QUALITY OF LIFE IN GYNECOLOGIC CANCER PATIENTS UNDERGOING CHEMOTHERAPY IN HOSPITAL UNIVERSITI SAINS MALAYSIA

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LIST OF ABBREVIATIONS

ACS	-	American Cancer Society
AIDS	-	Acquired Immune Deficiency Syndrome
CAM	-	Complementary Alternative Medicine
EPT	-	Estradiol Progestin Therapy
FTC	-	Fallopian Tube Cancer
HCP	-	Health Care Professionals
HIV	-	Human Immunodeficiency Virus
Hospital USM	-	Hospital Universiti Sains Malaysia
HRQOL	-	Health Related Quality of Life
HPV	-	Human Papilloma Virus
HT	-	Hormone Therapy
NCCDPHP	-	National Center for Chronic Disease Prevention and Health Promotion
NCCP	-	National Cancer Control Program
QOL	-	Quality of Life
WHO	-	World Health Organization

KUALITI HIDUP DALAM KALANGAN PESAKIT KANSER GINEKOLOGI YANG MENJALANI RAWATAN KEMOTERAPI DI HOSPTIAL USM

ABSTRAK

Kanser ginekologi atau kanser yang menjejaskan sistem peranakan wanita adalah antara kanser yang paling kerap berlaku di Malaysia. Pelaksanaan kemoterapi sebagai rawatan terbukti berkesan, namun ia sering dikaitkan dengan kesan buruk kepada kualiti hidup dalam pesakit-pesakit kanser ginekologi. Kajian ini adalah untuk mengakses kualiti hidup pesakit kanser ginekologi yang menjalani rawatan kemoterapi. Satu keratan, tinjauan deskriptif silang telah dijalankan. Tujuh puluh responden telah diserap dalam kajian ini dengan pemilihan tentuan di Hospital USM dan bersetuju untuk menyertai kajian dan melengkapkan soal selidik *European Organization for Research and Treatment of Cancer Quality of Life Questionnaires* (EORTC QLQ-C30). Data telah dianalisis menggunakan Pearson Chi-Square, Pearson Correlations dan one-way ANOVA. Kepentingan statistik dianggap pada p-nilai ≤ 0.05. Purata umur adalah 42.79 (SD=12.51) tahun, dengan 48.6% kanser ovari, 28.6% kanser serviks, 12.9% kanser vulva dan 2.9% *persistent trophoblastic disease*. Status perkahwinan dan pekerjaan dikaitkan dengan skor EORTC QLQ-C30 dalam fungsi (p=0.04) dan kualiti hidup global (p=0.04). Dalam komponen simptom, hubungan yang signifikan wujud antara kehilangan selera makan (p=0.001) dengan kualiti hidup. Peringkat kanser mempunyai hubungan yang ketara dengan skala berfungsi dan simptom (p=0.001). Kajian mendapati pesakit-pesakit yang menjalani satu hingga dua kitaran kemoterapi, sepuluh pesakit (18.2%) mempunyai skor kualiti hidup rendah. Profesional kesihatan yang menjaga pesakit kanser ginekologi perlu menentukan faktor yang menyebabkan kualiti hidup rendah dan ianya memerlukan kerjasama pelbagai pihak untuk meningkatkan kualiti hidup pesakit yang menjalani rawatan kemoterapi ke arah yang lebih baik.

QUALITY OF LIFE AMONG GYNECOLOGY CANCER PATIENTS UNDERGOING CHEMOTHERAPY IN HOSPTIAL USM

ABSTRACT

Gynecologic cancers, or cancers that affect a woman's reproductive system, are among the most common cancers in Malaysia. The use of chemotherapy as treatment prove to be promising, it is often associated with adverse effects on quality of life (QOL) in these cancer patients. Objective of this study was to assess the QOL in gynecologic cancer patients undergoing chemotherapy. A cross-sectional study was used. A total of 70 gynaecology cancer women sampled by non-probability purposive sampling at Hospital USM consented to participate and complete all the European Organization for Research and Treatment of Cancer Quality of Life Questionnaires (EORTC QLQ-C30) components. Data analyses were performed using the Pearson Chi Square, Pearson correlations and one-way ANOVA. A p value ≤ 0.05 was considered statistically significant. Mean age was 42.79 (SD=12.51) years, with 48.6% ovarian cancer, 28.6% cervical cancer, 12.9% vulva cancer and 2.9% persistent trophoplastic disease. Marital status and occupation were associated with EORTC QLQ-C30 scores in functional (p=0.04) and global QOL (p=0.04). Among symptoms subscales, significant association only existed in loss of appetite (p=0.001) with QOL. Stage of cancer were associated significantly with functional and symptoms scales (p=0.001). Among these patients undergoing one to two chemotherapy cycles, ten (18.2%) had poor QOL scores. Health professionals who care for gynaecology cancer patients need to determine the underlying reasons of poor QOL and initiate observations during multi-professional interventions to provide a better QOL during chemotherapy treatment.

CHAPTER 1 INTRODUCTION

1.1 Introduction to the Chapter

Gynecologic cancer is one of the most frequent groups of malignancies, ranging from virally induced cervical cancers to genetically associated cancer cluster (Goodman, Clark, & Bradford, 2012). According to Papadakos et al.'s (2012) study on informational needs of gynecologic cancer survivors, it is the fourth most common cancer in women and constitutes the second largest group of female cancer survivors. Despite the advances made in screening for these malignancies, a significant number of cases were still diagnosed in an advanced stage, contributing for the high morbidity (Papadakos et al., 2012). The word cancer in itself was debilitating. The different types of treatment modalities options available for the removal or management of cancer depend on the type and stage of the cancer, as well as the general health of the patient. The burden of gynaecologic cancers is on the increase worldwide but is disproportionately higher in developing than developed countries (Crane, 2010) and have an impact on women's QOL (Sau, Chatterjee, Saha, Sau, & Roy, 2013). Although chemotherapy is a cancer treatment option that uses strong drugs to kill cancer cells, it is often associated with adverse effects on QOL (American Cancer Society, 2015). An increasingly important issue in oncology was to evaluate QOL in cancer patients (M. S. Heydarnejad, Hassanpour, & Solati, 2011; Rizzo, Maronato, Marchiori, & Gaya, 2008). However, little is known about QOL of gynecology cancer patients undergoing chemotherapy in our local context.

1.2 Background of the Study

Female cancers including corpus uteri, cervix, ovary and breast has been shown a world incidence rate of 72.5/100,000 women per year in 2008. As the population ages and the number of cancer survivors grow dramatically, there will be an increase in depression by 2030 to a position of the greatest contributor to illness burden (Bifulco et al., 2012). Despite considerable advancements in diagnosis and treatment, symptoms or problems often arise during treatment and persist long-term to complicate improved survival and reduced QOL (Irwin, Olmstead, Ganz, & Haque, 2013).

Chemotherapy is one of the main treatments for cancer. There are 5 types of chemotherapy-induced emesis; acute onset, delayed onset, anticipatory, breakthrough and refractory. The two most commonly described types of emesis often causing clinical problems are acute and delayed emesis. Acute onset emesis generally peaks after 5–6 hours within the first 24 hours of chemotherapy. Delayed onset emesis commonly occurs with platinum administration (Rithirangsriroj, Manchana, & Akkayagorn, 2015). Discontinuation of treatment lead patient's condition becomes worsen. However, side effects that patient experienced also lead to decrease in patient's QOL and destroy patient's spiritual and social health. Assessment of factors that associated in patient QOL were the most important things in order to overcome the problem. Side effects such as pain, vomiting, sleeplessness, exhaustion, intense fear and anxiety caused by radiotherapy, chemotherapy, surgical and hormonal treatment affect patient's well-being (Reis, Beji, & Coskun, 2010).

1.3 Problem Statement

Cancer remains a major health problem around the world that often results in death. However, gynecologic cancer such as cervical and endometrial cancer are common diseases with high survival rates (Reis et al., 2010). In general, the primary and most effective treatment was surgery if the cancer was diagnosed in the early stages. Cervical cancers and endometrial cancers were more likely to be diagnosed in the early stages because of their symptoms and the availability of effective screening tools. Unfortunately, ovarian cancer was denoted the "silent killer" among the gynecologic cancer because it was often not diagnosed until an advanced stage when a cure was difficult (Keng, Abdul Wahab, Chiu, & Yusuf, 2015; Smith, 2015). Annually, there were increased of gynecologic cancer incidence rate, thus making gynecologic cancer the 4th leading cause of cancer-related death in women, after lung, breast and colorectal cancer (Barbera, Elit, Krzyzanowska, Saskin, & Bierman, 2010). In Malaysia, cancer of the cervix was the third most common cancer a while ovarian cancer was the fourth most common cancer among women after breast and colorectal cancer (National Cancer Registry, 2011). A total of 1735 gynecologic cancer patients were noted from 2010 to 2014 in Hospital Universiti Sains Malaysia (Unit Rekod Perubatan Hospital USM, 2015).

According to Rithirangsriroj et al. (2015), chemotherapy improves patient's outcomes, its adverse effects often decrease patient's QOL as chemotherapy induced nausea and vomiting which are serious problem in cancer treatment. Almost 80% of patients that receive chemotherapy treatments experience nausea and/or vomiting. These will cause decreasing in QOL of patient, cause poor compliance and become a major factor in the discontinuation of treatment (Rithirangsriroj et al., 2015).

Furthermore, although extensive research has been compile and conducted on defining and measuring QOL, the concept of QOL within itself was attached to a broad spectrum of aspects and differs among each individual's perspective. QOL of patients undergoing chemotherapy varies from one patient to another depending on the perceptions of their diagnosis. In addition, different domains aspects of QOL were interrelated and affect each individual in comparable ways. Other aspects such as if a cancer patient was currently in active treatment or not also plays a role in QOL. Considering these aspects and seeking to collaborate on understanding the repercussions of this cancer group on the lives of women, thus prompt the researcher to undertake this study to assess the QOL in gynecologic cancer patients undergoing chemotherapy in Hospital USM (Unit Rekod Perubatan Hospital USM, 2015).

To guide this study, the Health Related Quality of Life (HRQOL) model were used as the conceptual framework. The rationale behind the use of HRQOL was the model were conceived as dynamic, subjective, and multidimensional; and the dimensions often include physical, social, psychological, and spiritual factors (Jones et al., 2006).

1.4 Research Objectives

The scope of the investigator's research was determined by what the investigator wants to achieve (i.e the investigator's objectives) and the types of decisions it needs to help the investigator make (Denise F. Polit & Beck, 2012).

1.4.1 General Objective

To assess the QOL in gynecologic cancer patients undergoing chemotherapy in Hospital Universiti Sains Malaysia (Unit Rekod Perubatan Hospital USM).

1.4.2 Specific Objectives

a) To determine QOL in gynecologic cancer patients undergoing chemotherapy in Hospital USM.

b) To determine socio-demographic characteristics (age, ethnicity, marital status, level of educational status, occupation, household income) and medical factors among gynecologic cancer patients in Hospital USM.

c) To determine the association of socio-demographic characteristics (age, ethnicity, marital status, level of educational status, occupation, household income) on QOL among gynecologic cancer patients in Hospital USM.

d) To determine the association of medical factors (type of gynecologic cancer, time since diagnosis, staging, type of chemotherapy, number of chemotherapy cycles patient had) on QOL among gynecologic cancer patients in Hospital USM.

e) To determine Pearson's Correlation between different QOL scales and overall QOL in gynecologic cancer patients in Hospital USM.

1.5 Research Questions

Generating research questions is therefore important for each study that the researcher conduct as it is the research question that gave focus, sets boundaries and provide direction (Denise F. Polit & Beck, 2012). This research study seeks to address the following questions:

a) What is the QOL in gynecologic cancer patients undergoing chemotherapy in Hospital USM?
b) What is the association between socio-demographic characteristics (age, ethnicity, marital status, level of educational status, occupation, and monthly household income) on QOL in gynecologic cancer patients undergoing chemotherapy in Hospital USM?
c) Is there any association between medical factors (type of gynecologic cancer, time since diagnosis, staging, type of chemotherapy, number of chemotherapy cycles patient had, duration of chemotherapy) on QOL among gynecologic cancer patients undergoing chemotherapy in Hospital USM?

1.6 Research Hypotheses

Hypothesis 1 : There will be a significant association between socio demographic characteristics (age, ethnicity, marital status, number of children, level of educational status, occupation, and monthly household income) and QOL among gynecologic cancer patients undergoing chemotherapy (Ho#Ha).

Hypothesis 2 : There will be a significant association between medical factors (type of gynecologic cancer, time since diagnosis, staging, metastasis, type of chemotherapy, number of chemotherapy cycles patient had, duration of chemotherapy) and QOL among gynecologic cancer patients undergoing chemotherapy in Hospital USM (Ho#Ha).

1.7 Definition of Operational Terms

Chemotherapy - Chemotherapy is the use of strong drugs to treat cancer. It kills the cancer cells by damaging them, so they cannot reproduce and spread. Commonly used chemotherapy drugs include carboplatin, cisplatin, paclitaxel, docetaxel, doxorubicin and others. These medications are given either alone or in combination (American Cancer Society, 2015). In this study, it refers to a cancer treatment that uses strong drugs to kill cancer cells.

Gynecologic cancer - Gynecologic cancers are the uncontrolled growth and spread of abnormal cells originating in the female reproductive organs. In this study, gynecologic cancer refer to cervix cancer, ovarian cancer, uterine cancer, fallopian tube cancer, vagina cancer and vulva cancer. Gynecologic cancer begin in different places within a woman's pelvis, which is the area below the stomach and in between the hip bones (Foundation for Women's Care, 2015).

Quality of life - According to the general scientific notion, QOL is a multidimensional construct that is not directly measured but can only be displayed in its single components. There are differing opinions regarding the areas to be included. Based on a fundamental WHO definition on health, QOL includes the physical, psychological, and social condition of an individual. Also taken into account in QOL is the degree of concordance between the desired and the real-life situation (Augustin et al., 2014).

1.8 Significance of the Study

QOL is an important component of assessing the effects of cancer, therapy, and survivorship. Assessing QOL status in cancer patients undergoing chemotherapy is important for several reasons, particularly because it provides valuable information about the impact of the disease and its treatment on cancer patients to aid physicians in selecting both antineoplastic and supportive-care therapy (von Gruenigen et al., 2010). There were different domains of QOL of cancer patients undergoing chemotherapy treatments (von Gruenigen et al., 2010). This is even more relevant as QOL had been rarely tested in developing countries where a rising incidence of gynecologic cancers had been noted (von Gruenigen et al., 2010) .Therefore, it is important to evaluable the gynecologic cancer patient's baseline activity and physical, and emotional well-being before the doctor discusses various treatment options with the patients. Assuring that the patient begins chemotherapy with the right support will assist in achieving higher QOL during chemotherapy treatment.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction to the Chapter

This chapter provides a review of literature on gynecologic cancer, quality of life (QOL), impact of chemotherapy on QOL in gynecologic cancer patients by accredited scholars and researchers. Literatures were searched through electronic databases specifically for example PubMed, Ovid, and ProQuest, and general databases such as Google Scholar and Yahoo using key words and terms, which were either used singly or in various combinations: chemotherapy, QOL and gynecology cancer. The chapter also details the conceptual framework, Health-Related Quality of Life Models (HRQOL) guiding this study.

2.2 Gynecology Cancer

Cancer is one of the leading causes of death in the world (World Health Organization, 2011). The word cancer in itself with a number of medical, physical, emotional, psychological, and social issues; which becomes an ongoing process that brings alongside a plethora of side effects. Gynecologic cancer is any cancer that starts in a woman's reproductive organs. There were five gynecologic cancer types that begin in different places within a woman's pelvis, which is the area is below the stomach and in between the hip bones. Each gynecologic cancer is unique which are with different signs and symptoms, different risk factors and different prevention strategies. All women in the world are at risk for gynecologic cancer and it was increases with age. When gynecologic cancer was diagnosed early, treatment was most effective. Five main types of gynecologic cancers were cervical, ovarian, uterine, vaginal and vulvar. A sixth type of gynecologic cancer was the very rare fallopian tube cancer (Lurie, 2015).

2.3 Chemotherapy

Chemotherapy is a pivotal component in the treatment of patients with any type cancer, with patients receiving multiple types of chemotherapy throughout the course of their disease (Bourdeanu & Liu, 2015). Neo-adjuvant chemotherapy (NACT) and adjuvant chemotherapy has been recently emerging as a feasible and safe therapeutic option. Adjuvant treatment with 4 or 6 courses of platinum-based chemotherapy showed similar results in terms of overall survival and disease-free survival, with a favorable toxicity profile in favor of the first regimen (Angioli et al., 2015).

Platinum based combination chemotherapy has been used in chemotherapy treatment and it improves the survival of women with epithelial ovarian cancer and recommended first line chemotherapy for advanced cancers (stages III–IV) has been carboplatin and paclitaxel given three-weekly for six cycles. Evidence also supports adjuvant chemotherapy for early-stage cancers apart from low-grade, stage I/II cancers. Of patients who did receive chemotherapy, majority of patients received a platinum-based drug and about two-thirds started on carboplatin and paclitaxel. Besides, there were patients started on other regimens, mostly single-agent carboplatin or variant regimens of carboplatin and paclitaxel. Some of patients were started on 'non-standard' drugs such as cisplatin, epirubicin and docetaxel (Jordan et al., 2013).

2.4 The Influence of Chemotherapy on Health and QOL

Patients receiving chemotherapy suffer from a series of side-effects, comprising treatment related fatigue, pain, nausea and vomiting, dyspnea, lack of appetite, changes in skin and nails, oral sores and numbness in the hands (Bulley et al., 2014). Chemotherapy was associated with acute and persistent physical side effects that were closely related to psychological responses and poorer QOL outcomes (Ho, So, Leung,

Lai, & Chan, 2013). For example, Chinese breast cancer (BC) patients undergoing chemotherapy report more anxiety (26.9%) or depression (41.5%) than the BC patients undergoing radiotherapy (So et al., 2010). Patients who are receiving first chemotherapy regimen, before the first chemotherapy infusion or receiving AC (Adriamycine and Cyclophosphamide) chemotherapy combination sometimes used to treat breast cancer have high depression (Hack et al., 2010; Lim, Devi, & Ang, 2011) .

Nausea and vomiting were among the most common and unpleasant side effects to chemotherapy. Cisplatin, the chemotherapeutic agent with the highest emetic potential, was introduced in the late 1970s. In the 1990s, after the introduction of the 5-hydroxytryptamine (Aaronson et al.) 3-receptor antagonists, nausea became the most feared side effect, whereas vomiting was only ranked as number five. Apart from that, decreased renal function may occur to the patient because of the high risk of other toxicities seen with risk agent, cisplatin (Jakobsen & Herrstedt, 2009).

The three types of nausea and vomiting caused by chemotherapeutic agents include acute, delayed, and anticipatory nausea–vomiting. Nausea and vomiting reactions that begin within 1–2 hours after the administration of chemotherapy and which develop within the first 24 hours after chemotherapy are characterized as acute emesis. Delayed emesis is used as a term to describe nausea and vomiting experienced from the second to fifth days of chemotherapy administration and is generally experienced at home by most patients. The management and control of delayed emesis is very difficult (Taspinar & Sirin, 2010). The prevention and control of nausea and vomiting was more important than treatment in cancer patients. The nausea and vomiting experienced to different degrees by patients have a significant effect on their QOL issues and can cause serious metabolic complications, such as hyponatremia, hypokalemia and metabolic acidosis. In addition, a patient's inadequate intake of

nutrients due to nausea and vomiting decreases the patients' resistance to infection and causes weight loss (Taspinar & Sirin, 2010).

Acute treatment-related toxicities include dermatitis, mucositis, diarrhea, and dysuria, among others. These side effects can generally be managed with skin creams, anti-diarrhea medications, and pain medications, and may resolve shortly after the completion of therapy. These treatment-related morbidities may have short- and long-term implications for patient's QOL, which may be difficult to quantify. A study was able to discern three main domains of concern for female cancer survivors which are physical (dyspareunia, changes in the vagina, and decreased sexual activity), psychological (decreased libido, alterations in body image, anxiety related to sexual performance) and social (difficulty maintaining previous sexual roles, emotional distancing from partners, perceived change in partner's level of sexual interest) (Mirabeau-Beale & Viswanathan, 2014). On the other hand, a significant worsening of global QOL scores has been consistently reported in endometrial cancer patients administered radiation treatment; in particular, the most frequent symptoms involved in QOL impairment are urinary and bowel dysfunctions which can persist even after years since treatment. Although the long term evaluation of QOL in endometrial cancer patients has been prospectively investigated in endometrial cancer patients, some issues still remain to be addressed, such as the impact of socio-demographic features, comorbidities and obesity on QOL as well as emotional distress (Ferrandina et al., 2014).

2.4.1 Physical health

Chemotherapy affects patient's physical health in aspect of movement, physical activities and ability to success in work (Üstündag & Zencirci, 2015). Chemotherapy often precipitate symptoms such as fatigue, nausea/vomiting with decrease in well-being and functioning. These symptoms affect QOL of patients thus declines their performance on activity daily living. Moreover, chemotherapy appears to have greater negative impact on overall rates of daily activities compared to other treatment such as radiotherapy (Faul et al., 2011). Besides, it also causes sexual worries that lead to sexual dysfunction. Sexual worries comprise major causes of sexual life failure among gynecologic cancer survivors, which was manifested by declines quality of sexual experiences, fear of pain and unwillingness to involve any sexual activity (Barnas, Skret-Magierlo, Skret, & Bidzinski, 2012). In order to overcome these problems, physical exercise intervention had been introduced to improve physical health of gynecologic cancer patients. Although it may be a challenge for patients, evidence from randomized trial shown that initiate exercise during chemotherapy treatment are beneficial and feasible. When patient participate in exercise programs, they can improve physical QOL (Faul et al., 2011).

2.4.2 Psychological Health

Sexual dysfunction is a distressing, persistent and inappropriately problem among gynecological cancer survivors during chemotherapy treatment. It is an integral cause for psychological problems of patients. Studied shown that sexual arousal is the most distressing of their treatment-related symptoms. Sexual changes play an important role in a women's sexual identity and her personal relationship thus affects their QOL (Levin et al., 2010). Researchers recommend psycho-educational interventions should

be incorporated into routine care for gynecological cancer treatment to improve patient outcomes. They delivered a 12-week group psycho-educational intervention to post-operative gynecological cancer patients and found out that their sexual functioning and mood disturbance has been improved (Chow, Chan, Chan, Choi, & Siu, 2014).

2.4.3 Social Relationship

Social relationship includes family relationship, group memberships and resources that fulfill personal needs. The patient's satisfaction with the physician is a measurement of the social relationship between what patients expect from the treatment and what patient actually receives during treatment. The impact of treatment has on daily activities that will affects patient's QOL. Relationships with family will be altered because of side effects of chemotherapy itself. Side effects such as weakness, fatigue, mouth sores, vomiting definitely affects the relationship (Mincu & Taşcu, 2015). Complementary and alternative medicine (Ferrandina et al.) is widely used in by cancer patients in order to improve their QOL. CAM provides group discussion among cancer survivors with traditional practitioners and not health care professionals (HCP). Several studies shown that people that practices CAM can express well their feeling among their group thus improves their QOL (Wang, Lin, Chang, & Huang, 2015).

2.5 Quality of Life

Quality of life (QOL) is a fundamental consideration for patients with life threatening diseases. World Health Organization (WHO) has broadened the definition of QOL to include the context of the culture, personal value systems, goals, standards, and concerns instead of the domains that already focused in defining QOL (World Health Organization, 2011). QOL has been defined by the WHO as an individual

outlook on the aspects of life, values, objectives, standards, and interests in the preservation of culture (Dehkordi, Heydarnejad, & Fatehi, 2009). This definition reflects the view that QOL refers to a subjective evaluation which is embedded in a cultural, social and environmental context. Because this definition of QOL focuses upon respondents' "perceived" QOL, it is not expected to provide a means of measuring in any detailed fashion symptoms, diseases or conditions, but rather the effects of disease and health interventions on QOL. As such, QOL cannot be equated simply with the terms "health status", "life style", "life satisfaction", "mental state" or "well-being" (Harper, 1996). QOL also act as prognostic indicator. It is well known that patients with a good QOL at the start of treatment fare better than those with a poorer baseline score, but there is also an increasing body of literature in various cancers demonstrating the utility of QOL as an effective prognostic indicator. Sometimes, assessment of QOL had been shown to be stronger predictors of survival than computed tomography scans in patients. In some cases, assessment of QOL has been shown to provide a better estimate of survival than measurement of tumor size (Akin, Can, Aydiner, Ozdilli, & Durna, 2010). According to (National Center for Chronic Disease Prevention, 2012), QOL is a collection of positive and negative multidimensional perceptions of an individual's subjective outlook on life.

2.6 Health Related Quality of Life Models as Conceptual Framework

This study uses the Health Related Quality of Life Models as the conceptual framework. According to (Bakas et al., 2012), Health-related quality of life (HRQOL) has been identified as a goal for all people across all life stages by leading health organizations. HRQOL, that is, QOL relative to one's health or disease status, is a concern of policymakers, researchers, and health care practitioners (Bakas et al., 2012).

Wilson and Cleary proposed a conceptual model of health-related quality of life (HRQOL) that integrates both biological and psychological aspects of health outcomes. There are five different levels in their model, namely, physiological factors, symptom status, functional health, general health perceptions, and overall quality of life. Wilson and Cleary presented a conceptual model focused on relationships among aspects of health (Sousa & Kwok, 2006; Wilson & Cleary, 1995).

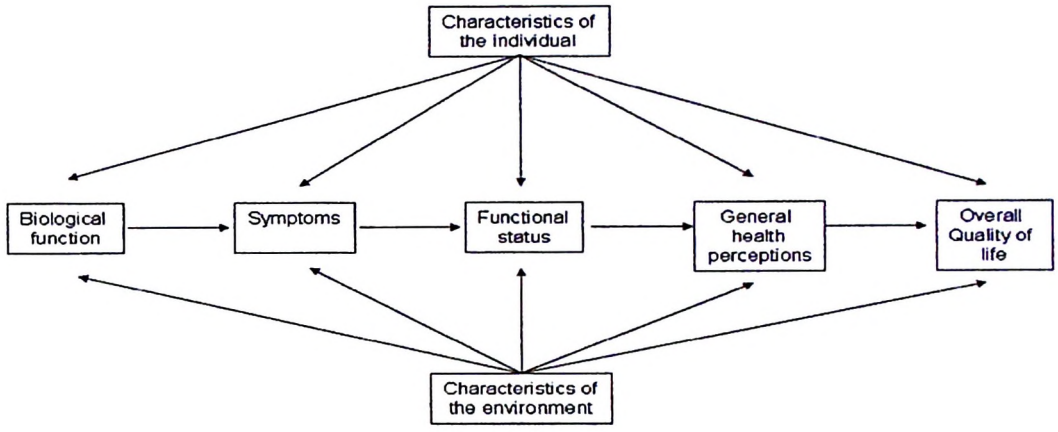

Figure 2.1 Health Related Quality of Life (HRQOL) Model
[Source: (Ferrans, Zerwic, Wilbur, & Larson, 2005)]

This model linked biological function, symptom status, functional health status, general health perceptions, and overall quality of life. Wilson and Cleary suggested that this health-related quality of life (HRQOL) conceptual model could be used to unify the biomedical and social science paradigms. The model focused on etiologic agents; pathological processes; and biological, physiological, and clinical outcomes. The ultimate goal of this model is to understand causal relationships and to classify patients into groups with specific prognostic or therapeutic meaning (Sousa & Kwok, 2006). In the model, the evaluation of biological function centers on cells, organs, and organ systems, while the assessment of symptom status shifts to the organism as a whole.

Functional health has been defined as the ability of an individual to perform and adapt to one's environment, measured both objectively and subjectively over a given period. Symptom status and functional health have been included in many HRQOL outcome studies. General health perceptions represent an integration of all the health concepts previously reviewed, plus others such as mental health (Sousa & Kwok, 2006). Figure 2.2 shows the adapted Health Related Quality of Life Model within this study. This conceptual framework will explains the measurement of QOL on gynecologic patients that undergoing chemotherapy treatment.

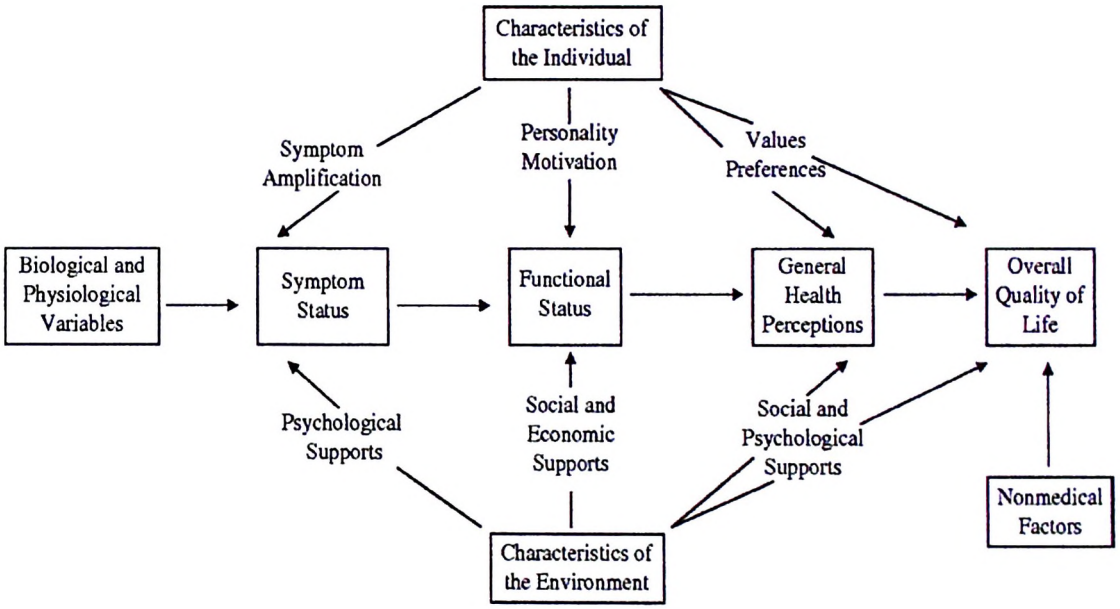

Figure 2.2 The Adapted Health Related Quality of Life (HRQOL) Model

CHAPTER 3 METHODOLOGY & METHODS

3.1 Introduction to the Chapters

This chapter outlines the research methodology and methods used in this study aiming to assess the quality of life (QOL) among gynecology patients undergoing chemotherapy in Hospital Universiti Sains Malaysia (Unit Rekod Perubatan Hospital USM). The chapter begins with the justification for choosing the research design. This was followed by a description of the study population and setting, participant selection criteria, and an explanation of sample size determination, instruments, data collection, ethical considerations, and data analysis.

3.2 Research Design

Research design is a master plan for a research project which escalates the control over factors that could interfere with the validity of the study finding (Burns & Grove, 2011). Choosing and understanding an appropriate research design is important for achieving the aims of the research. A cross-sectional study using a structured, self-administered questionnaire was used. The rationale for this research design was it can be captures a population in a single point in time and can help to remove assumptions (Polit & Beck, 2014; National EMSC Data Analysis Resource Center, 2010).

3.3 Study Population and Setting

The population of this study was gynecologic cancer patients undergoing chemotherapy at Hospital USM, Kubang Kerian, Kelantan. Hospital USM was chosen as the study setting, the environment within which this study was conducted due to the

reason it being a referral, teaching hospital where most cancer patients, including gynecology cancer patients were referred.

3.4 Sampling Plan

The sampling plan describes the strategies that was utilized by the researcher to obtain a sample for a study. It is developed to enhance representativeness, reduce systematic bias, and minimizes the sampling errors (Burns & Grove, 2011).

3.4.1 Sample

When conducting a research study, certain inclusion and exclusion criteria were considered in selecting an eligible sample from the population in Hospital USM, Kubang Kerian.

3.4.1.1 Inclusion Criteria

Subjects are eligible for inclusion in this study if they are:

i. Gynecologic cancer patients (ovarian, uterus, cervix, fallopian tube, & vulva) undergoing chemotherapy in Hospital USM
ii. Being over the age of 18 and above
iii. Able to understand, speak and write in English or Bahasa Malaysia
iv. Being fit based on the Karnofsky Performance Status >50 scales indicating fitness to participate in this study

3.4.1.2 Exclusion Criteria

Subjects are excluded from this study if they:

i. Receiving radiotherapy or surgery in Hospital USM
ii. Had lower than 50 Karnofsky Performance Scale (KPS) points
iii. Declined to participate in this study

3.4.2 Sampling Design

Sampling was guided by the designed sampling criteria and a sampling frame. In this research study, a purposive sampling was used to recruit the sample. The rational for purposive sampling is that it is a non-probability sampling in which the researcher utilized his or her judgement to select the subject who best meets the needs of the study as a respondent to represent the population of subject group (Chua, 2011).

3.4.3 Sample Size Determination

For objective 1, the sample size calculation was estimated based on Teng, Kalloger, Brotto, and McAlpine (2014) study. Figure 3.1 illustrates the calculation done using the Power and Sample Size formula:

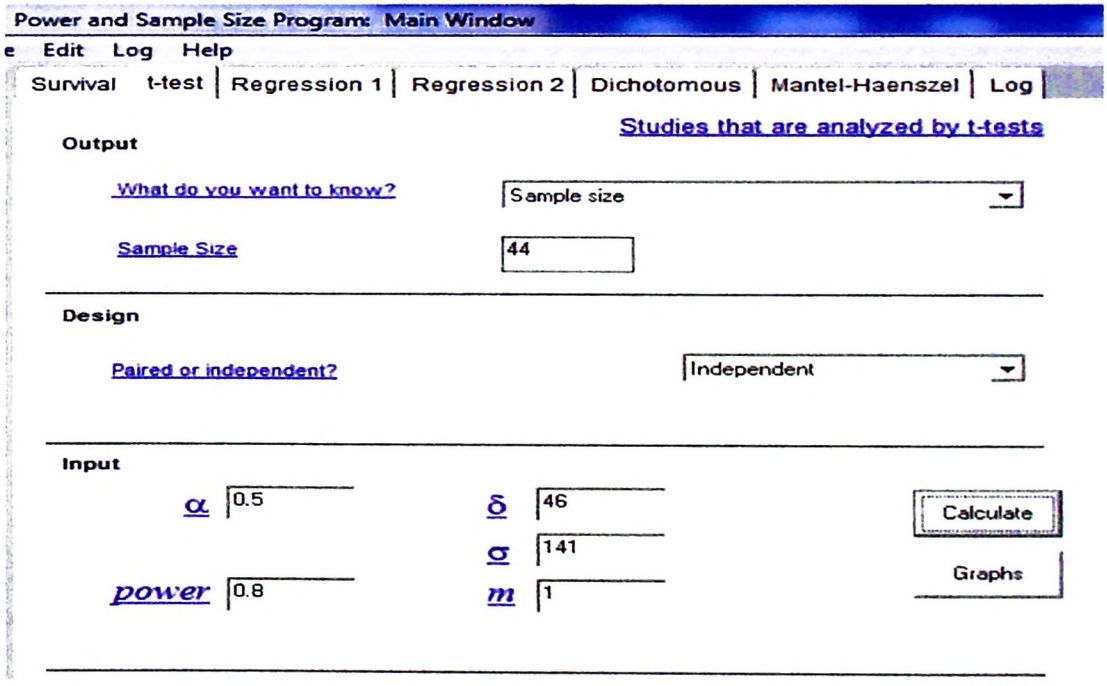

Figure 3.1 Determination of Sample Size Using the Power and Sample Size Program

By considering the dropout rate as 10%, the adjusted n was adjusted to allow the non-response of as much as 10%, resulting in the final sample size required for the study to be 49.

$$= \frac{\text{n calculated}}{1 - \text{dropout rate}}$$

$$= \frac{44}{1 - 0.1}$$

= 49 participants

For objective 2, sample size calculation was done based on Esher and Sappino's (2000) study using the G*Power 3.1.9.2 software (Escher & Sappino, 2000), 95% confidence interval and 80% power of study. The calculated sample size was 128 participants. Figure 3.2 illustrates the sample size.

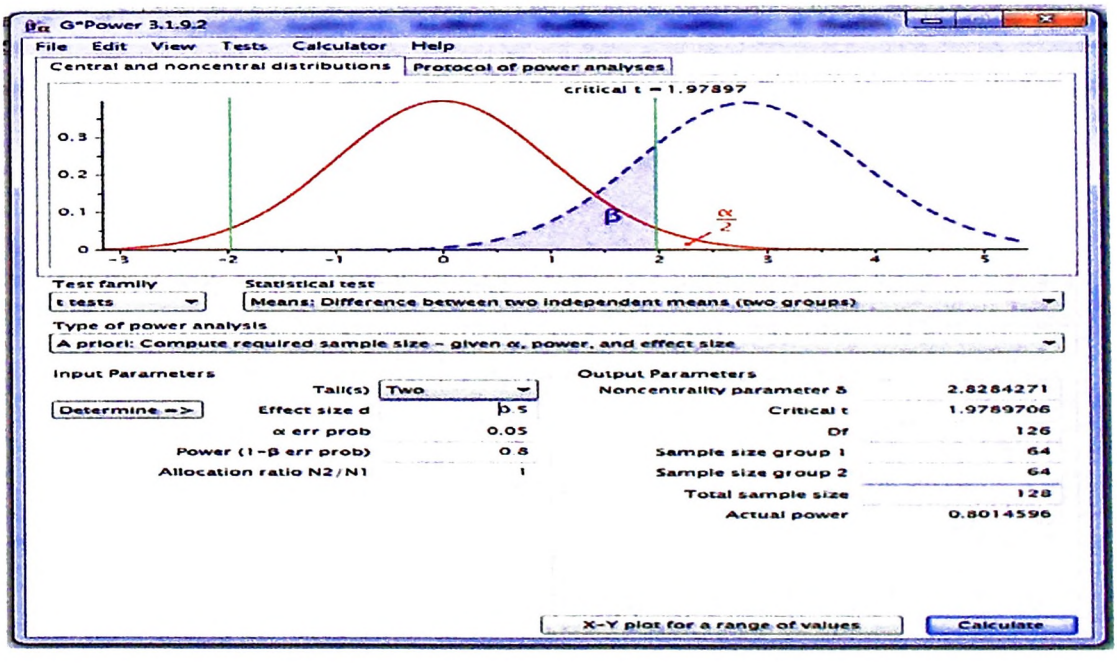

Figure 3.2 Determination of Sample Size Using the G*Power 3.1.9.2 software

By considering the dropout rate as 10%, the adjusted n is:

$$= \frac{n\ calculated}{1 - dropout\ rate}$$

$$= \frac{128}{1 - 0.1}$$

= 142 participants

For the purposes of this study, the maximum sample size of 142 participants was considered as a representative sample size.

3.5 Variables

Variables are characteristics or attributes of a person or object that varies within the population under study (Denise F. Polit & Beck, 2012). Variables are therefore those attributes that are measured or manipulated in a study.

3.5.1 Measurements of Variables

The measurement of variables are as follows:

Socio-demographic characteristics	-	Age, ethnicity, marital status, level of educational status, occupation, household income
Medical Factors	-	Type of gynecologic cancer, time since diagnosis, staging, type of chemotherapy, number of chemotherapy cycles patient had, duration of chemotherapy
Latent variables	-	Quality of life (QOL)

The variables of the study were measured by using the instrument tool in the study through survey answered by the participants who fulfill the inclusion criterions. In Section I and II, the independent variable was socio-demographic data (age, ethnicity, marital status, level of education, occupation, monthly income and diagnosis) and medical factors that associated with QOL changes (type of gynecology cancer, time since diagnosis, staging, type of chemotherapy, number of chemotherapy cycle patient had and duration of chemotherapy). In Section III, which determines the QOL of gynecologic cancer patients that undergoing chemotherapy, the scale appear in Likert scale format with answers as follows: "Not At All", "A Little", "Quite A Bit" and "Very Much". The scales range from 1 to 4 except for the global health status scale, which has 7 points ranging from 1 ("Very Poor") to 7 ("Excellent").

All of the scales and single-item measures range in score from 0 to 100. A high scale score represents a higher response level. Thus a high score for a functional scale represents a high / healthy level of functioning, a high score for the global health status / QoL represents a high QoL, but a high score for a symptom scale / item represents a high level of symptomatology / problems. For the purpose of interpretation, score 50 was used as cut-off point as it is a mid-point for full score 100:

Table 3.1 Variables measurement

Global QOL	:	≥ 50 (Good score) ≤ 50 (Poor score)
Functioning	:	≥ 50 (Good score) ≤ 50 (Poor score)
Symptoms	:	≥ 50 (Good score) ≤ 50 (Poor score)

[Source: (Fayers et al., 2001)]