

# Portuguese Version of the EORTC QLQ-OES18 and QLQ-OG25 for Health-Related Quality of Life Assessment



ARTIGO ORIGINAL

## Versão Portuguesa do EORTC QLQ-OES18 e do QLQ-OG25 para Avaliação da Qualidade de Vida Relacionada com a Saúde

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### ABSTRACT

**Introduction:** Health-related quality of life assessment is increasingly important as it can help both clinical research and care for patients, particularly among oncological patients. Quality of Life Questionnaire – OES18 (esophageal module) and Quality of Life Questionnaire – OG25 (esophagogastric module) are the European Organization for Research and Treatment of Cancer modules for the evaluation of quality of life in patients with esophageal and esophagogastric cancers, respectively. The aim of our study was to translate, to culturally adapt and to perform a pilot testing to create the Portuguese version of both questionnaires.

**Material and Methods:** The European Organization for Research and Treatment of Cancer guidelines were followed for translation, cultural adaptation and pilot testing of Quality of Life Questionnaire – OES18 (esophageal module) and Quality of Life Questionnaire – OG25 (esophagogastric module). The Quality of Life Questionnaire – OG25 (esophagogastric module) went through a process of forward (English → Portuguese) and backward (Portuguese → English) translation, by independent native speaker translators. After review, a preliminary version was created to be pilot tested among Portuguese patients. As a Brazilian version was already available for Quality of Life Questionnaire – OES18 (esophageal module), the questionnaire was simply culturally adapted and pilot tested. Both cancer and non-cancer patients were included.

**Results:** Overall, 30 patients completed the Portuguese version of each questionnaire. Afterwards, a structured interview was conducted to find and report any problematic items. Troublesome items and wording were changed according to the pilot testing results. The final versions were sent to the European Organisation for Research and Treatment of Cancer Quality of Life Group and approved.

**Conclusion:** The Portuguese versions of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – OES18 (esophageal module) and OG25 (esophagogastric module) questionnaires are useful, reliable and valid tools for measuring health-related quality of life in patients with esophageal and esophagogastric cancers, respectively. They can now be used in clinical setting and for scientific purposes.

**Keywords:** Esophageal Neoplasms; Portugal; Psychometrics; Quality of Life; Stomach Neoplasms; Surveys and Questionnaires; Translations

### RESUMO

**Introdução:** A avaliação da qualidade de vida relacionada com a saúde é cada vez mais importante, já que pode beneficiar a investigação clínica e os cuidados prestados aos doentes, particularmente entre doentes oncológicos. O *Quality of Life Questionnaire – OES18 (esophageal module)* e o *Quality of Life Questionnaire – OG25 (esophagogastric module)* são módulos da Organização Europeia para a Investigação e Tratamento do Cancro para avaliação da qualidade de vida em doentes com neoplasia esofágica e/ou esofagogastrica, respetivamente. O objetivo do nosso estudo foi traduzir, adaptar culturalmente e realizar um ensaio-piloto para criar a versão portuguesa de ambos os questionários.

**Material e Métodos:** Foram seguidas as orientações da Organização Europeia para a Investigação e Tratamento do Cancro para tradução, adaptação cultural e ensaio-piloto do *Quality of Life Questionnaire – OES18 (esophageal module)* e *Quality of Life Questionnaire – OG25 (esophagogastric module)*. O *Quality of Life Questionnaire – OG25 (esophagogastric module)* passou por um processo de tradução (inglês → português) e tradução-reversa (português → inglês), por tradutores independentes falantes nativos. Após revisão, uma versão preliminar foi criada para ensaio-piloto entre doentes portugueses. Uma vez que já estava disponível uma versão brasileira do *Quality of Life Questionnaire – OES18 (esophageal module)*, o questionário foi apenas adaptado culturalmente e alvo de ensaio-piloto. Foram incluídos doentes com e sem neoplasia.

**Resultados:** No total, 30 doentes preencheram a versão portuguesa de cada questionário. No final, foi conduzida uma entrevista estruturada para detetar e documentar quaisquer tópicos problemáticos. Tópicos e enunciados problemáticos foram alterados, conforme os resultados do ensaio-piloto. As versões finais foram enviadas para o grupo de Qualidade de Vida da Organização Europeia para a Investigação e Tratamento do Cancro e foram aprovados.

**Conclusões:** As versões portuguesas dos questionários da Organização Europeia para a Investigação e Tratamento do Cancro *Quality of Life Questionnaire – OES18 (esophageal module)* e *OG25 (esophagogastric module)* são instrumentos úteis, fidedignos e válidos para aferição da qualidade de vida relacionada com a saúde em doentes com neoplasia esofágica e/ou esofagogastrica, respetivamente. Podem agora ser utilizados em contexto clínico e para fins científicos.

**Palavras-chave:** Inquéritos e Questionários; Neoplasia do Esófago; Neoplasia do Estômago; Portugal; Psicometria; Qualidade de Vida; Traduções

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## INTRODUCTION

Both gastric and esophageal cancers remain serious public health problems. Gastric cancer (GC) is the second leading cause of cancer-related death<sup>1-3</sup> and in Portugal represents about a tenth of all cancer-related mortality, with almost twice the average mortality of European Union countries and the highest among all Western European countries.<sup>2,4</sup> Esophageal cancer (EC) is the sixth most common cause of cancer-related mortality worldwide.<sup>1,5</sup> Although GC incidence and mortality rates have been reported to be declining, the number of cases is expected to increase, due to an aging population.<sup>2,3</sup> Also, EC incidence is overall expected to rise over the next 10 years, mainly due to a rapid increase in distal esophageal adenocarcinoma, even if squamous cell carcinoma remains the most common histological type.<sup>6,7</sup>

However, the diagnosis is often made at an advanced stage, as a result of the late appearance and/or non-specificity of symptoms. Hence, the prognosis is almost invariably poor, with dismal 5-year survival rates, not exceeding 20% for EC and 25% for GC.<sup>3,5,8</sup>

Health-related quality of life (HRQoL) is a subjective concept, comprising four primary domains – physical, psychological/emotional, social and occupational well-being.<sup>9,10</sup> In oncology, the pertinence of its assessment has become increasingly clear, as it can help improving care for patients, not exclusively as a predictor of morbidity and mortality, but also as a noteworthy parameter in treatment decision making (moreover, when it comes to palliative care).<sup>10</sup>

When assessing HRQoL, it is pivotal to focus very clearly on specific domains.<sup>9</sup> Over the last decades, the European Organisation for Research and Treatment of Cancer (EORTC) has developed a multitude of instruments to appraise HRQoL in cancer patients.<sup>11</sup> For an overall assessment, a core general questionnaire, the EORTC Quality of Life Questionnaire – C30 (general module) (QLQ-C30), was created, comprising multi-item scales: five functional scales, three symptom scales and a global health and quality of life scale.<sup>12</sup> However, the need to evaluate more specific domains in order to enhance the sensitivity to detect small, but clinically important, differences in HRQoL, guided the creation of numerous disease-specific/site-specific modules.<sup>13</sup> Among those, Quality of Life Questionnaire – OES18 (esophageal module) (QLQ-OES18) and Quality of Life Questionnaire – OG25 (esophagogastric module) (QLQ-OG25) were produced with the intent of assessing HRQoL among patients with esophageal and esophagogastric (including tumours of the esophagus, the esophagogastric junction and the stomach) cancers, respectively.<sup>14,15</sup>

The goal of this work is to perform both the translation of the English version of the EORTC QLQ-OG25 and the cultural adaptation of the Brazilian version of the EORTC QLQ-OES18 to Portuguese (Portugal), with the purpose of providing suitable tools for HRQoL assessment in Portuguese-speaking patients with esophageal and/or

gastric cancers.

## MATERIAL AND METHODS

### Questionnaires: EORTC QLQ-OES18

This disease-specific module is a self-report 18-item questionnaire designed to appraise HRQoL among patients with EC undergoing any single or combination of treatments (esophagectomy, chemoradiation, endoscopic palliation or palliative chemotherapy and/or radiotherapy). The final version includes four symptom scales (dysphagia, eating restrictions, reflux and pain) and six single items. The single items measure difficulties swallowing saliva, choking, dry mouth, taste problems, coughing and speech problems. All items report to a specific length of time (“during the past week”) and each is scored on a 4-point scale, as follows: ‘not at all’ (1), ‘a little’ (2), ‘quite a bit’ (3), ‘very much’ (4). As with all disease-specific/site-specific modules, QLQ-OES18 should always be complemented by the QLQ-C30.<sup>14</sup>

### EORTC QLQ-OG25

This module is disease-specific and complementary to the general QLQ-C30. It evaluates HRQoL among patients with cancer of the esophagus, the esophagogastric junction and/or the stomach varying in disease stage and treatment modality (i.e. surgery, chemotherapy, radiotherapy, palliation, etc.). The final version has six symptom scales (in particular dysphagia, eating restrictions, reflux, odynophagia, pain and discomfort); two items evaluating anxiety; and 10 single items (eating with others, dry mouth, sense of taste, body image, saliva, choking, cough, speech, weight loss and hair loss), totalling 25 items. It reports to a specific length of time (‘during the past week’) and each of the items is scored on a 4-point scale similar to that of QLQ-OES18.<sup>15</sup>

### Translation procedure

The translation along with cultural adaptation and pilot testing of the QLQ-OES18 and QLQ-OG25 modules were authorized by the EORTC Quality of Life Department and performed according to the EORTC translation procedure.<sup>16</sup>

### Translation of QLQ-OG25

The original English version was given to two independent translators, Portuguese native speakers fluent in English, originating two initial Portuguese versions of the QLQ-OG25: forward translation 1 (FWT1) and forward translation 2 (FWT2). These translations were reviewed and compared and after discussion (between the project manager, the translators and third-party translators – Portuguese gastroenterology specialists) a reconciliated intermediate version (FWT12) was accomplished. FWT12 went through backward translation into English by two independent English native speakers, both professional translators fluent in Portuguese, generating backward translation 1 (BWT1) and backward translation 2 (BWT2). Thereupon, the project manager reviewed and compared the backward translations with the original English version.

A translation report was prepared and sent to the EORTC for approval. Few adjustments were suggested by the committee and were added to the FWT12, creating a secondary intermediary version. All the translation process documentation was compiled and sent to the EORTC Quality of Life Department. Based on the reports, EORTC approved the preliminary Portuguese version of the QLQ-OG25 and sent it back for pilot testing.

### Cultural adaptation of QLQ-OES18

For the QLQ-OES18, a Brazilian version was already available. However, as some items were not considered appropriate according to linguistic inaccuracies, the authors suggested that a cultural adaptation was made, while trying to minimize the number of amendments. After acceptance, the EORTC proposed that the researchers themselves rewrote the Brazilian version. A revised version was created and sent to the EORTC, who approved it and prepared it for pilot testing.

### Pilot testing of QLQ-OG25 and QLQ-OES18

Once the preliminary versions of both questionnaires

were approved, the modules were pilot-tested in a sample of patients (both cancer and non-cancer patients) attending at the Portuguese Institute of Oncology of Porto, Portugal. Ethics Committee of the Institution approved the study. Written informed consent was obtained from all enrolled patients.

Patients were asked to fill out the questionnaire. Thereafter, a structured interview focused on each item separately was conducted with the view to evaluate whether the individuals report any difficulty answering the questions, whether they found any of the items confusing, upsetting/offensive and/or containing difficult vocabulary. When a patient described finding an item problematic, he/she was asked to comment and, if possible, to hint an alternate wording. All data was recorded on a specific response sheet.

Once the pilot testing ended, bothersome items and wording were changed according to patients' comments. Following the advice of the EORTC Translation Office, all re-written items were re-tested by phone interview in those individuals reporting problematic items. A report was sent to the EORTC Quality of Life Department for final acceptance.

Table 1 - Sociodemographic and clinical information of the sample study for QLQ-OES18

QLQ-OES18 (n = 30)		
	Cancer patients (n = 12)	Non-cancer/under follow-up patients† (n = 18)
	Total	Total
<b>Age (years) Mean (SD)</b>	63 (9.85)	63 (11.74)
<b>Sex n (%)</b>		
<b>Male</b>	11 (91.7%)	9 (50.0%)
<b>Female</b>	1 (8.3%)	9 (50.0%)
<b>Educational level n (%)</b>		
<b>Elementary school</b>	11 (91.7%)	15 (83.3%)
<b>Secondary school</b>	1 (8.3%)	1 (5.6%)
<b>Higher education</b>	0 (0%)	2 (11.1%)
<b>Tumor type n (%)</b>		
<b>Squamous cell</b>	9 (75.0%)	NA
<b>Adenocarcinoma</b>	3 (25.0%)	NA
<b>Surgery n (%)*</b>	3 (25.0%)	NA
<b>Additional treatment n (%)*</b>		
<b>None</b>	4 (33.3%)	NA
<b>Chemotherapy (CT)</b>	2 (16.7%)	NA
<b>Radiotherapy (RT)</b>	0 (0%)	NA
<b>CT + RT</b>	4 (33.3%)	NA
<b>Endoscopic palliation</b>	5 (41.7%)	NA
<b>Present status n (%)</b>		
<b>Staging</b>	2 (16.7%)	NA
<b>Surveillance</b>	4 (33.3%)	NA
<b>Palliation</b>	6 (50.0%)	NA

\* In the present or past

† Included patients submitted to upper endoscopy for gastrointestinal symptoms, screening of EC (with negative results) and/or GC (irrespective of the result) or follow-up of lymphomas, neuroendocrine or stromal tumors as well as gastric malignancies

## Patients' selection

Patients were recruited between July and October 2015 at the Department of Gastroenterology of the Portuguese Institute of Oncology of Porto (Portugal) during their arrival for medical consultation diagnostic and/or therapeutic procedures. Patients with cancer demonstrated by endoscopy, endoscopic biopsy and histopathology study of the biopsy were included and assigned to answer to the corresponding questionnaire (or both, in the case of EC) – ‘cancer patients’ subgroup. Some patients submitted to upper endoscopy for gastrointestinal symptoms, screening of EC and/or GC (with negative results for either or both) or follow-up of lymphomas, neuroendocrine or stromal tumors have also been included – “non-cancer/under follow-up patients” subgroup. In the case of QLQ-OES18, the latter subgroup also included patients diagnosed with gastric malignancies, as they are outside the scope of this disease-specific module questionnaire. Study exclusion criteria were lack of consent and inability to understand or fill out the questionnaire. There were no restrictions as to the gender, age or education level. Information about every participant's clinical history was taken from patient interview and medical records.

## Statistical analysis

Once the interviews were finished, all data was compiled and analysed through simple descriptive statistics, using IBM SPSS Statistics software®.

## RESULTS

In total, 31 patients were recruited. However, one was illiterate (one of the few study exclusion criteria). Therefore, 30 patients completed each questionnaire. All relevant demographic and clinical information are presented in Tables 1 and 2. Overall, the mean age of respondents was 63.0 years (standard deviation [SD] 10.8 years; range 39 - 83 years) and two-thirds were male. Regarding education, 26 patients (86.7%) only attended elementary school.

Using the American Joint Cancer Committee (AJCC)/ Union for International Cancer Control (UICC) TNM system with corresponding stage grouping (7<sup>th</sup> edition), participants in the cancer subgroup were staged.<sup>17,18</sup> The study included patients from all cancer staging groups. In the QLQ-OES18 (Table 1), 75% of the patients had squamous cell carcinoma and half were under palliative treatment. In this subgroup, a quarter of patients had stage I cancer and another quarter had stage II; 33% were staged III and 2 patients had stage IV cancer. Among the QLQ-OG25 cancer subgroup (Table 2), all GC were adenocarcinoma; 9 out of 10 EC were squamous cell carcinoma. These participants were staged as follows: 6 patients on cancer staging group I; 4 on stage II; 8 on stage III and finally 4 on staging group IV.

The non-cancer/under follow-up subgroups of both QLQ-OES18 and QLQ-OG25 included three patients submitted to upper endoscopy for gastrointestinal symptoms and/or negative screening of EC and/or GC. There were also included five patients under follow-up for treated MALT

lymphoma (n = 1), neuroendocrine (n = 2) or gastrointestinal stromal tumor – GIST – (n = 2). In the case of the QLQ-OES18 sample study, this subgroup also comprised 10 patients with gastric adenocarcinoma, as explained in the ‘patients’ selection” section.

All patients completed the corresponding questionnaire in less than 20 minutes in a quiet environment in the hospital setting.

Once the pilot testing ended, patients' comments were analysed. There were no reports of upsetting/offensive items. The revised version of the QLQ-OES18 suffered only a minor rectification in wording on a single item (question 37). Concerning the QLQ-OG25, more items were found to be bothersome. In total, four items (out of the six where difficulties were reported) were changed in comparison with the preliminary version. Three patients reported difficulty understanding the meaning of the word ‘enjoying’ (*‘usufruir’* – question 34), but none suggested an alternate wording. Then, it was added the expression *‘ter prazer’*, just after the word *‘usufruir’*. Another proposed amendment concerns difficulties differentiating the words ‘pain’ (*‘dores’* – questions 41 and 42) and ‘discomfort’ (*‘desconforto’* – questions 40 and 43), as reported by three patients. In the final version, the word *‘desconforto’* was replaced by *‘mal-estar’*. A minor rectification in wording on a single item (question 35 – similar to QLQ-OES18 item 37) completed the changes in this module.

After revising both questionnaires, the new versions were re-tested by phone interview, as purposed by the EORTC Translation Office. None of the patients who have previously reported difficulties found any difficulty answering the questions and/or containing difficult vocabulary. All agreed the changes would facilitate understanding. Thereby, a final report was sent to the EORTC Quality of Life Department for acceptance. The Portuguese versions of QLQ-OES18 and QLQ-OG25 were approved.

## DISCUSSION

This article presents data from the translation, cultural adaptation and pilot testing of the EORTC QLQ-OES18 and QLQ-OG25. To the best of our knowledge, our study has been the first to perform the translation and linguistic adaptation of the QLQ-OG25 to Portuguese (Portugal) and also the cultural adaptation of the Brazilian version of the QLQ-OES18 to Portuguese (Portugal)

There is an increased research focus on HRQoL. Its assessment has invaluable importance for health care professionals, especially in oncology setting, where multiple interventions are aggressive and many survival rates are extremely low. It may not only be a predictor of morbidity and mortality, but also a relevant parameter in treatment decision-making, by providing clinical insights of the impact of the disease (and related treatments) on a myriad of domains.<sup>1,2,5,9,10,13</sup> By virtue of its epidemiological and clinical characteristics, EC and GC pose two malignancies where HRQoL is essential to guide clinical decisions.

Table 2 - Sociodemographic and clinical information of the sample study for QLQ-OG25

QLQ-OG25 (n = 30)		
	Cancer patients (n = 22)	Non-cancer/under follow-up patients† (n = 8)
	Total	Total
<b>Age (years) Mean (SD)</b>	64 (10.39)	61 (12.42)
<b>Sex n (%)</b>		
<b>Male</b>	15 (68.2%)	5 (62.5%)
<b>Female</b>	7 (31.8%)	3 (37.5%)
<b>Educational level n (%)</b>		
<b>Elementary school</b>	20 (90.9%)	6 (75.0%)
<b>Secondary school</b>	2 (9.1%)	0 (0%)
<b>Higher education</b>	0 (0%)	2 (25.0%)
<b>Tumor type n (%)</b>		
<b>Esophageal cancer</b>		
<b>Squamous cell</b>	9 (40.9%)	NA
<b>Adenocarcinoma</b>	1 (4.5%)	NA
<b>Esophagogastric cancer</b>		
<b>Squamous cell</b>	0 (0%)	NA
<b>Adenocarcinoma</b>	2 (9.1%)	NA
<b>Gastric cancer</b>		
<b>Squamous cell</b>	0 (0%)	NA
<b>Adenocarcinoma</b>	10 (45.5%)	NA
<b>Surgery n (%)*</b>	11 (50.0%)	NA
<b>Additional treatment n (%)*</b>		
<b>None</b>	10 (45.5%)	NA
<b>Chemotherapy (CT)</b>	6 (27.3%)	NA
<b>Radiotherapy (RT)</b>	0 (0%)	NA
<b>CT+RT</b>	4 (18.2%)	NA
<b>Endoscopic palliation</b>	7 (31.8%)	NA
<b>Present status n (%)</b>		
<b>Staging</b>	2 (9.1%)	NA
<b>Surveillance</b>	12 (54.5%)	NA
<b>Palliation</b>	8 (36.4%)	NA

\* In the present or past

† Included patients submitted to upper endoscopy for gastrointestinal symptoms, screening of EC and/or GC (with negative results for both) or follow-up of lymphomas, neuroendocrine or stromal tumors

The original version of both QLQ-OES18 and QLQ-OG25 has been checked for clinical and psychometric validity in multicentric studies.<sup>14,15</sup> Ever since, several translations and cultural adaptations have been performed to allow the use of these modules in different populations<sup>16</sup> and numerous clinical trials have been done to evaluate the impact of distinct procedures in HRQoL. However, it is important to note that sociodemographic and clinical variables asymmetries may markedly influence HRQoL and response patterns among different populations.<sup>19,20</sup> Such effects may influence decision-making, as the same intervention may have disparate effects among patients of different cultural backgrounds. This insight at least partly explains and justifies the importance of performing the

translation of QLQ-OES18 and QLQ-OG25 to the national native language (in this case, Portuguese).

The results of our study make us believe that QLQ-OES18 and QLQ-OG25 are ready to be implemented in the Portuguese population in clinical research and in clinical practice. First of all, most of the participants, although attending only the elementary school, have been able to understand and complete our questionnaires. Secondly, both questionnaires were applied in a sample of asymptomatic patients or respondents with benign esophageal or gastric disease, potential future targets of the EORTC modules. We believe both arguments strengthen the validity and reliability of our study.

The current study might have several flaws. First, pilot

testing was restricted to a convenience sample. Although small, we believe the sample size is satisfactory, as it follows the orientations of the EORTC translation procedure.<sup>16</sup> Second, patients were all inhabitants of the northern region of Portugal. Nevertheless, we presume no changes would be made if applied to any other Portuguese citizen, as there are no regionalisms. Third, although the sample size was acceptable for the analyses that we performed, a large prospective study would supply more reliable data on the psychometric properties of the Portuguese version of both questionnaires among patients with EC and/or GC.

## CONCLUSION

In conclusion, this study provides the Portuguese version of EORTC QLQ-OES18 and QLQ-OG25, two helpful instruments for measuring HRQoL among patients with esophageal and esophagogastric cancer (together with the core QLQ-C30), respectively. The implementation of these tools in clinical practice, and in research studies, will make apparent which interventions have a significant impact in patients' quality of life.

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## PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association. Written informed consent was obtained from all enrolled patients.

## DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patient's data publication.

## CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

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