

clinically important difference and validity (criterion validity and construct validity).

EuroQoL-5D-3L questionnaire

The EuroQoL-5D-3L (EQ-5D) questionnaire is a generic instrument for measuring HRQoL which can be completed by healthy individuals (general population) or by patients with a disease. The questionnaire consists of two parts, one of which is the descriptive system and includes five health dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each dimension has 3 levels: no problems, some problems or moderate problems, and extreme problems. The second part of the EQ-5D questionnaire is a visual analogue scale (VAS) with a score between 0 (worst imaginable health state) and 100 (best imaginable health state). Finally, it makes it possible to calculate a social tariff for each health status generated by the instrument which ranges from 1 (best health status) to 0 (death) (16).

COOP/WONCA charts

COOP/WONCA charts are a generic instrument for measuring HRQoL, which has been validated in the Spanish population (17). This instrument contains 9 charts, each consisting of a title, a question about health status in the last month and 5 possible answers. Each question also represents a quality of life dimension. The options are illustrated by cartoons showing the level of functioning on a 5-point Likert ordinal scale, where higher scores mean a worse level of functioning. The final score (5-45) is the sum of the scores given to each of the cartoon illustrations (17).

STATISTICAL ANALYSIS OF THE DATA

Descriptive analysis

A descriptive analysis of the study sample by socio-demographic (age, sex, etc.) and clinical (underlying disease, HEN description) variables was performed. We calculated relative and absolute frequencies for qualitative and mean variables and their respective standard deviations for quantitative variables.

Reliability

Reliability or the degree to which an instrument accurately measures what it purports to measure (18) was assessed by measuring internal consistency, intra-observer reliability or test-retest and inter-observer reliability (19,20). Internal consistency specifies the degree of correlation between the different items in the questionnaire, i.e. whether the items measuring the same construct produce similar scores. We assessed this property by the Cronbach's α (21). Intra-observer reliability or test-retest

is the degree of reproducibility or equivalence between repeated measurements with the same instrument in the same individual under identical conditions (18). This property is measured by the intraclass correlation coefficient (ICC) (22). Finally, inter-observer reliability involves assessing the degree of agreement or equivalence obtained in different observers. Previous properties were assessed from the answers of participants at baseline and after 3 ± 1 weeks.

Responsiveness

Responsiveness is the questionnaire's ability to detect changes irrespective of whether such change is relevant or significant (23). This questionnaire's feature is related to the size of the difference in the scores of a subject who has improved or deteriorated and of those which have not changed their situation (24). Since there is controversy about the best method for measuring an instrument's responsiveness, we calculated two different measurements, namely the effect size and the effect size of the standardised response mean (24,25). Both parameters provide direct information about the size of the change expressed in terms of variation in the measurement. Responsiveness was assessed from the answers of participants in three moments (at baseline and two times 1 month \pm 2 weeks apart).

Validity

Validity explores the extent to which an instrument measures what it purports to measure, i.e. what it was designed for (24). It can be estimated in different ways, we examined criterion validity and construct validity. Criterion validity measured with Spearman rank correlation enabled us to assess to what extent the questionnaire evaluates in the same way conceptually similar dimensions to those of two generic instruments: EQ-5D and COOP/WONCA charts (18). Construct validity is the degree to which an instrument conceptually measures what it was designed for. It is related to how far the measurement coincides with other instruments that measure the same dimension. It is measured by examining convergent and divergent validity, factor analysis and discriminant validity (24).

Subgroup analysis

The NutriQoL® questionnaire scores were compared between groups defined by underlying disease (cancer, neurological, malabsorption and other), route of administration (oral, nasenteric tube, ostomy or nasoenteric tube and oral without distinction), method of administration (oral, gravity, syringe or infusion pump) and the purpose of the HEN (food supplement or sole source of nutrition) using the ANOVA test. In all cases a value of $p < 0.05$ was considered significant. The SPSS version 19.0 software was used for all the analysis.

ETHICAL ASPECTS

This study was conducted in accordance with the principles of the Declaration of Helsinki while also ensuring compliance with Good Clinical Practice (GCP) rules. The Spanish Agency of Medicines and Medical Devices (AEMPS) was notified of the study and the protocol was approved by the Clinical Research Ethics Committee (CREC) at Hospital Clinic de Barcelona (Spain).

RESULTS

DESCRIPTION AND GENERAL CHARACTERISTICS OF THE SAMPLE

A total of 140 individuals, 61.4% men and 37.1% women, participated in the study. Most of the sample was receiving HEN due to a cancer disease (58.6%), followed by malabsorption and other (27.1%) and neurological diseases (13.6%). HEN was administered more frequently as a food supplement in 61.4% of patients and as the sole source of nutrition in 35.7% of cases. The HEN access route was mainly oral (54.3%), ostomy (31.4%) or nasoenteral tube (12.1%). Most subjects did not use any specific means to administer the HEN, while in 22.1% it was administered by gravity, 13.6% by syringe and 8.6% by infusion pump (Table III).

PSYCHOMETRIC TESTING OF THE NUTRIQoL[®] QUESTIONNAIRE

ICC was 0.88 (95%CI: 0.80-0.93), which means that NutriQoL[®] has a good level of reproducibility (ICC > 0.75) (20). The Cronbach's α was 0.77 on the first visit and 0.83 on the second (11), indicating good internal consistency (> 0.7). The effect size was 0.23 and the standardised effect size was 0.24 (13). Responsiveness is considered to be low when "effect size" values are below 0.20, moderate when they are 0.5 and high when they are above 0.80 (25). Thus, NutriQoL[®] shows low to moderate responsiveness. Analysis of inter-observer reliability led to an ICC of 0.82 (12) (ICC > 0.75) (20); this shows that NutriQoL[®] measures the HRQoL of a patient with HEN regardless of whether the responder is the patient or the caregiver.

Finally, the validity study of the questionnaire showed low but significant correlations between the items in NutriQoL[®] and EQ-5D and COOP/WONCA (14) (Table IV).

HRQoL OUTCOMES OF THE SAMPLE

The total score [mean standard deviation (SD)] for the NutriQoL[®] questionnaire for patients treated with HEN was 14.98 (14.86), the mean (SD) of the EQ-5D tariff was 53 (0.25), for the EQ-5D VAS 54.15 (20.64) and for the COOP/WONCA charts 23.32 (5.66).

Analysis of NutriQoL[®] questionnaire scores between groups showed that women had a higher mean (SD) score than men

[16.94 (15.36) vs. 14.02 (14.57)]. By age of the participants the highest mean (SD) score in the questionnaire was for the group of participants aged 18 to 45 [15.73 (14.15)] with the score falling as patient age increased: 15.05 (16.11) in the 46-65 age group and 14.77 (14.15) in those over 65.

When we compared the results obtained by underlying disease we found that patients with malabsorption and other [18.37 (14.17)] showed better HRQoL than neurological [18.11 (11.75)] or cancer [12.76 (15.60)] patients, although these results were not statistically significant ($p = 0.098$). In terms of the HEN route of administration, HRQoL perceived by patients with HEN was significantly higher in subjects who took it orally [mean (SD): 19.54 (13.23)], followed by those using a nasogastric tube [14 (11.71)] and ostomy [7.02 (15.48)]. As for the HEN method of administration, HRQoL was significantly higher in patients whose method of administration was oral [mean (SD): 19.54 (13.23)], followed by those whose HEN was administered by gravity [10.97 (14.46)], infusion pump [8.5 (19.78)] and finally those whose method of administration was by syringe bolus [7 (11.40)]. Lastly, by pur-

Table III. Participants' socio-demographic variables

Variable	n	Percentage
<i>Sex</i>		
Woman	52	61.4
Man	86	37.1
Missing data	2	1.5
<i>Underlying disease</i>		
Cancer	82	58.6
Malabsorption and other	38	27.1
Neurological	19	13.6
Missing data	1	0.7
<i>HEN purpose</i>		
Food supplement	86	61.4
Sole source of nutrition	50	35.7
Missing data	4	2.9
<i>HEN route of access</i>		
Oral	76	54.3
Ostomy	44	31.5
Nasoenteric tube	17	12.1
Oral and nasoenteric tube	1	0.7
Missing data	2	1.4
<i>HEN method of administration</i>		
No method (oral)	76	54.3
Gravity	31	22.1
Syringe bolus	19	13.6
Infusion pump	12	8.6
Missing data	2	1.4

Table IV. Correlation coefficients between the NutriQoL® questionnaire and the EQ-5D and COOP/WONCA questionnaires

Spearman's rho	
EQ-5D	NutriQoL® total score
Mobility	-0.193*
Self-care	0.202**
Daily activities	-0.245**
Anxiety/depression	-0.414**
COOP/WONCA	
Physical fitness	-0.261**
Feelings	-0.496**
Daily activities	-0.466**
Social activities	-0.473**
Change in health	-0.386**
Health	-0.451**
Social support	-0.157**
Quality of life	-0.547**

*p-value < 0.05; **p-value < 0.001.

pose of the HEN, the HRQoL score was significantly greater in patients who received HEN as a food supplement [19.33 (13.73)] compared to those using it as their sole source of nutrition [8.18 (14.23)] (Table V).

DISCUSSION AND CONCLUSIONS

HEN has become widespread as the solution of choice for malnourished individuals or those at risk of malnutrition who have a minimally functional intestine but are unable to meet their nutritional needs by themselves with normally consumed foostuffs (26). In addition to improving general health, functionality and clinical parameters, a primary goal of HEN is to increase the HRQoL of patients who in most cases present with disabling, chronic and progressive diseases (27). The HEN guidelines in the National Health System indicates that HEN should enable an improvement in the patient's HRQoL or a possible recovery from a life-threatening process (28), thus highlighting the need to assess HRQoL during the clinical monitoring of patients receiving this treatment.

There is insufficient information about HRQoL in patients receiving HEN. Studies published to date mostly used generic questionnaires such as The Short Form (36) Health Survey (SF-36) (29), EQ-5D (8,30,31), or European Organization for Research and treatment of Cancer (EORTC) (32,33). Jordan et al. 2006 (8) measured the HRQoL in patients with percutaneous endoscopic gastrostomy using the SF-12 questionnaire. Their results showed that patients' problems, as experiencing constant nausea, were not reflected by the questionnaire scores. Schneider et al. 2000 (33) used the SF-36 and EQ-5D to evaluate the HRQoL

Table V. HRQoL results measured with NutriQoL®

	Mean	SD	n	p-value
<i>NutriQoL® by sex</i>				
Man	14.02	14.57	86	-
Woman	16.94	15.36	52	
<i>NutriQoL® by age</i>				
18-45	15.73	14.15	15	-
46-65	15.05	16.11	59	
> 65	14.77	14.15	65	
<i>NutriQoL® by underlying disease</i>				
Cancer	12.76	15.60	82	0.098
Neurological	18.11	11.75	19	
Malabsorption and other	18.37	14.17	38	
Total	15.02	14.90	139	
<i>NutriQoL® by route of administration</i>				
Oral	19.54	13.23	76	< 0.05
Nasoenteric tube	14	11.71	17	
Ostomy	7.02	15.48	44	
Oral and nasoenteric tube	3		1	
Total	14.75	14.83	138	
<i>NutriQoL® by method of administration</i>				
Gravity	10.97	14.46	29	< 0.05
Infusion pump	8.5	19.78	12	
Syringe bolus	7	11.40	19	
No method (oral)	19.54	13.23	76	
Total	14.99	14.75	136	
<i>NutriQoL® by HEN purpose</i>				
Supplement	19.33	13.73	86	< 0.05
Sole source of nutrition	8.18	14.23	50	
Total	15.23	14.88	136	

SD: standard deviation n: number of participants.

in patients using long term HEN. Subgroup analyses between patients depending on age (less than 45 years vs. more than 45 years) and cancer diagnosis (with cancer vs. with other diseases) were performed. Results from EQ-5D did not reflect differences between subgroups; there were only statistical differences in physical functioning and role-emotional from SF-36 domains in age and cancer subgroups, respectively. Authors attributed the lower sensitivity of EQ-5D to the smaller number of items and the small sample, in fact, they declared that their results did not represent the HRQoL in HEN patients. Moreover, Wanden-Berghe et al. 2009 (3) also used the EQ-5D to assess the HRQoL in patients with home nutritional support. These authors highlighted the lack of specific and relevant validated measurement tools to evaluate the HRQoL in this kind of patients. They argued that measures

of HRQoL obtained by means of specific tools would have the ability to detect specific aspects of illnesses or treatments. Finally, other authors have focused on assessing side effects, HRQoL and nutritional care in patients with home enteral tube feeding. Bjuresäter et al. 2014 (34) measured patients' HRQoL using the SF-12 two and ten weeks after discharge. Results did not show differences in the two points of measurements, however the study had a small sample size that made findings not generalizable. All the described studies emphasized the need of having a specific questionnaire to measure the HRQoL in patients receiving HEN, which could help physicians to identify changes in the health of patients and modify the therapies based on the results obtained.

Results from the present study demonstrate that the NutriQoL[®] questionnaire is a tool that is valid, reliable, low to moderate responsiveness and easy to use which consists of 17 items that assess physical functioning and activities of daily living and aspects of social life (9,11-14). Values obtained in internal consistency (Cronbach's α) allow using the questionnaire to compare groups, however, for individual clinical application, values should be at least 0.90 (21). The low responsiveness is probably because the measurements were made over a shorter than desired period between visits and also in patients receiving HEN, where the underlying disease is usually a chronic problem and observed changes in outcome variables are usually evident over longer periods (25,33). Nonetheless, it is the only one of the specific questionnaires to measure the effect of nutritional status and nutritional therapies on HRQoL (CaVEN, HPN-QOL and QOL-EF) specifically designed for patients receiving HEN regardless of the route of administration and underlying disease, and which can be answered by the caregiver from the patient's perspective, giving similarly valid results.

As the total score of the NutriQoL[®] questionnaire covers a range from -51 to 51, we have established the following initial interpretation: -51 to -30: very poor HRQoL; -29 to -11: poor HRQoL; -10 to 10: acceptable HRQoL; 11 to 31: good HRQoL, and 32 to 51 excellent HRQoL (11-13), which will have to be corroborated in subsequent studies. Using these values and based on the results, it can be inferred that the sample had a good HRQoL measured with NutriQoL[®]. This contrasts with the results obtained with the two generic questionnaires (EQ-5D and COOP/WONCA), which showed a sample of patients with highly affected HRQoL when compared with the values described in the general Spanish population [EQ-5D tariff mean (SD): 0.916 (0.15)] (35) or in patients with type 2 diabetes mellitus [EQ-5D tariff mean (SD): 0.71 (0.23)] (36). In the same way, Wanden Berghe et al. in their validation study of the CaVEN instrument showed that generic questionnaires in these patients underestimated HRQoL compared with the results of the specific questionnaire. The authors explained this finding due to the weight of some diseases such as cancer, predominant in the sample, which significantly altered the general perception of health (37). The mentioned underestimation of HRQoL of generic questionnaires could explain the low correlations found between NutriQoL[®] and EQ-5D and COOP/WONCA.

The results of the responders of this study helps drawing a first draft of HEN patient's HRQoL. Male sex, over 65 years of age,

with cancer as the underlying condition, with ostomy, with syringe bolus as administration, taking HEN as sole source of nutrition are features that show worse NutriQoL[®] results compared to female sex, younger, with other conditions, route and mode of administration, and HEN as complementary nutrition mode. Even though these data must be corroborated with data from a larger number of patients, they help identifying patients that are most exposed to the risk of poor life quality related to HEN.

A major limitation of this study is that the results have been obtained in the context of the validation of a specific new questionnaire to measure HRQoL in two cohorts of patients receiving HEN. Additionally, the ranges established for global NutriQoL[®] scores are estimates based on the questionnaire validation data. Further studies should be performed including a larger number of patients with different underlying diseases and feeding methods in order to reduce the data variability. Only then will it be possible to learn about HRQoL in different population groups such as neurological, cancer and other kinds of patients, or patients with a particular type of neurological or cancer disease, and further define the ranges of the questionnaire's global scores and improve clinical interpretation of them.

In spite of these limitations, we believe that the contribution of this study is important given the meagre information available about HRQoL in patients receiving HEN. This is the first research where HRQoL is measured in patients receiving HEN with a specific questionnaire (the NutriQoL[®] questionnaire). This new tool has proven to be valid, reliable, sensitive to change and useful to measure HRQoL in this population in routine clinical practice. The HRQoL outcomes reported are a fact of interest to estimate HRQoL in a sample of patients which was used to assess psychometric qualities, yet much more information is needed to learn exactly what that HRQoL is like. We recommend implementing a register of additional studies involving larger numbers of patients with HEN who are given the NutriQoL[®] questionnaire to get a precise idea of HRQoL in numerous situations and have some national reference data.

REFERENCES

1. Ministry of Health, Social Services and Equality. Guía descriptiva de la prestación con productos dietéticos del Sistema Nacional de Salud. 2012. Available at: http://www.msssi.gob.es/profesionales/prestacionesSanitarias/publicaciones/docs/GUIA_PRODUCTOS_DIETETICOS.pdf
2. Wanden-Berghe C, Alvarez-Hernandez J, Burgos-Pelaez R, Cuerda-Compe C, Matia-Martin P, Luengo-Perez L, et al. A home enteral nutrition (HEN); Spanish registry of NADYA-SENPE group; for the year 2013. *Nutr Hosp* 2015;31(6):2518-22.
3. Wanden-Berghe C, Nolasco A, Sanz-Valero J, Planas M, Cuerda C. Health Related quality of life in patients with home nutritional support. *J Hum Nutr Diet* 2009;22:219-25.
4. Lizán-Tudela L, Paz S, Dilla T, Rodríguez JM, Lahoz R, Reig-Ferrer A. Resultados referidos y percibidos por los pacientes. *Aten Primaria* 2009;41(5):275-80.
5. Wanden-Berghe C, Cheikh-Moussa K, Sanz-Valero J. La calidad de vida y el estado nutricional. *Nutr Clin Med* 2015;ix(2):133-44.
6. Lizán-Tudela L. La calidad de vida relacionada con la salud. *Aten Primaria* 2009;41(07):1-416.
7. Bannerman E, Pendlebury J, Phillips F, Ghosh S. A cross sectional and longitudinal study of health-related quality of life after percutaneous gastrostomy. *Eur J Gastroenterol Hepatol* 2000;12:1101-9.

8. Jordan S, Philpin S, Warring J, Cheung WY, Williams J. Percutaneous endoscopic gastrostomies: the burden of treatment from a patient perspective. *J Adv Nurs* 2006;56:270-81.
9. Wanden-Berghe C. Calidad, Innovación y Desarrollo tecnológico en nutrición enteral en el siglo XXI. *Nutr Hosp* 2015;31(s05):67-76.
10. De la Cuerda C, Virgili N, Irlés JA, Cuesta F, Apezetxea A, Casanueva F, et al. Cuestionario NutriQoL[®]: desarrollo de un cuestionario específico de Calidad de Vida Relacionada con la Salud para pacientes con Nutrición Enteral Domiciliaria. *Nutr Hosp* 2013; 28(Supl. 3):S54.
11. Apezetxea A, Casanueva F, Carrillo L, Cuerda C, Virgili N, Irlés JA, et al. Reliability of a specific health related quality of life (HRQoL) questionnaire for home enteral nutrition (HEN) (NutriQoL[®] questionnaire). *Clin Nutr* 2014;33(1):S228.
12. Cuerda C, Virgili N, Irlés JA, Cuesta F, Apezetxea A, Casanueva F, et al. Inter-observer reliability of a specific health related quality of life (HRQoL) questionnaire for home enteral nutrition (HEN) (NutriQoL[®] questionnaire). *Clin Nutr* 2014;33(1):S230.
13. Cuerda C, Virgili N, Irlés JA, Cuesta F, Apezetxea A, Casanueva F, et al. Responsiveness and minimal clinically important difference of a specific health related quality of life (HRQoL) questionnaire for home enteral nutrition (HEN) patients. *Value Health* 2014;17(7):A575.
14. De la Cuerda C, Virgili N, Irlés JA, Cuesta F, Apezetxea A, Casanueva F, et al. Criterion Validity analysis of a specific Health Related Quality of Life questionnaire for home enteral nutrition: The NutriQoL[®] questionnaire. *Clin Nutr* 2013;32(1):S217.
15. Joyce CRB, Hickey A, McGee HM, O'Boyle CA. A theory based method for the evaluation of individual quality of life: the SEIQoL. *QualLife Res* 2003;12:275-80.
16. Herdman M, Badía X, Berra S. El EuroQoL-5D: una alternativa sencilla para la medición de la calidad de vida relacionada con la salud en atención primaria. *Aten Primaria* 2001;28(6):425-9.
17. Lizán-Tudela L, Reig-Ferrer A. La evaluación de la calidad de vida relacionada con la salud en la consulta: las viñetas COOP/WONCA. *Aten Primaria* 2002;29(6):378-84.
18. García de Yébenes MJ, Rodríguez-Salvanes F, Carmona-Ortells L. Validación de cuestionarios. *Reumatol Clin* 2009;5(4):171-7.
19. Hernández I, Porta M, Miralles M, García F, Bolívar F. La cuantificación de la variabilidad en las observaciones clínicas. *Med Clin (Barc)* 1990;95:424-9.
20. Prieto L, Lamarca R, Casado A. La evaluación de la fiabilidad en las observaciones clínicas: el coeficiente de correlación intraclase. *Med Clin (Barc)* 1998;110:142-5.
21. Bland JM, Altman DG. Cronbach's alpha. *BMJ* 1997;314:572.
22. Zumbo BD. Three Generations of DIF analyses: considering where it has been, where it is now, and where it is going. *Lang Assess Q* 2007;4(2):223-33.
23. Terwee CB, Dekker FW, Wiersinga WM, Prummel MF, Bossuyt PMM. On assessing responsiveness of health-related quality of life instruments: Guidelines for instrument evaluation. *Qual Life Res* 2003;12:349-62.
24. Carvajal A, Centeno C, Watson R, Martínez M, Sanz-Rubiales A. ¿Cómo validar un instrumento de medida de la salud? *An Sist Sanit Navar* 2011;34(1):63-72.
25. Husted JA, Cook RJ, Farewell VT, Gladman DD. Methods for assessing responsiveness: a critical review and recommendations. *J Clin Epidemiol* 2000;53(5):459-68.
26. Álvarez-Hernández J, Peláez-Torres N, Muñoz-Jiménez A. Utilización clínica de la nutrición enteral. *Nutr Hosp* 2006;(Supl.2):87-99.
27. Puiggròs C, Lecha M, Rodríguez T, Pérez-Portabella C, Planas M. Karnofsky index as a mortality predicting factor in patients on home-based enteral nutrition. *Nutr Hosp* 2009;24:156-60.
28. Ministry of Health and Consumer Affairs. Guía de nutrición enteral domiciliaria en el Sistema Nacional de Salud. 2008. Available at: <http://www.msssi.gob.es/profesionales/prestacionesSanitarias/publicaciones/docs/guiaNED.pdf>.
29. Elia M, Stratton RJ. A cost-utility analysis in patients receiving enteral tube feeding at home and in nursing homes. *Clin Nutr* 2008;27:416-23.
30. Malone M. Longitudinal assessment of outcome, health status, and changes in lifestyle associated with long-term home parenteral and enteral nutrition. *JPEN* 2002;26:164-8.
31. Scott F, Beech R, Smedley F, Timmis L, Stokes E, Jones P, et al. Prospective, randomized, controlled, single-blind trial of the costs and consequences of systematic nutrition team follow-up over 12 month after percutaneous endoscopic gastrostomy. *Nutrition* 2005;21:1071-7.
32. Loeser C, von Herz U, Kuchler T, Rzehak P, Muller MJ. Quality of life and nutritional state in patients on home enteral tube feeding. *Nutrition* 2003;19:605-11.
33. Schneider SM, Pouget I, Staccini P, Rampal P, Hebuterne X. Quality of life in long-term home enteral nutrition patients. *Clin Nutr* 2000;19(1):23-8.
34. Bjuresäter K, Larsson M, Athlin E, Nordström G. Patients living with home enteral tube feeding: side effects, health-related quality of life and nutritional care. *Clin Nurs Studies* 2014;2(3):64-75.
35. Ministry of Health, Social Services and Equality. Encuesta nacional de salud España 2011/2012. Available at: http://www.msssi.gob.es/estadEstudios/estadisticas/encuestaNacional/encuestaNac2011/informesMonograficos/CVRS_adultos_EQ_5D_5L.pdf
36. Mata-Cases M, Roset-Gamisans M, Badia-Llach X, Antofiazas-Villar F, Ragel-Alcazar J. Impacto de la diabetes mellitus tipo 2 en la calidad de vida de los pacientes tratados en las consultas de atención primaria en España. *Aten Primaria* 2003;31(8):493-9.
37. Wanden-Berghe C, Martín-Rodero H, Guardiola-Wanden-Berghe R, Sanz-Valero J. Cuestionario de calidad de vida relacionado con el estado nutricional. *Nutr Hosp* 2012;27:1876-85.