

The impact of radiotherapy on the quality of life in patients with early-stage clinical head and neck cancer

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ABSTRACT:

Introduction: Radiotherapy (RT) for patients with head and neck squamous cell carcinoma (HNSCC) affects vital functions related to the irradiation volume of the head and neck region and, in addition, has a negative impact on social functioning, thereby significantly impairing patients' quality of life (QoL).

Aim: The aim of this study was to assess changes in the quality of life in patients with head and neck cancer treated with curative RT at 12 months after completion of RT. The aim of this study was to assess the differences between the baseline QoL of patients with early clinical stage HNSCC and at 12 months after curative/radical RT.

Material and methods: The prospective clinical study included 92 patients in good general condition (ECOG 0–1 – Eastern Cooperative Oncology Group performance status), without regional or distant metastases, diagnosed with pathomorphologically confirmed early-stage head and neck squamous cell carcinoma treated with definitive RT. All patients participating in the study signed an informed consent form. QoL was assessed using the standard EORTC QLQ-C30 and QLQ-H&N35 questionnaires. In addition, information on clinical aspects and data relating to socio-demographic factors were obtained from each patient. Statistical analysis was performed using a statistical package (SPSS 17.0). T-test was used for dependent and independent samples. A general linear model was used for repeated measures.

Results: Patients' QoL deteriorated significantly after definitive RT. Worse QoL Core-30 scores in patients 12 months after the end of RT, compared with baseline QoL, before the start of RT, were observed in domains such as physical performance, fulfillment of life roles, cognitive functioning, loss of appetite, fatigue and constipation. For the QLQ-H&N35 questionnaires, patients 12 months after the end of RT reported problems in relation to aspects of life such as senses, mouth opening, dry mouth, thick saliva, pain, and weight loss.

Conclusion: RT, even in early clinical stage head and neck cancer, has a negative impact on QoL, despite modern treatment techniques.

KEYWORDS:

head and neck cancer, Quality of life, radiotherapy

ABBREVIATIONS

ECOG – Eastern Cooperative Oncology Group

HNSCC – head and neck squamous cell carcinoma

HRQOL – health-related quality of life

IMRT – Intensity Modulated Radiation Therapy

QoL – quality of life

RT – radiotherapy

INTRODUCTION

Radiotherapy (RT) for patients with head and neck squamous cell carcinoma (HNSCC) causes adverse effects that have a negative impact on the quality of life (QoL).

Well-known adverse effects of RT include taste disorders, problems with food intake (chewing and swallowing), xerostomia, dysphagia,

trismus, hoarseness, bone necrosis, soft tissue fibrosis, and hearing and speech disorders [1–7]. The QoL questionnaire describes the changes that the disease causes in patient's life, together with the side effects of treatment, but in a much broader scope than standard classifications of adverse effects of treatment. Another important feature of the QoL questionnaire is the fact that by definition it is a subjective survey and can only be assessed from the patient's perspective.

Changes in QoL may depend significantly on the type of treatment given and the patient's adaptation to certain situations [8–13]. The most validated tool for assessing QoL in oncology is the EORTC QLQ-C30 (European Organization for Research of Life Questionnaire 30 Items), including the H&N-35 module, dedicated to laryngology patients [14–19].

The effectiveness of malignant tumor treatment is determined by overall survival time and/or disease-free survival time.

Tab. I. Patient characteristics in relation to the selected clinical factors likely to affect QoL 12 months after RT.

VARIABLES	TOTAL NUMBER OF PATIENTS = 92	PERCENTAGE (%)
Tumor site		
<i>Oral cavity and oropharynx</i>	41	45
<i>Larynx and hypopharynx</i>	51	55
<i>Sociodemographic factors</i>		
Age [years]		
<60	57	62
>60	35	38
Sex		
<i>Male</i>	74	80
<i>Female</i>	18	20
Education		
<i>Primary</i>	66	71
<i>Secondary</i>	19	21
<i>Higher education</i>	7	8
Smoking (pack years)		
<i>More than 30</i>	59	64
<i>Fewer than 30</i>	25	27
<i>Never</i>	8	9

*Pack years were calculated by multiplying the number of cigarette packs smoked per day by the number of years of smoking.

The increased use of combination therapy and the possibility of alternative treatments, especially when head and neck cancer is diagnosed, have required greater attention to patients' feelings, expectations and subjective perception of treatment effects.

The results of different oncological treatments in early-stage clinical cancer are comparably good, so QoL is becoming an important tool for assessing outcomes.

The QoL questionnaire is also helpful in this case as it provides more information. It facilitates a better understanding of the potential physical, psychological, social and functional impact of different treatment methods. Therefore, the authors of this study aimed to compare changes in QoL during RT in patients with early-stage head and neck cancer. The influence of selected clinical and socio-demographic factors on the QoL of patients diagnosed with HNSCC was also assessed.

MATERIAL AND METHODS

Material

A prospective clinical study was conducted in a group of 92 patients with early clinical stage HNSCC treated with RT at the Greater Poland Cancer Center in Poznań. The study was approved by the Bioethics Committee of the Medical University of Poznan (decision no 1014/07). All patients participating in the study signed an informed consent form. The following inclusion criteria were considered: primary focus at clinical stage T1 or T2, no local or distant metastases, performance status 0 to 1

according to ECOG, treatment with Intensity Modulated Radiation Therapy (IMRT) with a prescribed fractional dose of 2 Gy and a total dose of 70 Gy.

Criteria included histopathological confirmation of HNSCC in one of the following locations: oropharynx, hypopharynx, larynx or oral cavity. Patients who did not meet the inclusion criteria were not included in the study. Clinical factors such as tumor location, clinical stage and socio-demographic factors (age, sex, education, smoking habit) were also analyzed. The characteristics of the patients are shown in Tab. I.

The standardized EORTC-QLQ-C30 questionnaire (version 3.0) and the QLQ-H&N35 module were used to assess QoL. The QLQ-C30 questionnaire is used to determine general health status and perform physical, emotional and social assessment.

It contains 30 questions grouped into 5 scales covering different domains of functioning: physical functioning (5 questions), role functioning (2 questions), emotional functioning (4 questions), cognitive functioning (2 questions) and social functioning (2 questions).

The questionnaire also contains 3 scales relating to symptoms – fatigue (3 questions), nausea (2 questions) and pain (2 questions), plus 6 individual questions assessing the severity of the following symptoms: dyspnea, insomnia, lack of appetite, constipation, diarrhea and financial problems. The last two questions concern the overall health assessment.

The answers to the questionnaire have a four-point scale (1 – never, 2 – sometimes, 3 – often, 4 – very often). Patients completed the

Tab. II. Assessment of QoL and its changes (before RT and compared with 12 months after RT) using the EORTC QLQ-C30 questionnaire in 92 patients treated with RT for HNSCC.

VARIABLES		MEAN	STATISTICAL T VALUE	STANDARD DEVIATION	DIFFERENCE BETWEEN MEANS	P VALUE
p 1	General condition (before RT)	61.14	20.756	20.756	3.261	ns
	General condition (1 year after RT)	57.88		24.595		
p 2	Physical performance (before RT)	79.93	3.628	13.823	11.52	<0.01
	Physical performance (1 year after RT)	68.72		25.096		
p 3	Life roles fulfillment (before RT)	83.15	2.352	15.915	7.42	<0.05
	Life roles fulfillment (1 year after RT)	75.72		27.560		
p 4	Cognitive functioning (the beginning of RT)	84.06	3.692	17.973	10.32	<0.01
	Cognitive functioning (1 year after RT)	73.73		28.197		
p 5	Social functioning (before RT)	79.89	1.578	23.896	4.71	ns
	Social functioning (1 year after RT)	75.18		29.906		
p 6	Fatigue (before RT)	31.28	-3.236	21.662	-8.57	<0.01
	Fatigue (1 year after RT)	39.85		24.331		
p 7	Nausea and vomiting (before RT)	7.07	-1.51	12.163	-2.71	ns
	Nausea and vomiting (1 year after RT)	9.78		15.851		
p 8	Pain (before RT)	22.28	-1.935	23.215	-6.15	ns
	Pain (1 year after RT)	28.44		29.910		
p 9	Insomnia (before RT)	34.42	-1.503	32.198	-5.43	ns
	Insomnia (1 year after RT)	39.86		33.965		
p 10	Loss of appetite (before RT)	20.65	-2.021	27.885	-6.52	<0.05
	Loss of appetite (1 year after RT)	27.17		30.833		
p 11	Constipation (before RT)	15.58	-2.034	24.435	-5.79	<0.05
	Constipation (1 year after RT)	21.38		27.771		
p 12	Diarrhea (before RT)	7.25	0.163	13.823	0.36	ns
	Diarrhea (1 year after RT)	6.88		18.182		
p 13	Financial difficulties (before RT)	33.70	-1.299	31.057	-4.34	ns
	Financial difficulties (1 year after RT)	38.04		33.728		

questionnaires on their own, and asked their doctor or family for help if they had difficulty understanding the questions.

The QLQ-H&N35 questionnaire assesses specific symptoms related to head and neck cancer and its treatment. It consists of 35 questions grouped into 7 scales: pain (4 questions), swallowing (5 questions), senses (2 questions), speaking (3 questions), eating in company (4 questions), social interactions (4 questions), sexuality (2 questions) and 11 individual questions relating to dental problems, difficulty opening the mouth, dry mouth, presence of thick saliva, coughing, awareness of the disease, taking pain medication, use of dietary supplements and weight loss or gain.

As with the baseline questionnaire, the patient gives one answer to each question and the answers have a four-point scale.

Statistical analysis

The EORTC QLQ-C30 and QLQ-H&N35 questionnaires were statistically processed according to the ESTRO guidelines. A raw coefficient was calculated for each patient and then, following the

guidelines, a linear transformation was performed to generate a score ranging from 0 to 100 for all scales and individual symptoms. For the QLQ-C30 questionnaire, a higher coefficient for the scales on functioning corresponds to a better level of functioning, and a higher level of general health corresponds to a better QoL.

Higher scores for individual symptoms, in turn, indicate greater severity of the problem – poorer patient's well-being. For all symptoms and scales included in the QLQ-H&N35 questionnaire, a higher score indicates greater severity of the problem – worse QoL. To assess the quality of life before and after RT, statistical calculations were performed using the Student's t-test for dependent samples with a linear distribution of the data.

Student's t-test for independent variables was used to assess the influence of the clinical and socio-demographic factors analyzed.

For a final check of the chosen method for analyzing the results, a general linear model for repeated measurements was used, which takes into account both changes between measurements and the influence of other factors. The statistical analysis was performed

Tab. III. Assessment of QoL (before RT vs 12 months after RT) using the EORTC QLQ-H&N35 questionnaire in 92 patients with HNSCC treated with RT.

VARIABLES		MEAN	STATISTICAL T VALUE	STANDARD DEVIATION	DIFFERENCE BETWEEN MEANS	P VALUE
p 1	Pain (before RT)	22.16	-1.938	20.646	-5.95	ns
	Pain (1 year after RT)	28.11		26.342		
p 2	Swallowing (before RT)	19.93	-1.156	24.646	-3.71	ns
	Swallowing (1 year after RT)	23.64		26.476		
p 3	Senses (before RT)	19.93	-4.620	26.753	-15.76	<0.01
	Senses (1 year after RT)	35.69		31.310		
p 4	Speech (before RT)	35.63	0.703	22.438	2.17	ns
	Speech (1 year after RT)	33.45		27.736		
p 5	Difficulties with eating in company (before RT)	20.02	-1.820	23.540	-5.34	ns
	Difficulties with eating in company (1 year after RT)	25.36		28.439		
p 6	Difficulties with social contacts (before RT)	17.46	-1.476	21.672	-4.49	ns
	Difficulties with social contacts (1 year after RT)	21.96		27.417		
p 7	Sexuality (before RT)	35.51	-0.755	31.663	-3.62	ns
	Sexuality (1 year after RT)	39.13		36.266		
p 8	Mouth opening (before RT)	22.10	-2.098	32.883	-7.97	<0.05
	Mouth opening (1 year after RT)	30.07		34.613		
p 9	Oral cavity dryness (before RT)	26.81	-5.795	27.620	-24.27	<0.01
	Oral cavity dryness (1 year after RT)	51.09		32.948		
p 10	Thick saliva (before RT)	28.62	-3.121	30.695	-14.13	<0.01
	Thick saliva (1 year after RT)	42.75		32.528		
p 11	Awareness of the disease (before RT)	25.00	-1.130	25.973	-3.98	ns
	Awareness of the disease (1 year after RT)	28.98		32.109		
p 12	Pain medications (before RT)	52.75	8.282	50.201	45.78	<0.01
	Pain medications (1 year after RT)	6.96		18.268		
p 13	Food supplements (before RT)	72.83	-0.537	44.729	-3.26	ns
	Food supplements (1 year after RT)	76.09		42.889		
p 14	Body weight decrease (before RT)	60.87	-2.479	49.072	-17.39	<0.05
	Body weight decrease (1 year after RT)	78.26		41.473		
p 15	Body weight increase (before RT)	57.61	-0.456	49.688	-3.26	ns
	Body weight increase (1 year after RT)	60.87		49.072		

at the Department of Methods and Techniques of Sociological Research, Adam Mickiewicz University in Poznan. All calculations were performed using the SPSS 17.0 program.

RESULTS

All patients (n = 92) completed the baseline EORTC QLQ-C30 and QLQ-H&N35 questionnaires before and 12 months after RT. In the EORTC QLQ-C30 questionnaire, a higher score for the scales on functioning indicates a better level of functioning, and a higher level of general health status indicates a better QoL.

A point difference of 10 or more on a scale of 0 to 100 was considered a clinically significant outcome, improving or worsening the quality of life. This is the typical cut-off value used in studies assessing QoL. It was introduced as recommended by King and

Persons et al. [19, 20]. A difference of 20 points indicates a parameter of great significance and a difference of 5 points only draws attention to its clinical importance.

Worse baseline C-30 QoL in patients 12 months after RT, compared with baseline QoL before RT, was observed in physical performance, fulfillment of life roles, cognitive functioning, loss of appetite, fatigue and constipation (Tab. II.).

Regarding the QLQ-H&N35 questionnaire, at 12 months after the end of RT, patients reported specific problems in aspects of life such as sensory, mouth opening, dry mouth, thick saliva, pain medication, and weight loss (Tab. III.).

Considering tumor location and age, both factors differentiated QoL in only two parameters. Speech disorders significantly reduced QoL in patients when the tumor was located in the larynx

Tab. IV. Age and tumor location and quality of life parameters assessed by the EORTC QLQ-C30 and QLQ-H&N35 questionnaires.

VARIABLES	AGE (YEARS)	STATISTICAL T VALUE	MEAN	STANDARD DEVIATION	DIFFERENCE BETWEEN MEANS	P VALUE
Emotional functioning	under the age of 60	-2.004	67.98	18.438	-5.41	<0.05
	above the age of 60		73.40	19.373		
Financial difficulties	under the age of 60	2.079	39.89	32.270	9.55	<0.05
	above the age of 60		30.34	31.411		
Pain	under the age of 60	2.323	24.54	21.585	7.01	<0.05
	above the age of 60		17.52	19.902		
Teeth	under the age of 60	2.740	23.36	31.234	10.53	<0.01
	above the age of 60		12.82	23.558		
Food supplements	under the age of 60	2.174	79.53	40.510	14.14	<0.05
	above the age of 60		65.38	47.882		
TUMOR SITE						
Speech	Larynx and hypopharynx	2.741	45.34	24.875	13.39	<0.05
	Oral cavity		31.94	24.238		
Mouth opening	Larynx and hypopharynx	-2.028	31.25	32.042	-13.54	<0.01
	Oral cavity		44.79	37.493		

and the hypopharynx. Difficulty opening the mouth, on the other hand, negatively affected QoL in patients with a tumor located within the oral cavity (Tab. IV.).

After comparing treatment methods, statistically significant differences were found in QoL parameters such as functioning in life roles, constipation and weight loss. Patients treated with postoperative CRT reported the greatest weight loss, which negatively affected their quality of life (Tab. IV.).

Age significantly differentiated the quality of life of patients before radiotherapy. Patients over 60 reported better quality of life in terms of emotional functioning and pain complaints, also experienced fewer dental problems and financial difficulties, and were less likely to use nutritional supplements compared with patients under 60 years of age.

Speech disorders occurring when the tumor was located in the larynx and laryngeal region of the pharynx significantly worsened QoL in this group of patients. On the other hand, difficulties in opening the mouth had a negative impact on the QoL of patients in whom the tumor was located in the oral cavity.

Other factors, i.e. mean radiation dose to the parotid glands, place of residence, professional activity, marital status and alcohol consumption, did not significantly affect QoL scores after RT.

DISCUSSION

The results of the present study are important in daily clinical practice as they show a change in QoL in patients with early stage HNSCC and in an initially good general condition. These types of patients are potential candidates for surgical treatment; hence information on how RT may affect their QoL becomes particularly important.

Unfortunately, there are no randomized clinical trials that directly compare these two treatments. The present study may therefore provide a valuable source in this area. The results presented here showed that, with respect to several areas, RT significantly negatively affected the QoL of patients with HNSCC at 12 months after completion of RT compared with baseline, pre-treatment parameters.

In the QLQ-C30 questionnaire, the use of RT worsened QoL on 6 of the 15 factors analyzed and thus had a significant negative impact on QoL. All results on the scales of functional assessment were lower, indicating poor performance in various spheres of life. Bjordal et al., analyzing 280 patients, obtained very similar results [21]. According to the aforementioned authors, a greater negative impact on QoL occurred in the first months after starting RT and thereafter.

Aspects that significantly worsened QoL in patients are physical performance, fulfillment of life roles, cognitive functioning, loss of appetite, feelings of fatigue and constipation. It is well known that head and neck cancer-specific factors affecting QoL remain more preserved with IMRT compared to older techniques, but unfortunately this method is still associated with some shortcomings of radiotherapy treatment.

It is interesting to note that physical performance, cognitive functioning and fulfillment of life roles remained impaired even 12 months after completion of RT. According to the authors, this may mainly be the psychological impact of the cancer on the aforementioned aspects of patient's life. It is natural that patients after completion of RT usually do not work or perform only minor housework. Their social activity almost completely disappears and their physical condition is significantly weakened.

On the other hand, loss of appetite and especially feelings of fatigue are well-recognized side effects of RT. The feeling of fatigue reported by patients after treatment has reached clinical

significance, confirming that this is a symptom that significantly worsens QoL. The present study shows that women experience more fatigue than men.

The most likely reason for these results is that even in early-stage clinical cancer, a low dose of irradiation, directed at a large volume of normal tissue, is applied when using the modern IMRT technique [22].

In the study by Bjordal et al., patient-reported feelings of fatigue peaked after the end of RT, which was also observed in this study [21]. Fang et al. assessed QoL changes before and at the end of the RT course in a group of 102 patients with advanced HNSCC using the Chinese version of the EORTC QLQ-C30 and QLQ-H&N35 questionnaires [23].

Furthermore, the authors found that pre-treatment fatigue levels were significantly correlated with survival time for patients treated with RT for advanced HNSCC. In the present study, fatigue level, as assessed by the QLQ questionnaire, was not interpreted in this way.

The analysis showed that in the group of patients with a primary tumor location within the oral cavity, there was damage to the sense of taste and problems with opening the mouth after RT, which was an understandable and expected effect. In this study, weight loss statistically significantly worsened health-related quality of life (HRQOL) in patients undergoing RT.

Recently, Langius et al. in a cohort of 1340 patients showed that weight loss can have a significant impact on patients' survival time [24]. The authors of the present study would like to highlight the impact of weight loss on patients' quality of life. In general, overall quality of life depends on both physical and psychological well-being, and patients who experience weight loss develop functional limitations, cognitive changes and emotional stress [25].

Oral and pharyngeal pain scores were high at the end of RT in the investigated group of our patients and similar results were

obtained by other authors in a group of 296 patients with oral and oropharyngeal cancer [26]. The present study also showed poorer emotional functioning among younger patients.

The study conducted by Alicikus in a group of 110 Turkish patients found an association between age and oral opening problems and dental problems [27]. Age above 60 years was a positive factor for patients' QoL in terms of emotional functioning and experiencing pain and minor dental problems and financial difficulties. Older patients, due to the presence of comorbidities, reacted less emotionally and accepted pain complaints [28].

CONCLUSION

In conclusion, the multifactorial nature of the quality of life is a particularly important issue for patients diagnosed with HNSCC. The study of patients with HNSCC using EORTC questionnaires contributes to the expansion of knowledge about the impact of the disease and treatment method on subjective QoL assessment [29].

This is due to the significant risk of complications associated with the primary location of the tumor in this region, as well as the relatively high prevalence of nicotine, drug addiction, alcoholism and psychiatric disorders in this population.

Apart from the aforementioned uncertainties regarding the assessment of QoL, in conclusion, it can be stated that RT worsened QoL in patients with HNSCC, even at an early clinical stage of the disease, with an initially good general performance status and in addition - despite the use of a modern radiotherapy technique such as IMRT. Tumour location and patient age were shown to have a statistically significant impact on the quality of life after RT.

The analysis of selected clinical and socio-demographic factors revealed that tumours located in the larynx and pharynx had the greatest negative impact on QoL.

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