

Cross-cultural adaptation of the EORTC QLQ-THY34 questionnaire to assess quality of life in patients with thyroid cancer in Colombia

Adaptación transcultural del cuestionario *EORTC QLQ-THY34* para medir la calidad de vida en pacientes con cáncer de tiroides en Colombia

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Resumen

Objetivo: adaptar transculturalmente, para su utilización en Colombia, el cuestionario *EORTC QLQ-THY34*, que evalúa la calidad de vida en pacientes con cáncer de tiroides.

Métodos: para el proceso de adaptación transcultural del instrumento se obtuvo la autorización y se siguieron los lineamientos del grupo *EORTC QoL*. Se revisó principalmente la versión en español para España y se propusieron algunos sinónimos y ajustes gramaticales. Luego, se realizó una prueba piloto entre agosto y septiembre de 2023 con 15 participantes del Instituto Nacional de Cancerología, mayores de 18 años, hispanoparlantes colombianos, con diagnóstico confirmado de cáncer de tiroides y sin limitaciones sensoriales o cognitivas que impidieran la aplicación del cuestionario.

Resultados: se ajustaron 7 de los 34 ítems para adaptarlos al español colombiano. En la prueba piloto participaron hombres y mujeres de distintos niveles educativos, ocupaciones, estratos económicos y regiones del país. Todos los ítems fueron comprendidos por los participantes y no hubo ítems ofensivos ni confusos. No fue necesario hacer ajustes adicionales tras la prueba piloto.

Conclusiones: se generó una versión en español para Colombia del cuestionario *EORTC QLQ-THY34*, la cual está disponible para su validación en la población colombiana.

Palabras clave: calidad de vida; encuestas y cuestionarios; neoplasias de la tiroides; Colombia.

Citation

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Conflicts of interest

The authors declare no conflicts of interest.

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Abstract

Objective: To cross-culturally adapt the EORTC QLQ-THY34 questionnaire, which assesses quality of life in patients with thyroid cancer, for use in Colombia.

Methods: Authorization was obtained for the cross-cultural adaptation of the instrument, and the EORTC QoL group guidelines were followed. The Spanish version for Spain was primarily reviewed, and some synonyms and grammatical adjustments were proposed. A pilot test was conducted between August and September 2023 with 15 participants from the *Instituto Nacional de Cancerología* (INC). Eligible participants were Spanish-speaking Colombian adults, over 18 years of age, with a confirmed diagnosis of thyroid cancer and no sensory or cognitive limitations that would prevent them from completing the questionnaire.

Results: Seven of the 34 items were adapted to Colombian Spanish. The pilot test included men and women from diverse educational levels, occupations, socioeconomic backgrounds, and regions of the country. The participants understood all items, and no offensive or confusing items were found. No further adjustments were required after the pilot testing.

Conclusions: A Colombian Spanish version of the EORTC QLQ-THY34 questionnaire was developed and is available for validation in the Colombian population.

Keywords: quality of life; surveys and questionnaires; thyroid neoplasms; Colombia.

Introduction

Thyroid cancer is the most common endocrine malignancy, ranking seventh among all cancer types in 2022, with 821,000 new cases worldwide. Conversely, during the same period, mortality from this cause was lower, ranking 24th globally with 47,507 cases, according to Globocan data (1), and was three times more frequent in women than in men (2). In 2023, at the *Instituto Nacional de Cancerología* (INC) of Colombia, thyroid cancer ranked second in cancer incidence for both sexes, with a total of 620 new cases, representing 9.3% of all cancer types (3).

The most common subtypes of thyroid cancer are papillary and follicular carcinomas (90.0–95.0%), which are generally slow-growing and rarely fatal. Less common (5.0–10.0%) are medullary, anaplastic, or poorly differentiated subtypes, which tend to have a moderate to severe prognosis and account for a large proportion of deaths attributable to thyroid cancer (4). Treatment is primarily surgical, along with thyroid-stimulating hormone (TSH) suppression therapy. Depending on the risk of recurrence, radioiodine

therapy is administered to reduce the likelihood of relapse, achieving a five-year relative survival rate of 98.2%, which decreases to 56.2% in cases of distant disease (5). Despite a generally good prognosis, concerns about recurrence, control of hypothyroidism symptoms, and surgical complications affect the quality of life of patients with this type of cancer (6), which is similar to that of patients with colon cancer, glioma, and gynecological cancers, and is even worse than that reported in patients with breast cancer (7).

The concept of health-related quality of life (HRQoL) is widely recognized in clinical practice worldwide. Its assessment requires various types of studies and the use of validated measurement tools, and it is fundamental to healthcare decision-making for both clinicians and patients, including survivors (8). Quantitative measurement of HRQoL improves communication among the medical team, the patient, and their family (9), making it an increasingly important patient reported outcome measure in oncology, as it has been shown to be associated with improved survival (10-11).

One of the most widely used generic instruments for measuring quality of life in patients with different types of cancer is the EORTC QLQ-C30 Quality of Life Questionnaire (European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire Core 30) (11), developed by the European Organization for Research and Treatment of Cancer (EORTC). This questionnaire has been adapted and validated in various languages and countries, including Colombia (12). In 2023, the EORTC published a specific module for patients with thyroid cancer, the EORTC QLQ-THY34 Quality of Life Questionnaire - Thyroid Cancer 34 (13), which enables a more comprehensive assessment of their particular health condition (8). The development of this questionnaire began in 2013 with the identification of relevant quality-of-life aspects in patients with thyroid cancer, in addition to those covered by the general questionnaire. In Phases I and II, two systematic reviews and structured interviews with 110 participants diagnosed with thyroid cancer resulted in a list of 47 items (14-15). In Phase III, a pilot test was conducted, and a series of predefined criteria was used to retain these items. These criteria included the items' importance and prevalence, the absence of floor and ceiling effects, adequate response variability, and acceptability, clarity, and patient compliance. Additionally, clinical relevance was considered, defined by the proportion of patients who identified items as especially important. Furthermore, the items were grouped into hypothetical scales, and Cronbach's alpha and scale error were evaluated, resulting in a reduced 34-item version (14). Finally, in 2023, Phase IV of the instrument's international validation was published. This phase confirmed the structure of the 34 items proposed in the previous phase and included multiple translations of the instrument, with validations for 12 languages, including the Spanish version for Spain (13). Since there is no validated version of the EORTC QLQ-THY34 questionnaire in the Spanish spoken in Colombia, the objective of this study was to perform its cross-cultural adaptation for subsequent clinimetric validation and use in the Colombian population.

Methods

Instrument

The EORTC QLQ-THY34 module consists of 34 items grouped into 9 scales that evaluate more than one item (multi-item)

and 8 scales composed of only one item. This module, which is complementary to the EORTC QLQ-C30 questionnaire, assesses symptoms such as dry mouth, difficulty swallowing, fatigue, drowsiness, worry, and social support, among others. Items were categorized ordinally using a Likert-type scale, assigning a specific score to each of the four response options: 1 (not at all), 2 (a little), 3 (quite a bit), and 4 (very much). The scores for items within each scale were then summed separately and standardized by converting these scores (from 1 to 4) into a measurable scale (from 0 to 100), according to the recommendations of the EORTC manual, where higher values indicate lower quality of life (16). Among the results of the international validation phase, the questionnaire scales showed adequate psychometric properties, with internal consistency values greater than 0.7 reported for most scales, as well as adequate test-retest reliability. Standardized factor loadings exceeded 0.4, and goodness-of-fit measures were appropriate. Convergent and divergent validity were consistent, as established by correlations with the general questionnaire, and the instrument was sensitive to change (13, 17-18).

Procedure

The cross-cultural adaptation of the EORTC QLQ-THY34 questionnaire was conducted within the framework of the study titled "Validation for use in Colombia of the EORTC QLQ-THY34 scale to measure the quality of life in patients with thyroid cancer," approved by the Research Ethics Committee of the INC of Colombia under Minute no. 0011-22. To achieve this, the following steps were followed in accordance with the EORTC guidelines (17):

1. **Request for authorization:** Authorization was requested from the EORTC QoL Translations group to carry out the cross-cultural adaptation of the EORTC QLQ-THY34 questionnaire to the Colombian context.
2. **Review of the questionnaire in Spanish:** The Spanish version was reviewed by three researchers who were subject matter experts, as recommended by the EORTC, and who were native speakers of Colombian Spanish, with the aim of producing a reconciled version in Spanish for Colombia. Some of them suggested using synonyms to improve understanding of the questions.

3. **Review by the EORTC translation group:** The reconciled Colombian Spanish version was sent to the EORTC QoL Translations group, and their approval was requested to conduct the pilot test.
4. **Pilot test:** This was conducted between August and September 2023 to verify that the Colombian Spanish adaptation of the questionnaire was understood. Following the EORTC QoL Translations group's recommendation to include 10 to 15 participants, each participant received a printed copy of the questionnaire to complete. An individual interview was then conducted to ask whether the participant found any items or words confusing, offensive, or difficult to understand, or had any additional comments. All observations were recorded in the format established by the EORTC.

The pilot study included patients over 18 years of age who received treatment at the INC, had a histopathologically confirmed diagnosis of thyroid cancer, and were Spanish-speaking Colombians. Patients with a history of a second primary cancer or with cognitive or sensory deficits that could hinder questionnaire administration were excluded. Patients were identified through a review of medical records and then contacted in person at the INC facilities.

Results

Adaptation of the questionnaire

The cross-cultural adaptation of the EORTC QLQ-THY34 questionnaire was carried out in April 2023. Following a recommendation from the EORTC QoL Translations group, the English-to-Spanish translation was omitted, and work began with items already translated into Spanish and validated in other studies. The questionnaire received by the development group contained 11 items in Colombian Spanish that required no adjustments. For the remaining 23 items, corresponding to the Spanish version for Spain, changes were proposed for 6 of them to use words more commonly used in Colombia to improve the clarity of the questions, and item 64 was modified to match its original English version (Table 1). No changes were made to the presentation of the response options. The original authors considered that the final reconciled version adequately preserved the purpose, linguistic properties, and grammatical components; therefore, they made no further modifications.

Table 1. Cross-cultural adaptation of the EORTC QLQ-THY34 questionnaire

Item number	Item in Spanish for Spain	Item in Spanish for Colombia
38	38. ¿Ha <u>tenido</u> la voz cansada?	38. ¿Ha <u>sentido</u> la voz cansada?
39	39. ¿Ha <u>tenido</u> el pelo <u>fino</u> o sin vida como consecuencia de su enfermedad o tratamiento?	39. ¿Ha <u>sentido</u> el pelo <u>débil</u> o sin vida como consecuencia de su enfermedad o tratamiento?
47	47. ¿Ha <u>tenido</u> latidos rápidos?	47. ¿Ha <u>sentido</u> que su corazón late rápidamente?
58	58. ¿Se ha preocupado <u>sobre</u> el futuro de las personas que son importantes para usted?	58. ¿Se ha preocupado <u>por</u> el futuro de las personas que son importantes para usted?
59	59. ¿Se ha preocupado por cómo <u>harán frente</u> a su enfermedad y tratamiento las personas cercanas a usted?	59. ¿Se ha preocupado por cómo <u>enfrentarán</u> su enfermedad y tratamiento las personas cercanas a usted?
63	63. ¿Se ha sentido apoyado/a por otros profesionales <u>sanitarios</u> (p. ej., los enfermeros)?	63. ¿Se ha sentido apoyado/a por otros profesionales <u>de la salud</u> (p. ej., los enfermeros)?
64	64. ¿Se ha sentido apoyado/a por sus familiares <u>y</u> amigos?	64. ¿Se ha sentido apoyado/a por sus familiares <u>o</u> amigos?

Pilot test

The reconciled Colombian Spanish version of the questionnaire was administered to 15 patients between August and September 2023, after they agreed to participate and signed an informed consent form. The median age was 57 years (interquartile range [IQR] = 19.5 years); slightly more than half were women (n = 8). Most belonged to socioeconomic strata 1 through 3 (n = 14) and had a median of 11 years of schooling (IQR = 9 years). The patients came from different departments of the country; most were married or in a common-law relationship (n = 8), and all were employed at the time of the interview (n = 6). For 14 of the 15 participants, the questionnaire completion time was recorded, with a median of 7.4 minutes (minimum 3.2 minutes and maximum 15.4 minutes) (Table 2).

Table 2. Sociodemographic characteristics of the participants

N.º	Sex	Age	Origin	Education level	Age of schooling	Socioeconomic stratum	Marital status	Occupation	Time (minutes)
1	M	46	Tolima	Postgraduate studies	21	6	Common-law union	Independent	3.1
2	F	76	Cundinamarca	Completed primary education	5	3	Widow	Home	14.3
3	F	59	Chocó	Higher education	14	2	Separated	Independent	4.4
4	M	48	Huila	Postgraduate studies	18	3	Married	Employed	2.3
5	M	76	Boyacá	Incomplete high school education	7	3	Married	Retired	9.1
6	M	58	Tolima	Completed high school education	11	2	Common-law union	Employed	7.0
7	M	66	Bogotá	Incomplete primary education	3	2	Married	Unemployed	No data
8	M	67	Bogotá	Completed high school education	11	3	Widower	Retired	9.1
9	F	55	Caldas	Completed primary education	5	2	Single	Independent	8.5
10	F	21	Bolívar	Completed high school education	11	3	Single	Student	8.1
11	F	69	Atlántico	Higher education	14	2	Single	Retired	8.6
12	F	57	Caquetá	Incomplete high school education	6	1	Married	Home	5.2
13	F	39	Meta	Higher education	15	3	Married	Independent	3.4
14	M	23	Nariño	Higher education	15	1	Single	Student	2.6
15	F	53	Norte de Santander	Incomplete primary education	3	1	Common-law union	Home	15.3

F: female; M: male.

Higher education: technician, technologist, or professional.

After the questionnaire was administered, none of the participants commented on their understanding of the questions. Four participants requested that the questions be read to them; one said, “*I’m too lazy to read*,” while the other three did so because refractive errors made independent reading difficult. Regarding item 51: “Have you worried about having to come off your thyroid hormone replacement tablets to prepare for a radioiodine body scan or radioiodine treatment?”, one participant stated that, because they had not received radioiodine therapy, they could not answer this question with certainty; another stated that the question frightened them because of their previous experience with this treatment; and a third

participant requested that the question be read to them twice and stated that they understood it the second time. For item 64, one patient paused before answering and commented, “It’s hard being a burden... It’s hard for everyone”; however, they did not consider it offensive, nor did they suggest rephrasing it. Finally, it was not necessary to explain any of the questions; no suggestions for modifications were received from the participants, nor was any discomfort expressed regarding the questions. In this way, an instrument adapted to Colombian Spanish was obtained for use with patients with thyroid cancer in Colombia (Table 3).

Table 3. Spanish version adapted for Colombia of the EORTC QLQ THY34 questionnaire

Los pacientes a veces dicen que tienen los siguientes síntomas o problemas. Por favor, indique hasta qué punto ha experimentado usted estos síntomas o problemas durante la última semana. Por favor, responda encerrando en un círculo el número que mejor se aplique a su caso.

Durante la última semana:

Número de ítem	Ítem en español para Colombia	Para nada	Un poco	Bastante	Muchísimo
31	¿Ha sentido un cansancio repentino?	1	2	3	4
32	¿Se ha sentido mentalmente agotado/a?	1	2	3	4
33	¿Se ha sentido físicamente agotado/a?	1	2	3	4
34	¿Ha tenido dolor en la garganta?	1	2	3	4
35	¿Ha tenido alguna molestia en el cuello?	1	2	3	4
36	¿Ha tenido problemas de ronquera?	1	2	3	4
37	¿Ha sonado distinta su voz como consecuencia de su enfermedad o tratamiento?	1	2	3	4
38	¿Ha sentido la voz cansada?	1	2	3	4
39	¿Ha sentido el pelo débil o sin vida como consecuencia de su enfermedad o tratamiento?	1	2	3	4
40	¿Ha tenido caída de pelo?	1	2	3	4
41	¿Ha tenido problemas para tragar comida sólida?	1	2	3	4
42	¿Se ha atorado cuando traga?	1	2	3	4
43	¿Ha tenido sequedad en la boca?	1	2	3	4
44	¿Ha tenido problemas para tolerar el calor o el frío?	1	2	3	4
45	¿Se ha sentido menos atractivo/a físicamente a causa de su enfermedad o tratamiento?	1	2	3	4
46	¿Se ha sentido inquieto/a o nervioso/a?	1	2	3	4
47	¿Ha sentido que su corazón late rápidamente?	1	2	3	4
48	¿Tuvo dificultad para levantar el brazo o moverlo a los lados?	1	2	3	4
49	¿Ha sentido como si tuviera un nudo en la garganta?	1	2	3	4
50	¿Ha estado preocupado/a por una posible recaída de su enfermedad?	1	2	3	4
51	¿Se ha preocupado por tener que suspender sus pastillas de terapia hormonal sustitutiva tiroidea para prepararse para una gammagrafía tiroidea con yodo o un tratamiento con yodo radioactivo?	1	2	3	4
52	¿Se ha preocupado por tener que tomar medicamentos durante el resto de su vida?	1	2	3	4
53	¿Ha tenido dolor en las articulaciones?	1	2	3	4
54	¿Ha sentido hormigueos o adormecimiento en los dedos de las manos o de los pies?	1	2	3	4
55	¿Ha sentido hormigueos o adormecimiento alrededor de su boca?	1	2	3	4

Número de ítem	Ítem en español para Colombia	Para nada	Un poco	Bastante	Muchísimo
56	¿Ha tenido algún calambre muscular?	1	2	3	4
57	¿Se ha sentido afectado al ver a las personas cercanas a usted afligidas como consecuencia de su enfermedad o tratamiento?	1	2	3	4
58	¿Se ha preocupado por el futuro de las personas que son importantes para usted?	1	2	3	4
59	¿Se ha preocupado por cómo enfrentarán su enfermedad y tratamiento las personas cercanas a usted?	1	2	3	4
60	¿Se ha preocupado por llegar a convertirse en una carga para los demás?	1	2	3	4
61	¿Ha tenido algún problema con su trabajo o sus estudios como consecuencia de su enfermedad o tratamiento?	1	2	3	4
62	¿Se ha sentido apoyado/a por los médicos?	1	2	3	4
63	¿Se ha sentido apoyado/a por otros profesionales de la salud (p. ej., los enfermeros)?	1	2	3	4
64	¿Se ha sentido apoyado/a por sus familiares o amigos?	1	2	3	4

Discussion

This work fulfilled the objective of cross-cultural adaptation of the EORTC QLQ-THY34 questionnaire for use in Colombia. Spanish is one of the most widely spoken languages in the world, and works aimed at adapting instruments have found that their content is understood by most Spanish speakers (18). In this study, the questionnaire adaptation process was facilitated by the EORTC QoL Translations group, which provided items from the Spanish version used in Spain. However, because subtle changes in language can alter interpretation and affect the semantic equivalence of scales measuring complex phenomena such as HRQoL (19), it is important to adhere to the standardized cross-cultural adaptation procedure, as was done in this study.

During the review by the researchers, adjustments were not needed for most items; however, in three items, the verb “sentir” (“feel”) was used instead of “tener” (“have”) because the former (*sentir*) often connotes a more direct, subjective perception of a physical sensation, whereas the latter (*tener*) can sound more like an event or a diagnosis, rather than a personal experience (20-21). The change from “sanitarios” (“healthcare workers”) to “profesionales de la salud” (“health professionals”) is due to the terminological difference of the word “sanitarios,” which is common in Spain but rarely used in Colombia. Item 64 was adjusted

based on its original English version, which uses the conjunction “or,” whereas the Spanish translation used “y” (“and”).

The proposed adjustments did not alter the evaluated construct but rather facilitated understanding of the statements by confirming that, although the same language is used, linguistic and cultural adaptations are necessary to ensure the semantic equivalence of the instruments and thus optimize their application in clinical practice and research in Colombia.

Regarding the pilot test, the time required to complete the questionnaire was deemed adequate, with most participants taking less than 10 minutes, consistent with findings from Phase IV of the questionnaire validation (8). No adjustments were made to the final version because no items were difficult to understand, confusing, offensive, or bothersome to the participants. This finding was consistent with the validation study conducted in India (22) and contrasted with results from China, where items 38 and 44 had to be modified (23).

The limitations of this study included the absence of participants without an educational level in the pilot group, the predominance of participants from the Andean region, and the lack of representation of socioeconomic strata 4 and 5. These limitations are likely attributable to the location of the INC and the sociodemographic

profile of the population it serves; however, it was possible to have participants from different social groups, contributing diversity to the sample.

The adaptation process of the EORTC QLQ-THY34 questionnaire followed the guidelines established by the EORTC group, an essential step that must be completed before the instrument's psychometric validation to ensure a valid and reliable tool for measuring quality of life in patients with thyroid cancer. At the time of this study, no publications were found on the cultural adaptation of the EORTC QLQ-THY34 questionnaire in other Spanish-speaking populations.

As a result of this work, an adapted version of the EORTC QLQ-THY34 questionnaire was developed for Colombian patients with thyroid cancer. This advancement will enable the continuation of its validation phase in Colombia and provide a tool for measuring the quality of life in this patient group.

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