A HEALTH RELATED QUALITY OF LIFE ASSESSMENT IN TREATED HEAD AND NECK CANCER PATIENTS IN EAST COAST OF MALAYSIA

By

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ACKNOWLEDGEMENTS

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRAK (BAHASA MALAYSIA)

PENGENALAN

Jangka hayat dan kes barah berulang telah lama dijadikan sebagai asas penilaian ke atas keputusan rawatan bagi pesakit kanser kepala dan leher. Walaubagaimanapun sejak 20 tahun yang lalu dengan penurunan kes barah berulang dan peningkatan jangka hayat pesakit, kualiti hidup bagi pesakit yang masih meneruskan kehidupan telah menjadi sebagai satu ukuran bagi keberkesanan rawatan. Data terkini daripada Amerika Syarikat telah menunjukkan peningkatan angka pesakit kanser kepala dan leher sejak kebelakangan ini dan ianya kemungkinan adalah sama bagi negara Malaysia.

Kualiti kehidupan adalah satu konsep yang luas yang merangkumi beberapa komponen yang penting iaitu fungsi fizikal, keadaan psikologi, interaksi sosial dan deria sakit. Terdapat pelbagai jenis soalan kajiselidik yang telah disahkan diseluruh dunia dan soalan kajiselidik dari Universiti Washington adalah yang paling kerap digunakan bukan sahaja di Amerika Syarikat, tetapi juga di United Kingdom. Seperti juga di bahagian lain di dunia, kini terdapat kecenderungan yang mendesak bagi pengkaji selidik – pengkaji selidik di Malaysia untuk mengkaji kualiti kehidupan pesakit kanser kepala dan leher.

TUJUAN

Tujuan utama kajian ini adalah untuk menganalisa kualiti kehidupan pesakit kanser kepala dan leher selepas rawatan.

KAEDAH

Ini adalah kajiselidik secara keratan-rentas terhadap pesakit kanser kepala dan leher yang telah menjalani rawatan. Kajian telah dilakukan di klinik telinga, hidung dan tekak Hopsital Tengku Ampuan Afzan (HTAA) Kuantan di negeri Pahang dan juga di Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian di negeri Kelantan. Pesakit-pesakit Melayu yang memenuhi kriteria pemilihan telah diambil untuk kajian ini.

KEPUTUSAN

"Reliability" telah diuji dengan "inter-item correlation coefficient" dimana nilai alfa adalah 0.80. "Test-retest reliability" seperti yang ditunjukkan oleh "intraclass correlation coefficient" adalah 0.85. Pesakit yang menghidap kanser di peringkat awal (peringkat I dan II) cenderung menghasilkan markah kajiselidik yang lebih tinggi daripada kanser peringkat lewat (peringkat III dan IV). Kedudukan kanser dan kaedah rawatan tidak mempengaruhi kualiti kehidupan pesakit secara berkesan.

KESIMPULAN

Data ini mengesahkan bahawa versi Bahasa Malaysia UWQOL adalah sah dan dipercayai apabila diuji terhadap sampel pesakit kanser kepala dan leher di Malaysia. Peringkat kanser merupakan faktor yang utama dalam menentukan kualiti kehidupan pesakit kanser kepala dan leher.

ABSTRACT

INTRODUCTION

Length of survival and tumour recurrence has long been used as the assessment of treatment outcome in Head and Neck cancer patients. However for the past 20 years with reduction in tumour recurrence and increasing survival rates, quality of life (QOL) of the survivors has becoming the measure of treatment outcome. Recent data from United State indicated that the number of patients with Head and Neck cancer is increasing over the years and the trend is probably similar in Malaysia.

QOL is a broad concept which covers four essential components which are physical function, psychological state, social interaction and somatic sensation. There are many validated instruments available worldwide and the University of Washington quality of life (UWQOL) questionnaire is the most commonly used in United Kingdom as well as United States. As in other parts of the world, there has been an increasing demand for Malaysian researchers nowadays to assess the QOL in their Head and Neck cancer patients.

OBJECTIVES

The main objective in this study is to evaluate quality of life in the treated Head and Neck cancer patients.

METHODOLOGY

This is a cross-sectional study in a treated Head and Neck cancer patients conducted in Ear, Nose and Throat clinic (ENT) of Hospital Tengku Ampuan Afzan (HTAA) Kuantan in the state of Pahang and ENT clinic of Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian in the state of Kelantan. Those Malay patients who fullfilled the inclusion and exclusion criteria were recruited into this study.

Standard validation process were followed which include forward and backward translation of the originial version UWQOL. Patients were asked to answer the Malay version UWQOL. Data were analysed using statistical software SPSS version 12.0 for Windows.

RESULTS

Reliability was tested by inter-item correlation coefficient with Cronbach's alpha value of 0.80. Test-retest reliability as reflected by intraclass correlation coefficient was 0.85. Patients with early stage tumour (stage I and II) tend to score higher than advance stage tumour (III and IV). Site of tumour and mode of treatment does not significantly affect the patients QOL.

CONCLUSION

This data suggest that Malay version of UWQOL is reliable and valid qestionnaire when applied to a sample of Head and Neck cancer patients in Malaysia. Tumour stage was the strongest determinant of quality of life in Head and Neck cancer patients.

CHAPTER 1

INTRODUCTION

CHAPTER 1: INTRODUCTION

1.1   General Introduction

Traditionally, health care providers pertaining to Head and Neck cancer were only concentrating on tumour recurrence and length of survival as a measure of treatment efficacy. Therefore an effort was made to improve those aspects of treatment outcome by either improving the surgical skill or innovation of better surgical instruments which include the use of laser. Less was emphasized on the psychosocial well-being of the individual and to what extent the individual has been able to return to pre-illness function. However since the last two decades, with reduction in tumour recurrence and increasing survival rates the health care providers are becoming more aware regarding the psychosocial dimension of cancer care and also the impact of treatment intervention towards the quality of life (QOL) of the survivors. This can be seen through the number of published papers regarding this subject though majority of the literatures came from the developed countries. As in other parts of the world, there has been an increasing need for Malaysian researchers nowadays to assess the quality of life in their patients. Their practice reflects a growing appreciation of the importance of how these groups of patients feel in term of satisfaction regarding the various treatment modalities available, in addition to the additional focus on disease outcomes.

Quality of life (QOL) is a broad concept that applies to the level of one's general well-being and life satisfaction. Up to date, there is no single definition of QOL that is universally accepted. Emerging of many new assessment tools reflect the difficulties in

1

defining the QOL. Many authors agreed that QOL is a subjective rather than objective assessment in which only perceived wellbeing and not functional assessment should be used to determine QOL. The essential components of QOL comprise of physical function, psychological state, social interaction and somatic sensation. In a definition given by World Health Organisation (WHO) , QOL can be defined as the individual's perception of his/her position in life in the context of the culture and value system in which he/she lives and in relation to his/her goals, expectations, standards and concerns. Gill and Feinstein (1994) in their paper on A Critical Appraisal of the Quality of Quality-of-Life Measurements stated that QOL is a reflection of the way that patients perceive and react to their health status and to other non medical aspects of their lives. Calman, (1984) however gave a more constructive and detail description and indicated that the quality of life can only be described and measured in individual terms, and depends on present lifestyle, past experience, hopes for the future, dreams and ambitions. Quality of life must include all areas of life and experience and take into account the impact of illness and treatment.

American Cancer Society data indicate that 40,000 to 60,000 cases of Head and Neck cancer occur each year in the United States. In Malaysia, data from National Cancer Registry indicate that Head and Neck cancer attribute 9.8% of all tumours diagnosed in male and female and nasopharyngeal carcinoma (NPC) was the most common Head and Neck cancer followed by cancer of oral cavity and larynx (GCC Lim and Y Halimah, 2003). Sani et al., (1992) in a retrospective analysis of the carcinoma of larynx in Hospital Universiti Kebangsaan Malaysia (HUKM) and General Hospital Kuala Lumpur (GHKL) managed to collect about 137 cases within 7 years period between 1981 and 1988. Hooi and Devaraj, (1998) in their hospital based study of 1333 cancer patients indicated that

2

NPC was the second commonest malignancy and cancer of larynx was rank sixth. Some of these patients have survived for many years after the primary treatment however their QOL have never been assessed in a standard manner. The morbidity that was left behind as a result of the treatment itself may give an impact to the psychosocial aspect of the patient's life and this part of treatment plan and follow up need to be more focused.

Head and Neck region is anatomically and functionally very much different from other parts of human body. It composed of those vital structures crucial for breathing, swallowing as well as for speech. Therefore therapeutic intervention in Head and Neck cancer may cause a major impact on the quality of an individual's daily life. Moreover, the disfigurement and functional disability that sometimes results from the cancer and its treatment often alters an individual's perception of self and their interactions with others. Deterioration in their functional status and ineffective coping strategies may lead to poor psychological outcome in such patients (Hassanein et al., 2005)

Measurement of QOL in Head and Neck cancer patients is a challenging task and QOL itself has special relevance for Head and Neck cancer patients because of the particular difficulties that they may encounter with everyday activities. One can imagine how a laryngectomised patient communicate with people and how an irradiated patient is going to enjoy eating in public.

Fig. 1.1: A patient with end stoma after total laryngectomy for laryngeal cancer.

Eventhough the main priority of the treatment in head and neck cancer is to improve survival rates, their unwanted side effects give unpleasent morbidity to the patients and thus reduced the quality of the survival. Treatment modalities in head and neck cancer include either surgery or radiotherapy alone or combination of both and these are usually followed by chemotherapy. The choices of treatment generally depend on the types and stages of tumour in the upper aerodigestive tract. For example, nasopharyngeal cancer is best treated with radiation therapy whereas surgery would be the best treatment for recurrence tumour in selected cases. However in advanced cancer of larynx, surgery would be the ideal primary modality of treatment in operable cases with curative intention and this will be

followed by radiation therapy if indicated. Chemotherapy is administered in certain cases and usually as adjuvant, neoadjuvant or concurrent regimes with radiation therapy. The side effects of treatment for head and neck cancer in general include speech, swallowing and breathing difficulties, disfigurement, pain as well as psychosocial problems. More specifically, radiotherapy can cause xerostomia and mucositis of the oral mucosa. Therefore, chewing and swallowing become painful and difficult. Frequently patients would bring along a bottle of plain water in their pocket in order to wet their oral mucosa and to fascilitate swallowing as well as speech. The impact of surgery on the other hand can be worsened not only due to the result of the surgery at the primary site per se (Figure 1.2), but also include the neck dissection as well as reconstructive surgery that usually followed in advanced stage operable tumour. All these surgical interventions will give rise to facial disfigurement, stiff shoulder and neck as well as head and neck pain. Eventhough chemotherapy has lots of early unfavourable side effects such as nausea and vomiting, alopecia and risk of infection following neutropenia, these will not last long. Therefore the effect of chemotherapy was only apparent in the early course of the treatment.
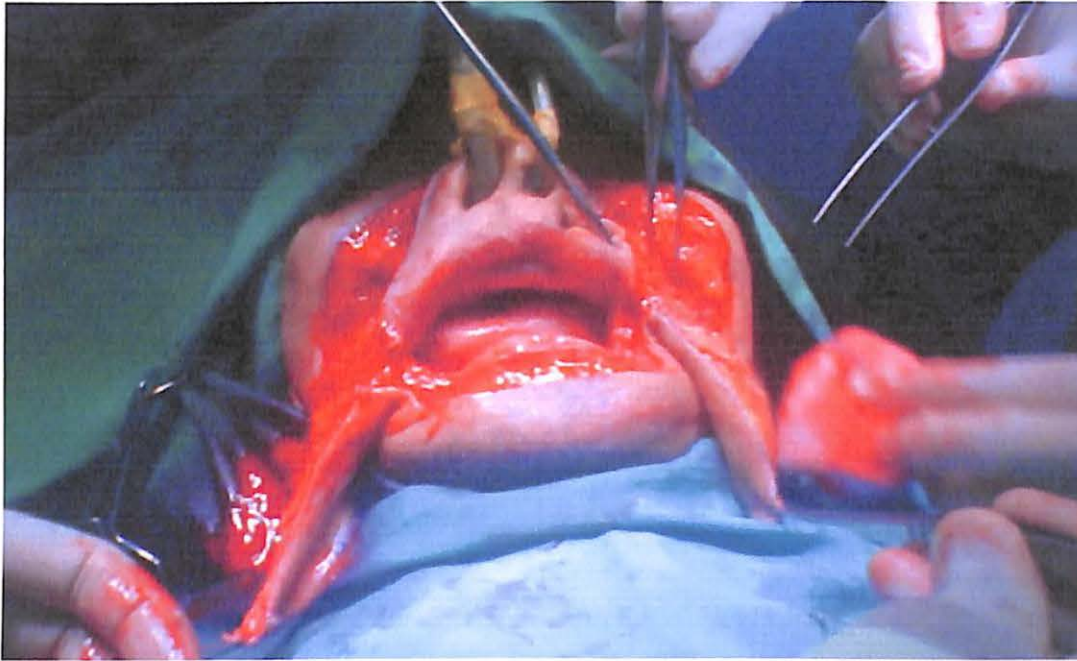
Fig. 1.2: Surgery being performed for a patient with oral cancer

1.2 Health Related Quality of Life (HRQOL) Instruments

There are at least 14 validated head and neck questionnaires available worldwide and most workers in this field agreed that there is no single instrument ideal for all purposes. Questionnaires commonly used in the UK include the European Organisation for Research and Treatment of Cancer in Head and Neck cancer module (EORTC QLQ-H&N35), the Functional Assessment of Chronic Illness Therapy (FACIT), Perfomance Status Scale for Head and Neck Cancer Patients (PSS-HN) and the University of Washington Head and Neck Cancer (UWQOL) version 4. In general, the ideal instrument should cover all aspects of a patient's QOL such as physical functions for example ability to swallow, emotional for example mood, social interaction as well as somatic sensation such as pain.

In a study done by Kanatas and Rogers (2004), UWQOL instrument was favored most by the ENT surgeons, oral and maxillofacial surgeons, clinical oncologists and least so by the plastic surgeons. The ideal instrument for assessment of QOL should be completed by the patient, easy to understand and quick to fill out and score. It should also cover all the relevant aspects of patient's QOL as well as being reliable, validated and able to reflect changes over time (Maguire and Selby, 1989). Gill and Feinstein, (1994) did an extensive critical appraisal on the quality of QOL measurement involving hundreds of published quality of life instruments and recommended the use of global ratings, rate severity and its importance to be added into the instruments in order to improve QOL measurements. Bjordal et al., 1994 recommended that functional and emotional outcome should be prospectively evaluated in future clinical trials in Head and Neck cancer as these are important parameters in determining QOL. The UWQOL version 4.0 fulfills all the above mentioned criteria and therefore, in this study we preferred UWQOL instruments to be used for our target population.

1.3   Literature review

Eventhough this is a cross sectional study in post treatment subjects, we would like to see whether tumour sites, stages, treatment choices and duration from the last completed treatment does influence the overall QOL. In many prospective studies, the researchers manage to highlight the association between these variables with the QOL of the patients.

Tumour stage appeared to have the strongest impact on QOL whereby patients with a more advanced tumour stage reported significantly worse QOL scores for majority of variables

reflecting function or problems (Hammerlid et al., 2001). The relationship between tumour stage and QOL in Head and Neck cancer patients was likely to be due to the increased pain and dysphagia that accompany increased tumour stage (Morton, 2003).

Patients with stage III/IV had significantly worse physical symptoms compared to patients with stage I/II respectively (De Graeff et al., 1999). The effect of tumour stage is more apparent in seperate analysis of the domain variables. Advanced stage was correlated with lower QOL scores in the domains of disfigurement, chewing ability, speech and eating in public (Campbell et al., 2000).

Weymuller et al., (2000) had pointed out that tumour stage influenced the total QOL scores in a statistically significant fashion and site of tumour (oral cavity, oropharynx, hypopharynx and larynx) also affected composite QOL scores.

Certain aspect of QOL is specifically affected as a result of the specific site of the primary tumour such as speech score was worst in patients with laryngeal cancer and swallowing was worst in hypopharyngeal cancer (Morton, 2003). However, with early voice rehabilitation either by esophageal speech or via tracheoesophageal puncture, most laryngectomised patients could communicate in some manner and that their speech and communication was not a determinant of QOL (Carr et al., 2000).

Although for early stages no clear advantage in QOL outcome was noted for the radiotherapy (RT) group compared with the surgery group, for advanced-stage disease an advantage favoring radical RT seemed apparent. For those patients, if an equivalency

between the two treatment strategies could be assumed regarding oncologic results, then nonsurgical treatment should be considered the preferred option (Allal et al., 2003).

Longitudinal study showed that psychological distress was the most consistent factor in the determination of global QOL over time. Head and neck pain was a prominent determinant of QOL early in the course of the treatment, whereas difficulty in breathing seemed to be more important in the later stages (Morton et al., 2003).

Bjordal et al. (1994) said that long term survivors of head and neck cancer reported a high level of disease and treatment related symptoms. Among these symptoms, emotional function was significantly influenced by the type of surgical procedure that was done. He recommended that future trials in head and neck cancer should continue to attempt to stress conservative surgical approaches and coordinated adjuvant therapy to maximize local regional control and quality of life.

Chaplin and Morton (1999) in a prospective longituinal study of pain in head and neck cancer patients have found out that there is an increase in prevalence of shoulder and arm pain from 14% at diagnosis to 37% at 1 year post treatment and this was strongly correlated with surgical treatment of the neck. The ongoing pain was predictable and it impacts adversely on patients QOL.

Pertaining to neck dissection, extensive surgery which include radical neck dissection is associated with statistically significant worse shoulder dysfunction if compared to those without neck dissection (Laverick et al., 2004).

Mean overall QOL score for patients undergoing surgical treatment for head and neck malignancy were significantly worse at 3 and 6 months post treatment and returned to preoperative scores at 12 months (Lloyd et al., 2003).

Radiotherapy on the other hand will be given either as a primary modality of treatment or following surgery. The most significant impact of RT in head and neck region would be mucositis and also diminish production of saliva secondary to damage of the salivary glands either temporary or permanent. These side effects will cause dryness of mouth, difficulty in swallowing as well as speech and therefore patients QOL would be affected to some extent. In majority of early stage of head and neck cancers, there are always treatment options, either surgery or RT or in combination with chemotherapy.

Smith JC et al. (2003) managed to compare 11 patients treated with RT and 44 patients with surgery for early laryngeal cancer and reported that no significant difference in the two treatment modalities in term of QOL in all domains. This is supported in a study by Lo Tempio et al. (2005) whereby they concluded that most patients with laryngeal cancer, whether treated primarily with chemoradiation or total laryngectomy, reported excellent functional outcomes and health-related quality of life.

However in a cohort of 3-year-survivors of head and neck cancer patients, Campbell et al. (2000) reported that laryngectomy and composite resection survivors had lower QOL scores than patients treated with irridiation alone.

Surgical resection however can offer good functional and overall QOL results for advanced tumours when combined with reconstruction. The morbidity associated with postoperative radiotherapy includes reduced swallowing, taste, saliva production and difficulty in chewing (Winter et al., 2004).

The impact of RT alone is best seen in nasopharyngeal carcinoma (NPC) patients because RT in this disease group is the primary choice of treatment. Treated NPC patients with RT mainly had poor score in domains of chewing, dry mouth and also ear problems. However their overall QOL appeared to be good (Talmi et al., 2002).

Zuydam et al., (2005) have shown that RT together with primary surgical closure or with laser surgery was the main predictors of good swallowing and speech.

With each of the sugery and RT treatment have their own impact, combination of both treatment interventions would definitely give poorer QOL outcome as compared to single treatment modality. As one can expect, combination of treatment is usually being given to an advanced stage tumour and this group of patients will definitely received a relatively aggressive treatment with compound effects. Several studies have tried to compare the QOL outcome between single mode and combination of treatments and some came out with poorer QOL in group treated with combination of treatment in certain domains, while others said that the impact of combination therapy is only apparent few years after treatment completion.

The use of combined treatment had the greatest negative impact on quality-of-life scores of head and neck cancer patients (Vartanian et al., 2004).

Patients treated with irradiation alone had statistically better QOL scores than those treated with combined surgery/radiation therapy in the pain, disfigurement, chewing, and speech domains (Campbell et al., 2000).

At 1 year post treatment, when analysis of the effect of single or combined modality treatment comparing with surgery and radiotherapy was done, there were no significant difference in overall QOL. However at 2 years post treatment, those patients treated with combined modalities showed significantly greater difficulty with swallowing and speaking (Morton, 2003).

Weymuller et al., (2000) reported that composite scores did not demonstrate clinically or statistically significant differences with regard to differences in QOL between different methods of treatments.

Surgical treatment for oral or oropharyngeal cancers resulted in significant deterioration of physical functioning and symptoms during the first year, especially when combined with radiotherapy (De Graeff et al., 1999).

Long-term survivors of head and neck cancer experience QOL effects well after completion of treatment. Effects are most pronounced in survivors who required combined surgery and radiation therapy (Campbell et al., 2000).

1.4   Quality of life in head and neck cancer patients in Malaysia

Little can be said about QOL study in Malaysia with regard to the head and neck cancer. From our limited literature search, no previous study was done on assessing quality of life in head and neck cancer patients. Majority of the literatures mainly highlighting about incidence and prevalence of cancer cases, outcome of treatment intervention in term of locoregional control and other non quality of life issues.

Among all types of Head and Neck cancer, NPC was extensively studied involving the total of 53 articles from our search through pubmed (National Library of Medicine), compared to only a single article regarding carcinoma of larynx. However, from our working experience there are also significant number of patients who had other types of head and neck cancer such as those involving the larynx, oral cavity and maxilla but lacking in studies probably due to poor survival.

Therefore, it is a big opportunity for us to embark on this area of research on QOL issues in Head and Neck cancer in Malaysia. We hope, in the near future there will be more literatures regarding this issues which is becoming more important in the treatment plan and follow up of the head and neck cancer patients in Malaysia.

CHAPTER 2

STUDY OBJECTIVES

CHAPTER 2: OBJECTIVES

2.1 General objectives;

2.1.1 To evaluate the Health Related Quality of Life (HRQOL) in treated Head and Neck cancer patients using the Malay version of the UWQOL questionaire.

2.2 Specific objectives;

2.2.1 To determine the association between the stages and sites of the tumour and HRQOL

2.2.2 To determine the association between mode of treatments and HRQOL

CHAPTER 3

METHODOLOGY

CHAPTER 3: METHODOLOGY

3.1   Background of study centre

Patients were recruited from the Hospital Tengku Ampuan Afzan (HTAA) Kuantan in the state of Pahang and Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian in the state of Kelantan. Both are located on the East Coast of Peninsular Malaysia. HTAA is a General Hospital which is situated in the district of Kuantan. It is a 673 bedded tertiary centre which received referral from majority of district hospitals within the state of Pahang and also from the southern part of its neighboring state Terengganu which is also located on the East Coast of Malaysia. HUSM on the other hand is a 733 bedded teaching hospital for the undergraduates and postgraduates students of University Sains Malaysia medical school. It has been operational for about 25 years and provides multi disciplinary medical care to outpatient as well as inpatient. It also possesses certain subspecialty services and serves as a tertiary centre for all parts of Kelantan and northern part of Terengganu.

HUSM has an oncology centre with radiation therapy facilities, unlike HTAA whereby the cases who need radiotherapy as the primary modality of treatment or the continuation of treatment following surgery will usually be sent to Hospital Kuala Lumpur or Hospital Universiti Kebangsaan Malaysia for the treatment.

3.2   Study Design

This is a cross-sectional retrospective study whereby all survivors of treated primary head and neck cancer were invited to participate into the study. Ethical approval was obtained from the Medical Advisory Committee HTAA (representative of Ministry of Health). This study takes about 18 months which commenced from Oct 2004 and ended in April 2006.

3.3   Study Sample

3.3.1   Sample Size

Sample size was calculated using the sample size calculation formula software. With significant level taken as 0.05 and power of study set as 0.8, with the value from previous study, estimated sample size was 142. But in our study, we only managed to get a total of 48 patients due to some limitations that will be discussed later.

3.3.2   Inclusion Criteria

    i.   Malay patients diagnosed with Squamous Cell Carcinoma of :

        a. Nasopharynx

        b. Oropharynx

        c. Hypopharynx

        d. Larynx

        e. Maxilla

        f. Oral cavity

ii.   Received either one or combination of the following treatment :

    a. Surgery

    b. Radiation therapy

    c. Chemotherapy

iii.   Patients under the follow-up of ENT clinic HTAA and HUSM and must also be able to answer all the questionnaires.

3.3.3 Exclusion Criteria

i.   Patients having intercurrent medical illnesses such as uncontrolled diabetis mellitus, hypertension or unstable angina as well as ischaemic heart disease.

ii.   Patients with tumour metastasis, recurrent tumour and in terminally ill condition.

ii.   Patients who are unable to answer the questionnaires as a result of senile dementia or mental disturbances

3.4   University of Washington Quality of Life (UWQOL) Questionaire

UWQOL is a disease specific questionnaire which was well designed, validated and standardised for assessing QOL in head and neck cancer patients (Hassan and Weymuller, 1993). It is self administered and elicits responses only from the patients. It contains 12 domain specific items covering physical, functional and emotional aspects of the patient's

QOL. Each domain is given scores which range from 0 to 100, with 100 being the best possible QOL and 0 being the worst. Intermediate scores depend on the number of responses to each question. On 3 point items, scores are 0, 50 and 100. On 4 point items, scores are 0, 33, 67 and 100. On 5 point items, scores are 0, 25, 50, 75 and 100. In addition, there are three global QOL questions and an area for free text in which the patients can make any special comments. The global QOL questions are marked out of 5, with 1 representing good QOL and 5 for poor QOL. Since its first publication, UWQOL has undergone various changes and other implementation which include the addition of mood and anxiety domains to the scale (Rogers et al., 2002). The original author commented that to make statistical analysis is more meaningful, analysis of an individual domain would be more appropriate rather than looking at the total QOL score.

3.5   Translation of UWQOL into Malay language

Upon approval from the original author, the original version of UWQOL questionnaire was downloaded from the internet through the website given by the author. In our study, 2 persons involved in forward translation with one of them are bicultural and bilingual while the other is only bilingual. The principle researcher himself discussed with both translators in getting the appropriate translated Malay words. The word codeine and non-narcotic were eliminated from the questionnaire as these might not be fairly understood by some of the Malays from rural area. Having satisfied with the Malay translation, backward translation was then done by Pusat Bahasa HUSM. The researcher himself discussed with the translators in getting the nearest translated Malay words. The different between the

18

original and backward translation of Malay version of UWQOL was not apparent. Therefore the finalised translated Malay version was used in this study.

3.6 Procedure

Since the UWQOL questionnaire is a disease specific questionnaire, pilot test will be done on the Head and Neck cancer patients and data from the same group of patients will be analysed statistically. From the clinic registration book, all Head and Neck cancer cases were listed down. Their records were then traced according to the registration number. Informations such as adress, telephone number, age, socioeconomic status, site of tumour, tumour stage, diagnosis, treatment received and date of last treatment received were transferrred into a data collection sheet. There was only one researcher involved in the whole study right from the consent process till data collection and analysis. Patients consented their participation either during their clinic visit or by telephone or mail services. Those patients whom fullfilled the inclusion and exclusion criteria and come to clinic for their usual follow up were asked to participate into the study. Detailed explanations were given to them about the study and upon their approval (after signing the consent form) they were given the Malay version of UWQOL to be completed. Among those whom were contacted by phone similar explanation were given to them and upon approval they were invited to come to hospital for the interview or if they were reluctant, the questionnaire were posted to them. For those who were unable to be contacted by phone, the questionnaire were posted to them with an assumption that for those who replied the questionnaire with a signed consent form they may be taken into the study.

From our observation, about half of our patients were staying in rural area and majority of them have poor financial income. A significant number of patients had passed away as being told by relatives when the telephone numbers were contacted. From 73 cases that we are able to trace, 16 managed to come for the interview process. It is rather a patients self-administered interviewer supervised process and the overall time taken to complete the questionnaires was about 5 to 10 minutes. In the remaining 57 patients, the questionaire were posted to them using Pos Express services. This service is well known for its fast delivery and this is also to make sure that the posted questionnaires will reach to the patients within 2 to 3 days. From these, only 32 patients replied the questionnaire making a total of 48 patients that were truly enrolled into this study. For the retest, the questionnaires were mailed to these 48 patients within 2 week after the first questionnaires were completed and only 24 patients replied. The data then entered into statistical software SPSS version 12.0 and analysed.

3.7   Data Analysis

3.7.1   Reliability

Reliability is a measurement of the reproducibility of the data collected during a study. In order for the Malay version UWQOL to be considered reliable, similar results should be achieved on repeated administration of the questionnaire to stable patients under similar conditions. This is termed as "test-retest reliability".

3.7.2 Validity

Validity indicates the ability of the test under investigation to measure what it was intended to measure. Criterion validity however is a detail method to assess validity in which the outcome values of a particular questionnaire is compared to those obtained from another well-established or gold standard questionnaire in the same field of study. In our study, the validity and reliability result will be compared with the original version of UWQOL and also the Malay version of WHOQOL-BREF which was done by Hasanah et al. (2003).

3.7.3 Statistical analysis for dermographic data and QOL variables and outcomes.

Descriptive data were presented with number of cases and percentages for gender, level of education, socioeconomic status and different clinical groups. Mean with standard deviation was used for age and overall total score as both are assumed to show normal distribution. Instead of mean and standard deviation (SD), the median value with interquartile range (IQR) needed to be used for discriptive purpose of the total score and domain score in each clinical group. This was because of small sample size in majority of the groups to allow subgroup analysis. Because of the small sample size, non parametric test was used as normality of the data was not assumed. Therefore Kruskall Wallis test for comparison between groups was appropriate and sigificant level was taken as 0.05.

In majority of QOL studies done worldwide, it was conducted prospectively and the changes in QOL score were observed over time such as at pre-treatment, 3 month, 6 month, 12 month and 24 month post treatment. Since our study method was cross-sectional, we

attempted to look for any information that can be obtained from this data and therefore the patients were grouped into less than 6 month, 6 to 12 month, 12 to 24 month and more than 24 month post treatment.

The statistical software SPSS 12.0 for Windows was used in the analyses. As we were using the median and not mean value, an advice from King (1996) and Osoba et al. (1999) which they regarded a difference of 10 on a scale of 0 to 100 to be of moderate clinical significance, and a difference of 20 was regarded as a large difference is not appropriate for this study. Therefore the differences between groups of patients were only presented with regard to statistical significant differences. Statistical significant refers to the probability that a difference occurred by chance and it depend on the size of the difference between the groups, amount of variation within the groups and on the number of patients in the study.
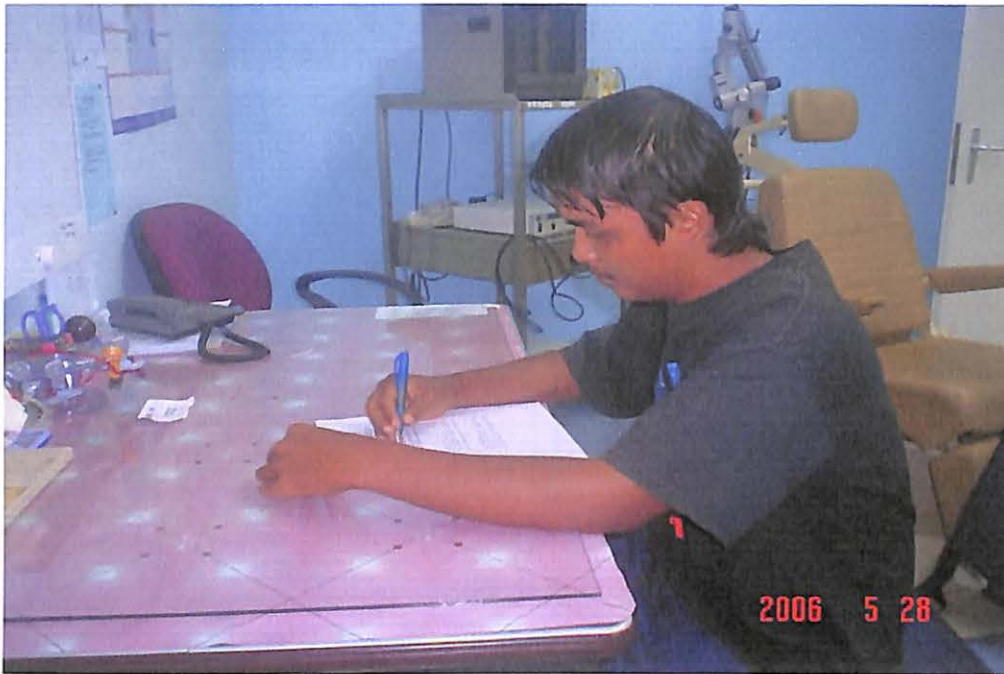
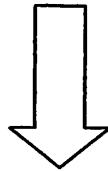Fig. 3.1: A patient answering the Malay version UWQOL questionnaire

Fig. 3.2: Pos Express service that was used in this study
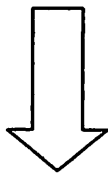
3.8   Flow chart of the study

Referrence Population

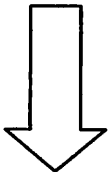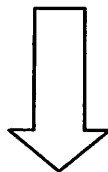All patients attending ENT clinic
HTAA and HUSM

Source Population

All head and neck cancer patients under
follow up ENT clinic HTAA and
HUSM

Inclusion and Exclusion
Criteria

Questionnaire given

Data Analysis