

**Aim of the study:** To assess influencing factors and main health-related quality of life (HRQoL) issues in patients with cancers of the oesophago-gastric region using the European Organization for Research and Treatment of Cancer (EORTC) quality of life questionnaire Core 30 (QLQ-C30) and its oesophago-gastric module (QLQ-OG25).

**Material and methods:** Patients were qualified for this study based on the histological confirmation of oesophageal, oesophago-gastric or gastric cancers. Each patient filled out the Polish version of the EORTC QLQ-C30, the QLQ-OG25 module and a personal questionnaire. Patients were divided into groups based on gender, age, treatment intention, tumour localization, working status and level of education.

**Results:** Our study included 112 patients – 39 women (35%) and 73 men (mean age  $\pm$  SD; 60.2  $\pm$  10.9). Thirty-five patients (31.3%) completed the questionnaires twice. Eighty-four (75%) patients had gastric cancer (GC), twenty-six (23.2%) oesophageal cancer (OC) and two (1.8%) cancer of the oesophago-gastric junction (OGJC). Eighty (71.4%) patients underwent surgical treatment prior to either chemo-, radio- or chemoradiotherapy. The Global Health Status scale of the QLQ-C30 inversely correlated with all the other QLQ-C30 and QLQ-OG25 symptom scales ( $r = -0.26$  to  $-0.61$ ;  $p < 0.05$ ).

**Conclusions:** The main HRQoL problems of Polish OC, OGJC and GC patients are fatigue, insomnia, anxiety, and appetite and weight loss. Older age, receiving palliative treatment, having gastric cancer, being on retirement and having lower education are factors associated with higher symptom scores (worse symptoms) and thus poorer HRQoL.

**Key words:** cancer, oncology, quality of life, QLQ-OG25, QLQ-C30, oesophago-gastric.

# Main influencing factors and health-related quality of life issues in patients with oesophago-gastric cancer – as measured by EORTC tools

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## Introduction

Over the last three decades the epidemiology of oesophageal and gastric cancers has demonstrated significant changes [1]. In Poland cancers of the oesophagus (OC) and the oesophago-gastric junction (OGJC) are rare – below 2% of all malignant neoplasms [2]. In men oesophageal cancer is the 10th cause (2.3%) of cancer-related deaths. On the other hand, gastric cancers are still fairly common in Poland and constitute 5.7% and 3.4% of all malignant neoplasms in Polish men and women respectively. Gastric cancer remains the 3<sup>rd</sup> (7.4% in men) and 5<sup>th</sup> (5.5% in women) cause of cancer-related deaths [3]. Thus GC in Poland still represents a huge social and oncological problem.

Worldwide the incidence of OC and gastric cardia cancers is increasing, while the incidence of non-cardia adenocarcinomas of the stomach is decreasing [1]. Health-related quality of life (HRQoL) measurement is an important component of the assessment of cancer patients, including patients with OC, OGJC and gastric malignancies. Having in mind the number of people with oesophago-gastric cancers, we should understand that HRQoL problems in this group of patients currently represent a major challenge, firstly, because of the nature of the disease, and secondly, because of the number of people suffering from oesophago-gastric region cancers. Not only is HRQoL an important outcome measurement in everyday oncological practice, but also it is more and more commonly taken into account as one of the endpoints in clinical trials, providing a lot of information about the state of our patients [4, 5]. For some patients, especially with metastatic disease, it is the most important thing, even more important than prolonging life. That is why it is imperative to get to know the main HRQoL issues which oesophago-gastric cancer patients have to face every day. This knowledge will help physicians meet the needs of their cancer patients. There are studies stating that by simply measuring HRQoL also the patient-physician communication may be improved [6].

Quality of life questionnaires (QLQ) for measuring HRQoL in cancer patients are created by the European Organization for Research and Treatment of Cancer (EORTC). There are questionnaires designed to measure HRQoL in OC and GC patients. The QLQ-C30 is the core questionnaire and there are additional modules that are meant to be used with it [7]. Those are the QLQ-STO22, specific for gastric cancers [8]; the QLQ-OES18, specific for oesophageal cancers [9]; and the QLQ-OG25 (created by combining the corresponding ques-

tions from the previous two), specific for oesophago-gastric cancers [10]. By using the QLQ-OG25 instead of two separate questionnaires, one can avoid the existing overlapping in HRQoL issues between oesophageal and gastric cancer patients. This has decreased the number of questions the patient has to answer during the interview. All of the questionnaires have been translated and validated into many languages and their Polish versions are available from the EORTC [10, 11]. Our group has translated and validated the Polish version of the QLQ-OG25 module [12].

The aim of this study was to assess the influencing factors and main health-related quality of life issues in patients with cancers of the oesophago-gastric region using the EORTC QLQ-C30 and its QLQ-OG25 module.

## Material and methods

### Patients

In this study patients were recruited prospectively between January 2011 and May 2012. The recruitment process took place at the Department of Clinical Oncology at the University Hospital in Krakow. Patients were eligible if they had a histologically confirmed diagnosis of oesophageal or gastric cancer, including neoplasms located at the oesophagogastric junction. Location of the tumour was reconfirmed on the basis of computed tomography (CT). All histological types of OC, GC and OGJC were included in the study.

Patients included in the study were classified into groups based on gender (female vs. male), age (below vs. above or equal to 60 years of age), treatment intention (curative vs. palliative), tumour localization (oesophagus vs. stomach) and working status (employed vs. retired/pensioner).

Patients were interviewed during their visits at the outpatient clinic or during their stay at the ward. The second interview took place after a minimum of two weeks counting from the first interview. During the interview each patient completed the Polish version of the EORTC QLQ-C30, the QLQ-OG25 module and a personal questionnaire. Clinical history and physical examination were registered for all patients.

Exclusion criteria included lack of consent to participate in the study, inability to understand or complete the questionnaires and presence of concurrent malignancies. There were no restrictions as to gender or age. All patients gave their informed consent to participate in this study. The research protocol was approved by the Jagiellonian University Ethics Committee (registry KBET/250/B/2011).

### Translation and pilot testing

The Polish version of the EORTC QLQ-C30 (version 3.0) was previously translated. The translation process of the EORTC QLQ-OG25 Polish version was authorized by the EORTC. Items deriving from the Polish versions of the QLQ-STO22 and the QLQ-OES18 were used in an unchanged state. The remaining items were translated according to the official EORTC guidelines [13].

The translated, initial version of the QLQ-OG25 was pilot-tested on 25 Polish patients with OC, OGJC or GC. Their comments were analyzed and minor language changes were made to the initial translation. This version was once again tested on 15 additional patients. After this phase the final transla-

tion of the Polish version of the QLQ-OG25 was obtained and approved by the EORTC Quality of Life Department.

### Questionnaires

The QLQ-C30 is a 30-item questionnaire comprised of a global health status, five multi-item functional scales, three multi-item symptom scales, and six symptom single items.

The QLQ-OG25 is a 25-item module comprised of six multi-item scales: dysphagia, eating restriction, reflux, odynophagia, pain and discomfort, and anxiety. In addition to the six multi-item scales the QLQ-OG25 has 10 single items. Higher scores indicate worse symptomatic problems.

All of the QLQ-C30 and the QLQ-OG25 multi-item scales and single items were scored on a 1 to 4 point Likert scale ("not at all", "a little", "quite a bit", "very much"), apart from items 29 and 30 of the QLQ-C30, which were scored on a 1 to 7 point scale. Items 29 and 30 comprise the global health status. Detailed information on how to score the EORTC questionnaires can be found in the QLQ-C30 scoring manual and its addendum [14].

### Statistical analysis

Statistical analysis was conducted using Statistica 10.0 PL computer software by StatSoft Poland. Scores for multi-item functional or symptom scales and for single items were calculated by linear transformation of raw scores into a 0-100 score, with 100 representing the best global health, functional status or worst symptoms – depending on the measuring property of each multi-item or single-item scale, as described by the EORTC [14, 15]. To analyse the data we used elements of descriptive statistics (mean, standard deviation, percentage distribution).

Group comparison was used to assess the differences in HRQoL issues between known groups. Known groups used in this study were: gender (female vs. male), age (below vs. above or equal to 60 years of age), treatment intention (curative vs. palliative), tumour localization (oesophagus vs. stomach), working status (employed vs. retired/pensioner) and level of education (elementary vs. high school vs. vocational vs. university). Differences between groups were tested with ANOVA, t-test and Mann-Whitney tests as appropriate.

Spearman correlation analysis was performed to explore the relationship between scales of the QLQ-C30 and the QLQ-OG25.

A subset of patients completed the questionnaires twice ( $n = 35$ ) to evaluate whether HRQoL issues can change over a short period of time. The significance level was set at  $p < 0.05$ .

## Results

### Patient characteristics

A total of 112 patients were recruited into the study – 39 women (35%) and 73 men. Mean age of the group was 60.2 years  $\pm$  standard deviation (SD) of 10.9 years. Eighty-four patients had gastric cancer, twenty-six oesophageal cancer and two cancer of the oesophago-gastric junction. Patients' clinical and demographic data are presented in Table 1. Eighty (71.4%) patients underwent surgical treatment prior to either chemo-, radio- or chemoradiotherapy.

**Table 1.** Patients' demographic and clinical data

	Overall (n = 112)	Curative treatment (n = 52)	Palliative treatment (n = 60)
Gender (%)			
Female	39 (35%)	19 (36.5%)	20 (33.3%)
Male	73 (65%)	33 (63.5%)	40 (66.7%)
Age (SD)	60.2 (10.9)	59.8 (9.5)	61.2 (12.5)
Cancer site (%)			
Oesophagus	26 (23.2%)	8 (15.3%)	18 (30%)
Stomach	84 (75%)	42 (81%)	42 (70%)
Oesophago-gastric junction	2 (1.8%)	2 (3.7%)	0
Education (%)			
Elementary	20 (17.9%)	10 (19.2%)	10 (16.7%)
High school	28 (25%)	12 (23.1%)	16 (26.7%)
Vocational	46 (41.1%)	20 (38.5%)	26 (43.3%)
University	18 (16%)	10 (19.2%)	8 (13.3%)
Employment (%)			
Full time/part time	63 (56.3%)	40 (77%)	23 (38.3%)
Retired/Pensioner	49 (43.7%)	12 (23%)	37 (61.7%)

SD – standard deviation

No patients rejected taking part in the study. All 112 patients answered both the QLQ-C30 and the QLQ-OG25. Thirty-five patients were selected to complete the questionnaires a second time after a minimum of 2 weeks following the first interview.

### Main health-related quality-of-life issues

When taking into account the whole patient group the main HRQoL issues (basing on the QLQ-C30) were Fatigue (49/100 points), Insomnia (42.7/100 points), Appetite Loss (41.7/100 points) and Role Functioning (40.1/100 points). The scale assessing Diarrhoea (16.4/100 points) had the smallest impact on the overall HRQoL.

Based on the QLQ-OG25 the scales assessing Anxiety (58.3/100 points), Weight Loss (45.5/100 points), Body Image (43.6/100 points) and Eating Restriction (37.6/100 points)

had the biggest impact on the overall HRQoL. The scale assessing Trouble Talking (6.9/100 points) had the smallest impact on the overall HRQoL.

### Group comparison

Comparing overall scores from the first and second interview, one can say that HRQoL in patients with OC, OGJC and GC does not change over a short period of time ( $p > 0.05$ ).

Comparison by gender shows that scales and items distinguishing between sexes are Pain (31.8 vs. 20;  $p = 0.0223$ ), Diarrhoea (22 vs. 4.8;  $p = 0.0076$ ), Odynophagia (22.5 vs. 11.1;  $p = 0.0144$ ) (men having significantly higher scores) and Hair Loss (10.2 vs. 41.6;  $p = 0.0010$ ) (women having significantly higher scores).

Known group comparison by age is shown in Table 2. Scales and items that distinguish ( $p < 0.05$ ) between age

**Table 2.** Group comparison by age. Only statistically significant data are shown

Scale/Item	Age <60			Age ≥ 60			p-value
	n	Mean	SD	n	Mean	SD	
Physical Functioning	53	45.8	13.7	59	61.8	27.7	0.0002
Fatigue	53	41.9	21.4	59	55.2	26.3	0.0043
Nausea and Vomiting	53	8.3	12.2	59	30.0	31.8	< 0.0001
Pain	53	20.0	27.1	59	35.4	30.6	0.0059
Appetite Loss	53	28.9	32.4	59	52.9	38.6	0.0006
Eating Restriction	53	26.9	25.3	59	47.1	27.5	0.0001
Pain and Discomfort	53	15.0	21.6	59	31.4	31.7	0.0020

SD – standard deviation

**Table 3.** Group comparison by tumour location. Only statistically significant data are shown

Scale/Item	Stomach			Oesophagus			p-value
	n	Mean	SD	n	Mean	SD	
Global Health Status	84	63.6	42.3	26	41.2	43.9	0.0212
Role Functioning	84	59.0	37.0	26	35.3	31.4	0.0039
Pain	84	41.0	30.9	26	24.7	28.8	0.0187
Dyspnoea	84	51.3	42.2	26	19.6	27.6	0.0005
Insomnia	84	61.5	18.5	26	37.9	30.6	< 0.0001
Appetite Loss	84	61.5	30.0	26	36.6	37.9	0.0008
Dysphagia	84	49.1	33.7	26	19.2	24.9	< 0.0001
Eating Restriction	84	54.2	20.9	26	33.8	28.4	0.0001
Odynophagia	84	32.0	25.1	26	15.7	25.0	0.0046
Eating with Others	84	38.9	37.2	26	9.3	20.3	0.0002
Trouble Swallowing Saliva	84	44.4	38.5	26	5.8	17.1	< 0.0001
Trouble with Coughing	84	55.6	38.5	26	13.5	20.1	< 0.0001
Trouble Talking	84	25.0	37.9	26	2.6	11.2	0.0037
Choking when Swallowing	84	27.8	31.3	26	5.8	15.8	0.0008
Weight Loss	84	63.9	33.2	26	41.2	36.9	0.0037

SD – standard deviation

**Table 4.** Group comparison by working status. Only statistically significant data are shown

Scale/Item	Working			Retired			p-value
	n	Mean	SD	n	Mean	SD	
Physical Functioning	63	42.5	17.7	49	31.2	28.1	0.0128
Fatigue	63	42.6	23.2	49	57.6	24.9	0.0014
Appetite Loss	63	31.5	34.2	49	55.6	38.1	0.0006
Constipation	63	18.9	25.5	49	40.5	39.9	0.0007
Dysphagia	63	17.0	23.1	49	34.9	32.8	0.0010
Eating Restriction	63	30.3	25.8	49	47.0	28.7	0.0014
Pain and Discomfort	63	17.1	23.4	49	32.1	32.4	0.0053
Dry Mouth	63	25.9	29.9	49	44.1	36.4	0.0044
Trouble with Coughing	63	15.7	28.2	49	28.6	29.7	0.0207

SD – standard deviation

groups are Physical Functioning, Fatigue, Nausea and Vomiting, Pain, Appetite Loss, Eating Restriction, and Pain and Discomfort. Overall older age was associated with higher symptom scores.

Known group comparisons by treatment intention showed that patients in the curative intention group versus patients in the palliative treatment group present lower scores (less symptoms) on the Physical Functioning (25.6 vs. 42;  $p = 0.0147$ ), Fatigue (40 vs. 56.8;  $p = 0.0058$ ), Insomnia (34.4 vs. 50;  $p = 0.0372$ ) and Appetite Loss (30 vs. 52;  $p = 0.0183$ ) scales. No significant differences between the curative and the palliative treatment group were noted in any of the scores of the QLQ-OG25 scales or items.

Table 3 presents mean scores according to tumour location. As for the QLQ-C30, scales that distinguished ( $p < 0.05$ ) between

the two groups were Global Health Status and Role Functioning. Single items of the QLQ-C30 that distinguished between the two groups were Pain, Dyspnoea, Insomnia and Appetite Loss. As for the QLQ-OG25, scales that distinguished between the two groups were Dysphagia, Eating Restriction, and Odynophagia. Single items of the QLQ-OG25 that distinguished between the two groups were Eating with Others, Trouble Swallowing Saliva, Trouble with Coughing, Trouble with Talking, Choking when Swallowing and Weight Loss.

When scores were calculated by working status (Table 4) both the QLQ-C30 and the QLQ-OG25 showed significantly lower scores (less symptoms) in patients who are still professionally active.

Comparing patient scores by level of education (elementary vs. high school vs. vocational vs. university) showed that

patients with university level education cope better with pain (Pain scale of the QLQ-C30) than patients with less education ( $p = 0.0482$ ). Scores from other scales presented no significant differences in HRQoL associated with level of education ( $p > 0.05$ ) but a trend was observed suggesting that higher education is associated with lower symptom scores.

#### Correlations between the QLQ-C30 and the QLQ-OG25

The Global Health Status scale of the QLQ-C30 inversely correlated with all the other QLQ-C30 and QLQ-OG25 symptom scales ( $r = -0.28$  to  $-0.61$ ;  $p < 0.05$ ). An especially strong, inverse correlation was noted between the Global Health Status and Fatigue scales ( $r = -0.61$ ;  $p < 0.0001$ ).

Strong correlations were also noted between the Nausea and Vomiting scale of the QLQ-C30 and the Dysphagia and Eating Restriction scales of the QLQ-OG25 ( $r = 0.63$  and  $r = 0.65$  respectively;  $p < 0.0001$ ).

Three scales of the QLQ-OG25 correlated strongly with each other – Dysphagia, Eating restriction and Odynophagia ( $r = 0.62$ - $0.75$ ;  $p < 0.0001$ ).

#### Discussion

This study presents influencing factors and main HRQoL issues in oesophago-gastric cancer patients as measured by EORTC tools – the QLQ-C30 and the QLQ-OG25.

Measuring HRQoL is becoming an important outcome in clinical trials and daily clinical practice. Several studies have already used patient-reported outcome measures to assess HRQoL in patients with oesophageal, gastric and oesophago-gastric junction cancers [16-18].

Taking into account the obtained results, firstly we should remember that cancer patient HRQoL problems should not be viewed in a short-term perspective. As we can see, a two to four week period is not enough to observe significant changes in HRQoL.

Our study shows that women tend to experience less severe (or admit to experiencing less severe) symptoms than men. This is especially visible in scales such as Pain, Diarrhoea and Odynophagia. Our results stand in contradiction to those obtained by van der Schaaf *et al.* [19]. We lack a good explanation as to why such gender-dependent symptom changes exist. For example, laboratory studies conducted thus far on humans have showed no significant differences in pain perception among men and women [20]. On the other hand, women, compared to men, seem to focus more on appearance issues such as hair loss, which is consistent with the culturally based idea of women wanting to feel more visually attractive than men. Similar gender-related differences in EORTC questionnaire scale scores were noted in other studies [21].

Age had a substantial impact on the amount and severity of symptoms. The overall trend was that older age was associated with higher symptom scores, but not all scales achieved statistical significance. We have found this to be consistent with other HRQoL studies [19, 22].

When comparing HRQoL by tumour location, patients with stomach cancer consistently present higher symptom scores (higher severity of symptoms), even when it comes to symptoms specific for oesophageal cancer such as “Trouble Swal-

lowing Saliva” or “Choking when Swallowing”. This partially stands in contradiction to data presented by Onate-Oceana *et al.* [23], which shows that as far as the above mentioned symptoms are concerned, they are more specific for oesophageal cancer patients than for gastric cancer patients. It is impossible to argue which type of cancer would cause more severe symptoms. This relies rather on the stage of the disease, not the disease type.

When taking into account professional activity, we observed a trend that patients remaining professionally active present less severe symptoms than patients on retirement. This is not so easily explained. First of all, in the case of our study it is impossible to determine whether being professionally active prevents development of severe symptoms or whether the development of severe symptoms forces a patient to retire. Secondly, our “retired patient” group has a higher mean age and that can also contribute to increased symptom severity as described earlier. Hence the difficulties in establishing the correct chain of events that creates the base for more severe symptoms to develop in patients on retirement. Nevertheless, our findings concerning the role of professional activity among cancer patients are consistent with literature data [24].

Analysing the obtained correlations we can see that Fatigue is the factor with the strongest impact on overall health status. We think it is so because fatigue, at least in our cancer patient group, was the symptom most often reported and also associated with the highest number of additional problems. Other factors that most significantly affected the health status were Appetite loss and Eating restriction. All three of those elements – Fatigue, Appetite loss and Eating restriction – are related to the cachexia-anorexia syndrome. Studies conducted among patients with malignancies including cancers of the upper gastrointestinal tract showed that the severity of cachexia-anorexia has a huge impact on the quality of life in these patients [25, 26].

The strong correlation between the Dysphagia, Eating restriction and Odynophagia scales can be explained by the fact that patients often merged these three problems into one, even when supplied with additional information from the interviewer.

What is interesting, patients attribute most of their HRQoL issues to problems due to fatigue, anxiety, insomnia, body image, appetite and weight loss. This is partially consistent with other studies that show that especially anxiety is a major problem among cancer patients [23].

Anxiety, insomnia, appetite loss and body image can be considered more as psychological issues than purely medical ones. Symptoms such as dysphagia, reflux, odynophagia, nausea and vomiting are ranked lower and do not contribute as much to the overall HRQoL score as psychological problems. This points to the fact that Polish cancer patient care should focus even more on patient psychological problems.

To allow for a comparison of the data from this manuscript (results from a single-centre study) to the general population, certain comments, on the subject of study group characteristics, are needed. A study by Krstev *et al.* [27], conducted on 443 Polish patients with newly diagnosed gastric cancer, shows similar data in regard to gender distribution (35.7% women) and mean age (mean age of 63.8) of participants.

This points to the fact that the results obtained in this study can be related to the general Polish population. Though the incidence of GC in Poland is predicted to decrease [28] in the next 12 years, this cancer will still be more common in men than in women. The fall in the incidence of GC will be notably slower in the group of people older than 65 years [28]. Thus, this age group will remain the dominant one among Polish GC patients. The GC gender percentage distribution is not predicted to change [28].

In conclusion, the main HRQoL problems of Polish OC, OGJC and GC patients are fatigue, insomnia, anxiety, appetite and weight loss. Polish cancer patients report fewer organic HRQoL issues than their western European counterparts. Older age, receiving palliative treatment, having a cancer of the stomach, being on retirement and having lower education are factors associated with higher symptom scores (worse symptoms) and thus poorer health-related quality-of-life.

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