Quality of life of head and neck cancer patients after tumor treatment and subsequent maxillofacial rehabilitation

Summary of Ph.D Thesis

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Abbreviations

AR: after rehabilitation
BR: before rehabilitation
CARES: Cancer Rehabilitation Evaluation System
EORTC: European Organization for Research and Treatment of Cancer
EORTC C30: QLQ of EORTC for cancer patients as concerns the general staging
EORTC H&N 35: QLQ of EORTC for head and neck cancer patients
HRQOL: health-related quality of life
IARC: International Agency for Research on Cancer
KPS: Karnofsky Performance Scale
PSS-H&N: Performance Status Scale - Head and Neck
UW QOL: University of Washington Quality of Life Questionnaire
QOL: quality of life
QLQ: quality of life questionnaire
List of scientific publications related to the subject of the thesis

Articles:


Published abstracts:


Presentations related to the present work:


1. Introduction

Head and neck cancer is a very common tumor worldwide. It can be treated surgically, with irradiation, with chemotherapy, or with a combination of these. Progress achieved in the treatment of oral cancer has made it possible to reduce the post-treatment mortality, and the survival rate has increased. However, the length of survival alone is an unsatisfactory measure of success. Cancer and its treatment continue to cause devastating suffering, not only for patients who die from their illness, but also for those who are successfully treated. This is especially true as regards the treatment of head and neck cancer: Head and neck cancer and its associated treatment regimens can decrease the quality of life (QOL) of patients in consequence of the loss of structural and functional integrity in this region. Important functions such as eating, speech and aesthetics can be damaged by surgical treatment, irradiation or chemotherapy, with resultant adverse effects on the patient’s physical, psychological and social functioning. Defects after surgical treatment and the side-effects of irradiation decrease the QOL, and if this post-treatment status is left without medical and prosthetic rehabilitation, the physical, psychic and social state of head and neck cancer patients can suffer a major deterioration.

1.1. Maxillofacial rehabilitation

Maxillofacial rehabilitation is the final step in the treatment of head and neck cancer. It is a complex process of restoration of a previous state following a major change. It is very important after tumor treatment to strive to attain a return to the pre-illness function. As a result of treatment such as surgery and/or radiation therapy, chemotherapy, cryosurgery or laser surgery, many patients are left with various defects in this area. Oral tumor resection often results in serious disabilities, and aesthetic and functional disorders, as concerns mastication, phonation, swallowing, breathing, etc. The degree of disability varies with the location and extent of the defect Anatomical damage and functional integrity of the oral cavity or face can be restored either with microvascular reconstruction flaps or with
prosthetic methods when surgery is not feasible. Maxillofacial prosthetics is used as an adjunct to or a replacement for reconstructive surgery. Maxillofacial rehabilitation, and hence prosthodontics, occupies a special position in the achievement of a complex somatic, psychic and social improvement. The deterioration in the QOL can lead to socio-economic failure, depression and suicide. The maximal rehabilitative effort is essential in order to correct the physiological deficit whenever possible and to provide the necessary emotional and occupational support in returning these patients to society. A team approach is required to attain successful rehabilitation. There are two main aspects of maxillofacial rehabilitation: intraoral and extraoral reconstruction, depending on the site of the defect.

1.1.1. Intraoral rehabilitation
Surgical treatment of malignancies in the oral cavity and subsequent radiotherapy can result in a challenging environment for prosthodontic rehabilitation. Maxillary and mandibular tumor patients after surgical treatment may exhibit intraoral defect differences as regards the method of rehabilitation, the postsurgical QOL and the psychosocial function. Patients who have undergone some form of surgical treatment can have various problems involving important functions such as eating, swallowing and speech. Which function suffers the greatest deterioration, depends on the location of the defect.

1.1.2. Extraoral rehabilitation
The restoration in cases of persons who have lost a portion of their faces through surgical removal of a malignant tumor or through a congenital absence or trauma poses one of the greatest challenges for the maxillofacial prosthodontist. A defect of the face, as the most conspicuous body part, means a huge handicap for patients. It leads to a decreased QOL, depression and barriers in resocialization. Restoration of these defects is very important from functional and aesthetic perspectives. The success of the prosthetic restoration of any part of the body, including the head, depends on the availability of a method of attaching the artificial substitute securely in the
appropriate place without causing discomfort or irritation to the tissues with which it comes in

1.2. Quality of life

The QOL in patients treated for head and neck cancer is an important outcome parameter in the post-treatment follow-up. QOL has been defined in many ways by numerous of groups. The WHO originally defined QOL in 1947 as a „complete physical, mental and social welfare state and not only the absence of the disease” Nowadays, it is defined by the WHO as „an individual’s perception of their own position in life, in the context of the culture and value systems in their life and in relation to their goals, expectations, standards and concerns. QOL can be defined as a concept that reflects several aspects of life, and an individual’s perception of overall well-being with regard to disease and treatment-related symptoms is specifically called the „health-related HRQOL”.

QOL has also been defined as a multidimensional construct that includes, at a minimum, physical, functional, psychological and social well-being. Other dimensions include spirituality, sexuality, occupational functioning, treatment satisfaction and the overall rating of the QOL.

Cancer and its treatment regimens can result in the disruption of one or more dimensions of the QOL. That is why the QOL is a parameter increasingly used in daily clinical practice to assess the effectiveness of a treatment and has possibly become a parameter that helps patients and physicians make therapeutic decisions

1.3. Measurement of quality of life

The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Study Group has developed a measurement strategy for the assessment of QOL in clinical trials.

The ideal measurement procedure for routine clinical practice should be short, easy for patients to understand, address pertinent QOL issues, and be reliable and responsive to change. Patients are themselves unable to complete exhaustive
questionnaires and a short, simple measurement which takes less than 10 minutes to complete is ideal for routine review.

There are specific instruments with which to measure the QOL of head and neck cancer patients, e.g. questionnaires - the University of Washington Quality of Life Questionnaire (UW QLQ), the QLQ of EORTC for head and neck cancer patients (EORTC H&N 35), the QLQ of the Cancer Rehabilitation Evaluation System (CARES) and the Performance Status Scale - Head and Neck (PSS-H&N), indices such as the Karnofsky Performance Scale (KPS), the Obturator Functioning Scale and the quantity of saliva measure. The QLQ measures the individuals’ perceptions of their own physical, mental and social health status, or some aspects of their health status resulting from cancer and its treatment.

The questionnaires are self-administered but, depending on the patient input, with minimal assistance from a health-worker if absolutely necessary.

1.3.1. UW - QOL questionnaire

The UW QOL questionnaire is a simple, well-validated and widely-used head and neck cancer-specific QOL instrument. It is potentially suitable as an instrument for busy clinical practice as it is quick and simple for patients to complete and is easy to process. Version 1 comprises 9 domains that cover a range of disease-specific functional items including pain, disfigurement, activity, recreation/entertainment, employment, speech, chewing, swallowing and shoulder disability.

1.3.2. EORTC H&N 35 QOL questionnaire

The EORTC H&N 35 QLQ comprises 35 tumor-specific questions assessing symptoms and side-effects of treatment. Most items are scored on a four-point response scale: 1 (not at all) to 4 (very much). 25 questions are organized into 7 multi-item subscales: pain (HNPA: items 1-4 regarding pain in the mouth, pain in the jaw, soreness in the mouth and painful throat), swallowing (HNSW: items 5-8 and 17 items that assess different degrees of swallowing problems: problems in swallowing liquid, pureed food or solid food, and choking when swallowing), senses (HNSE: items 13-14 regarding smell and taste), speech (HNSP: items 16
and 23-24 assess hoarseness and problems with talking to other people or on the phone, social eating (HNSO: items 19-22 regarding trouble in eating, individually or in front of family or others), social contact (HNSC: items 18 and 25-28 regarding trouble with body image and having physical and social contact with family and others) and sexuality (HNSX: items 29-30 assess interest in sex and sexual enjoyment). The remaining 10 single items address problems with teeth, dry mouth, sticky saliva, cough, mouth opening, weight loss, weight gain, use of nutritional supplements, feeding tubes and pain medication.

2. Aims of the study
The aims of my study were to examine the patients treated and rehabilitated at our Maxillofacial Rehabilitation Department, to establish how the QOL of head and neck cancer patients deteriorates after treatment (operation, radiotherapy and chemotherapy) and to determine how it can be improved through maxillofacial rehabilitation.

Questions to be answered
I set out to collect epidemiological data on head and neck cancer patients in order to learn their distribution and information concerning their smoking and alcohol drinking habits and oncological characteristics. I wished to establish which treatment and rehabilitation methods are most frequent.

I wished to know which of the important functions such as speech, eating, swallowing and aesthetics are mainly impaired after treatment.

A further question to be answered related to whether the QOL of head and neck cancer patients can be improved through maxillofacial rehabilitation and, if so, which of the impaired functions is most improved by rehabilitation.

I additionally wished to learn whether the QLQ can be used as a routine examination in the post- treatment follow- up of head and neck cancer patients, and which questionnaire is best or gives more information about the QOL.
3. Materials and methods
The study protocol and the informed consent form were approved by the Ethics Committee of the Faculty of Medicine, at the University of Szeged.

3.1. Clinical study
3.1.1. Patient selection
In the period between 1994 and 2010, 92 head and neck cancer patients were rehabilitated following tumor treatment at the Maxillofacial Rehabilitation Unit, Department of Oral Surgery, Faculty of Dentistry, University of Szeged. In the above period, 21 of the patients subsequently died and 12 patients failed to respond to the invitation letter. The remaining 59 patients completed two QLQs. The eligibility criteria included tumor treatment administration due to head and neck cancer, followed by maxillofacial rehabilitation, and the patient’s ability to understand written and spoken Hungarian.

3.1.2. Data collection
The following data were obtained from patients who had undergone rehabilitation and from them who later died: (a) socio-demographic characteristics such as age at treatment, and gender; (b) behavior: smoking and drinking habits and (c) clinical status: site of primary tumor, type of treatment and nature of rehabilitation. The information on these patients was recorded retrospectively from the clinical documentation.

Additional investigations were performed to review the changes in QOL after maxillofacial rehabilitation in comparison with the QOL status after tumor treatment without rehabilitation. Two questionnaires were used for this study.

3.1.3. Patient self-report questionnaires
Two QLQs were completed: one of them was the UW QOL, version 1.0 questionnaire and the other was the EORTC QOL H&N 35 questionnaire. Both of them were the official translated Hungarian version. We did not wish to utilize the EORTC C30 together with EORTC QLQ H&N 35 because we wished to use these other two special questionnaires for head and neck cancer patients and we
considered that three questionnaires would be too much for the patients. The questionnaires were completed on two occasions: first, following treatment but before rehabilitation, and then following maxillofacial rehabilitation. On both occasions, the patients were recalled to complete the QLQs as part of an interview and follow-up. All the patients completed the questionnaires themselves, but received helpful instructions if this was necessary. A doctor who rehabilitates head and neck cancer patients and had been specifically trained in connection with the questionnaires was therefore present at the interview. The completed forms were carefully checked.

3.2. Statistical analysis
Statistical analysis based on the program Stata was carried out by the Statistics Team of the Faculty of Medicine at the University of Szeged. The collated data were entered into an Excel worksheet. The sociodemographic data such as the age at treatment, the gender and mortality were collected in Tables. The site of the primary tumor, the treatment mode and the rehabilitation methods were recorded in other Tables. The program Stata was used. Descriptive statistics were utilized to describe the mean, the standard deviation (SD), and the distributions of the treatment and rehabilitation methods. The Wilcoxon signed-rank test was used to compare the situations after tumor treatment with and without maxillofacial rehabilitation. A p value less than/equal to 0.05 was considered significant.

4. Results
4.1. Demographic results / Patient characteristics
In the period in question, 92 patients underwent tumor treatment and maxillofacial rehabilitation at the Faculty of Medicine and the Faculty of Dentistry, at the University of Szeged. 12 patients failed to reply to the invitation letter. 21 of the 80 processed patients had died before the start of the present study. The related mortality was therefore 26.25%. However since these patients had received treatment for their tumor and also undergone maxillofacial rehabilitation, their
epidemiological data were nevertheless included in the study. The surviving patients were recalled several times during the follow-up period for control purposes and to complete the UW QLQ and the EORTC H&N 35 QLQ. The epidemiological data on 80 patients were therefore processed. The recorded information included the age at treatment, the gender, the tumor localization, the treatment method and the type of rehabilitation. 53 (66.25%) of the patients were men and 27 (33.75%) women. The male: female ratio was therefore 2:1. The average age was 53.86 years (ranging from 9 to 74 years), with more than half of the patients (55 (56.25%)) aged between 50 and 69.9 years.

The incidence of smoking and alcohol consumption was rather high. 60 (75%) of the patients were smokers, and 45 patients (56.25%) drank alcohol regularly.

As far as the locations were concerned, the cancer developed most frequently in the floor of the mouth area, in 21 patients (26.25%), followed by the mandibular or maxillar gingiva in 17 cases (21.25%), the maxilla in 12 cases (15%) and the tongue in 9 cases (11.25%).

41 patients (51.25%) received combined surgery and radiotherapy. 26 patients (32.5%) were treated surgically alone, and 2 patients (2.5%) with radiotherapy alone. 11 patients (13.75%) participated in other forms of combined therapy.

In the course of rehabilitation, a special defect prosthesis was prepared for about half of the patients (43.75%): an obturator was fitted in 14 patients (12.5%), an implant-retained removable denture was applied in 23 patients (20.54%), and reconstruction with an epithesis was applied in 12 patients (10.71%). Most of the epitheses were for an orbital defect, in 7 cases (6.25%). Other parts of the face were also rehabilitated, with an ear epithesis in 3 cases (2.7%) and a nasal epithesis in 2 cases (1.8%).

4.2. Statistical results of QOL questionnaires

The UW QOL and EORTC H&N 35 questionnaires were well accepted by the patients, who appeared cooperative; none of the eligible participants refused to complete the questionnaire.
4.2.1. Results of UW QOL questionnaire

The UW QOL questionnaire, which was well accepted by the patients, included 9 questions, each answer is scaled from 0 (best) to 100 (worst). A composite score was calculated by adding together the scores for 9 answers for the various domains and then dividing by 9 to give a result on the scale from 0 to 100. The composite score, which before rehabilitation was reasonably high, at 66.62, improved to 36.2 following rehabilitation. The change was significant (p=0.000)

The improvement in the QOL is shown in Figure 1.

![Figure 1. Changes in results of UW QLQ after rehabilitation](chart.png)

The greatest problems after treatment but before rehabilitation were associated with chewing (BR: 88.58), activity (BR: 68.8) and recreation (BR: 68.2). All of these improved considerably after rehabilitation. Nevertheless, especially the subscale of pain was increased after rehabilitation.

Employment displayed a high score both before and after rehabilitation (87.8 and 92), and tended to deteriorate in the course of time after rehabilitation. As concerns the question of family relations, the scores were good in both situations (BR: 25.4 and AR: 21.4), as was the shoulder function (BR: 26 and AR: 23.6).
Significant improvements after rehabilitation were observed as regards pain, appearance, activity, recreation, chewing, swallowing, speech, resocialization with friends and the overall score. There was no significance from the aspects of employment (p=0.732), shoulder function (p=0.452) and family relations (p=0.062).

4.2.2. Results of EORTC H&N 35 QOL questionnaire

The improvement in QOL is shown in Figures 2 and 3.

Figure 9. Means of results of 7 scales in EORTC H&N 35 QLQ before and after rehabilitation

(HNPA: pain, HNSW: swallowing, HNSE: senses, HNSP: speech, HNSO: social eating, HNSC: social contacts, HNSX: sexuality)
After tumor treatment, the worst score in the subgroups was that for HNSW (swallowing), followed by HNSO (social eating) and HNSP (pain). From the single items, the worst problem was an illness feeling and dry mouth with sticky saliva as side-effects of irradiation. The rehabilitation led to considerable effects on swallowing, social eating and speech. The highest improvement for the single items after rehabilitation was in the illness feeling. Only the weight gain gave an inverse result.

All of the items showed a significant increase (p<0.05) after rehabilitation in comparison with the results before rehabilitation.
5. Discussion

5.1. Epidemiological and oncological results

In my study, I set out to collect data on rehabilitated head and neck cancer patients in the descriptive part of the search. I was looking for the most affected age, the primary tumor site, and the treatment and rehabilitation methods, and was seeking answers concerning which primary tumor site and its treatment need special maxillofacial rehabilitation most frequently. A further aim of my study was to examine the changes in the QOL of head and neck cancer patients through comparisons before and after maxillofacial rehabilitation and to investigate whether our prosthetic methods can improve the QOL of head and neck cancer patients significantly.

In my study, the gender difference, with a male:femail ratio of 2:1, appeared to be significantly less marked than reported in earlier studies, which is explained by increasingly higher rates of women smoking and drinking alcohol. The majority of our patients consumed alcohol and smoked on a regular basis, which further worsen the QOL through increase of the risk (and the related stress) of a local recurrence, and affect the patients’ family and social relations.

A majority of the patients (51.25%) had received a combination of surgery and radiation as therapy, which is in line with the oncotherapy protocol applied nowadays. The tumor localization and the treatment method, together with the general disease stage, play essential roles not only in the treatment of head and neck cancer, but also in the incidence and intensity of the side-effects and the QOL.

In the course of the rehabilitation, about half (43.75%) of the cases involved the preparation of a special prosthesis as a solution: the application of obturators after maxillectomy (14 cases/12.5%), implant-retained dentures (23 cases/20.54%) in cases of an acquired mandibular defect or after surgery on a tumor of the tongue or the floor of the mouth, or epitheses (12 cases/10.75%) in cases of facial defects. Interforaminal located implants in the mandible for improvement of the stability of a fully removable lower denture are increasingly used by healthy patients. This is
more to be expected in cases of mandibular defects because of the decayed mucosal
supplement and diminished vestibulum. Most of our head and neck cancer patients
with this intraoral situation are rehabilitated with an implant- retained removable
denture on 2 or 4 interforaminal implants. This method is applied after the
irradiation on the patients, and our experiences show that the success rate of
osseointegration of dental implants in irradiated bone is over 90%.

5.2. Comparative analysis of measurements of QOL questionnaires

Head and neck cancer and its treatment can have a profound effect on the patient’s
physical, functional and emotional well-being, especially decreasing the QOL.
QOL evaluation has increasingly become an important supplement in the
interpretation of the outcome information in head and neck cancer treatment. It can
be measured by the administration of specific questionnaires to the affected
patients. In Hungary, there have been no such examinations of the QOL. A survey
of the international literature revealed numerous papers related to the comparison
and validation of different QLQs, the comparative analysis of the QOL before and
after treatment, and the comparison of the outcome following several treatment
methods, but I have found no studies involving a review of the QOL of head and
neck cancer patients before and after maxillofacial rehabilitation. This was the
background in my selection of the goals in my study.

In my study, I analyzed which function is especially damaged by tumor treatment
and measured the changes in the QOL through a comparison before and after
rehabilitation.

Most of the available studies made comparisons between some special QLQs
(e.g. comparative studies with KPS, CARES or UW QOL questionnaires) or with
only one or two domains (e.g. the speech domain), or between healthy and tumor
patient groups, or between the pretreatment and the posttreatment situation, or on
the longitudinal effects of cancer treatment. Merely a few studies extended to the
changes in the QOL after maxillofacial rehabilitation. This study can give a new
comparison profile and data for the Hungarian and international literature.
5.2.1. Results with the UW QOL questionnaire
In the employment domain, a common answer was ”I am retired-due to the cancer treatment or not related to it”. It was connected with the basic tumor disease, with habitual problems of smoking and drinking alcohol, and the age and general health status of the patients. It means that most of the patients were retired and the majority of the treatment did not seem to alter the employment status. This scale was the only one for which the result after rehabilitation was decreased. Rehabilitation had much less influence at this stage of life.
There was no significant change in shoulder function before and after rehabilitation and in this scale the score was already low after treatment (BR: 26). This means that most of the surgical procedures do not affect the accessorital nerve which is responsible for the abductor movement of the shoulder.
The family relations did not show any significant change and the BR and AR answers were equally positive. This is good from the aspect of the QOL because it means that the family stands up for the patients in their enormous problems and help them in the healing period.
The best improvements following rehabilitation were in activity and recreation. This is related with the overall feeling ill, mood and global health status. A great improvement in pain emerges with the passage of time.
5.2.2. Results of EORTC H&N 35 QOL questionnaire
The international literature relating to the QOL most frequently involves studies with the EORTC H&N 35 QLQ. It is usually used together with EORTC C30, but I decided to apply two questionnaires specific for head and neck tumors, and did not wish to overburden the patients with too many questionnaires demanding a long completion time.
All of the examined subscales and single items displayed significant changes in comparison with the situation before rehabilitation.
5.2.3. Comparison of results of UW QOL and EORTC H&N 35 questionnaires
For my study, I chose these two questionnaires because they complement each other well, and both of them are very extensively applied in their own field. The UW QLQ contains more questions about the psychological and social well-being of the patients. The EORTC H&N 35 questionnaire deals much more with the physical tumor- and treatment-related symptoms of head and neck cancer patients. This causes difficulties in comparisons of the answers of the two questionnaires: In the former, swallowing, activity, recreation and pain gave the worst results before rehabilitation, while activity and recreation displayed the best increases after maxillofacial rehabilitation. In the other questionnaire, swallowing, social eating, pain and dry mouth were the worst problems for the patients, and the rehabilitation led to the greatest changes in swallowing, social eating and speech. Swallowing and pain proved to be the most serious problems before rehabilitation in both QLQs.

The UW QOL was the most frequently used questionnaire (72%) among members of the British Association of Head and Neck Oncologists, followed by the EORTC C30 and the EORTC H&N 35 (52%).

Statistical analysis of the results of the questionnaires suggests that post-treatment patients awaiting rehabilitation experienced the greatest difficulties in the areas of eating and speech.

The results of the UW QLQ demonstrated that the worst problems after treatment related to chewing, employment, activity and recreation, and the best increase after rehabilitation was experienced as concerns pain, with additional significant improvements in activity and recreation. There was no change in the level of family relations. This means that tumor as a disease does not affect personal contacts in the family in a negative way and it does not need improvement. There was no positive change in employment, because most of the head and neck cancer patients had already retired before the tumor treatment, because of the general staging or some other illness. There was no significant difference between the results before and after rehabilitation as concerns the shoulder function.
The EORTC H&N 35 questionnaire was somewhat easier to complete. It indicated that the worst subscale problems after tumor treatment were the swallowing and social eating, followed by pain. Among the single items, the worst problems were dry mouth and sticky saliva as side-effects of irradiation. The rehabilitation resulted in the greatest changes in swallowing, social eating and speech and feeling ill.

6. Summary of the thesis
The tumor treatment of head and neck cancer patients causes the QOL of the patients to deteriorate considerably after treatment, owing to the impairment of important functions. In my study the greatest problems after treatment but before rehabilitation were associated with chewing, activity, recreation, swallowing, social eating, pain, illness feeling and dry mouth with sticky saliva.

As a means of assessing changes in the QOL with the aim of a subsequent improvement, QOL questionnaires appear to provide an easily applicable, routine procedure in the care of head and neck cancer patients. We conclude that the UW QLQ and the EORTC H&N 35 questionnaires are useful tools for the evaluation of the HRQOL in patients with cancer in this region.

Significant improvements after rehabilitation were observed as regards pain, appearance, activity, recreation, chewing, swallowing, speech, resocialization with friends and the overall score by the UW-QOL questionnaire and all of the items showed a significant increase (p<0.05) after rehabilitation in comparison with the results before rehabilitation by the EORTC H&N QOL questionnaire. This is why maxillofacial rehabilitation has such an important place as the last step in the tumor treatment procedure.

Overall, maxillofacial rehabilitation leads to significant improvements in all impaired functions and to positive changes affecting the QOL. The results of my investigations allow me to state that prosthetic rehabilitation can play a key role in the life of head and neck cancer patients through the resulting improvement in their QOL.
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