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QUALITY OF LIFE AMONG COLORECTAL CANCER PATIENTS DURING CHEMOTHERAPY

A Thesis Submitted in Partial Fulfillment
of the Requirements for the Degree of
Master of Science

Than Minh Chau

College of Natural and Health Sciences
School of Nursing
Advanced Nurse Generalist

May, 2020

This Thesis by: Than Minh Chau

Entitled: *Quality of Life Among Colorectal Cancer Patients During Chemotherapy*

Has been approved as meeting the requirement for the Degree of Master of Science in College of Natural and Health Sciences in the School of Nursing, Advanced Nurse Generalist Program

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ABSTRACT

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This study had the general goal of surveying the quality of life (QoL) and related factors affecting the QoL of colorectal cancer (CRC) patients participating in cancer chemotherapy at University Medical Center (UMC) in Ho Chi Minh City. The study also had the following specific objectives: (a) determining the demographic and clinical characteristics of CRC patients and (b) determining health-related quality of life (HRQoL) and related factors affecting HRQoL of CRC patients receiving cancer chemotherapy.

A descriptive cross-sectional design was used. Sixty CRC patients being treated at the UMC participated in this study. The research used the European Organization for Research and Treatment of Cancer's (1995) QLQ-C30 questionnaire to assess the quality of life in CRC patients during chemotherapy.

The results of the study concluded the QoL of CRC patients was impaired by the following factors: deficits in emotional and social functioning; physical-related restrictions such as fatigue, shortness of breath, insomnia, constipation, and diarrhea; and financial difficulties.

The results of the study improved the knowledge regarding each stage CRC patients experienced and their understanding of symptoms and any abnormalities.

Although more research is needed, this information will be helpful to health professionals as they assist patients in maintaining their activities and QoL during chemotherapy.

Keywords: Quality of Life, Colorectal Patient, Chemotherapy, QLQ-C30.

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CHAPTER I

INTRODUCTION

Background and Significance of Problem

According to the World Health Organization (WHO, 2018), cancer is the second leading cause of death in the world. In 2018, about 9.6 million people died from cancer, which means one out of six people die from cancer. In addition, 70% of cancer deaths occur in low- and middle-income countries (WHO, 2018). In 2018, with a population of 96 million people, Vietnam had 165,000 new cases of cancer and about 115,000 people died of cancer (WHO, 2019). From these statistics, it can be seen that cancer has a great impact on human health.

Colorectal cancer (CRC) is a type of cancer that starts in the colon or rectum (American Cancer Society [ACS], 2018b). According to the WHO (2018), about 1.8 million people around the world suffer from CRC, the third most common cancer after lung and breast cancers. In 2017, there were nearly 135,500 new cases and more than 50,000 deaths from CRC in the United States (ACS, 2017). According to ACS (2018b) estimates, in 2019, there will be about 145,600 new CRC cases and about 51,000 CRC deaths in the United States. In Vietnam, CRC is one of the top five most common cancers. According to WHO (2019) statistics, there were 14,733 new cases and 7,607 deaths due to CRC in Vietnam in 2018.

More and more people suffer from cancer diseases in the world and CRC is one of them. The deterioration of health caused by CRC symptoms or the consequences of

treatment could lead to physiological, functional, and social damage. As a result, these effects could impair a CRC patient's health-related quality of life (HRQoL; Stefano et al., 2013). According to the Centers for Disease Control and Prevention (CDC, 2018), the HRQoL concept is based on two levels: individual and community. On the individual level, HRQoL includes physical and mental health perceptions (e.g., energy level, mood) and their correlates include health risks and conditions, functional status, social support, and socioeconomic status. On the community level, HRQoL includes community-level resources, conditions, policies, and practices that influence a population's health perceptions and functional status. Health-related quality of life plays an important role in assessing the extent of disease, injury, and disability in order to provide preventive solutions and to identify risk factors in treatment (CDC, 2018). For cancer patients, in addition to facing fear, they have to endure the complications of the disease and the side effects of drugs, which have a negative impact on their HRQoL. Therefore, appropriate interventions should be provided to help them control disease and have a better HRQoL (Malathi et al., 2017). The results of a study conducted in 2016 showed the quality of life of colorectal cancer patients was impaired by the following factors: deficits in emotional and social functioning; physical-related restrictions such as fatigue, shortness of breath, insomnia, constipation, and diarrhea; and financial difficulties (Volker, Henrike, Christa, Hartwig, & Hermann, 2016).

Currently, many cancer treatments have been applied. However, depending on the condition of the patient, the doctor will give specific treatment regimens. Besides patients who use only one treatment, most cases have to combine two to three methods, i.e., surgery with chemotherapy or radiation therapy (National Cancer Institute, 2015).

Chemotherapy is one of the most popular and effective treatments for cancer patients. According to the ACS (2018a), chemotherapy (chemo) is explained simply as the use of strong drugs to treat cancer and people began to use this method in the 1950s. Before starting chemotherapy, patients receive information about the effects of the drugs including the benefits as well as the side effects. The main beneficial effects of chemotherapy in cancer treatment are to prevent or inhibit cancer cell growth, to kill cancer cells, and to reduce symptoms caused by cancer. On the other hand, chemotherapy also brings unwanted side effects to the lives of patients including nausea and vomiting, hair loss, bone marrow changes, mouth and skin changes, changes in sexual function, fertility problems, and memory changes. These unintended effects depend on many factors such as the type of cancer, where it occurs, stage, health status, type of medication, and dose prescribed for each patient (ACS, 2018a). During chemotherapy, HRQoL of patients and caregivers is greatly affected and interventions to improve their mental health are necessary (Ioannis et al., 2012). However, according to conclusions from other studies, the effects of the chemotherapy cycle can yield positive improvements in patients' HRQoL (Heydarnejad, Dehkordi, & Dehkordi, 2011). In other words, chemotherapy can reduce some of the tumor effects and also promote a patient's more positive attitudes toward the cancer treatment (Harminder, Kamalpreet, Raja, Shaminder, & Ritu, 2014).

Vietnam Context

University Medical Center (UMC) in Ho Chi Minh City is a public hospital established in 1994. After 25 years, UMC has built a reputation in the field of medical examination and health care. Every year, UMC receives more than two million

outpatients. The Chemotherapy Department (CD) was established and started to operate in 2016. Along with a team of experienced staff in the field of chemotherapy and cancer treatment, the CD is a prestigious cancer treatment facility for patients. Currently, the CD is an outpatient department with an increasing number of patients being treated with chemotherapy every year. In 2018, the total number of patients receiving treatment was 25,000. At the same time, the faculty also coordinated with other clinical departments in the diagnosis and treatment of cancer, forming a framework for cancer treatment in the spirit of multi-modal treatment. However, in the process of care and treatment, clinicians often paid more attention to symptoms and clinical and subclinical indicators but were less concerned about the nutritional, psychological, operability, and chemotherapy impacts on the QoL of cancer patients. Therefore, ensuring the QoL of cancer patients needs to be paid more attention. Additionally, understanding and assessing the HRQoL of cancer patients is necessary because cancer patients are often anxious about chemotherapy and how it will affect their appearance, digestive system, ability to live, current work, and social relationships. Related issues for cancer patient's HRQoL have not been clarified and have not received needed attention. For that reason, this study was conducted to examine the HRQoL among CRC patients during first stage chemotherapy and related factors.

Purpose of Study

This study had the general objective of surveying QoL and related factors affecting colorectal cancer patients participating in cancer chemotherapy at UMC. The study also had the following specific objectives: determining the demographic and

clinical characteristics of CRC patients and determining HRQoL and related factors affecting CRC patients receiving chemotherapy.

Theoretical Framework

In the nursing discipline, mid-range theories not only play a guiding role but also link research and clinical practice. In 1995, the middle-range theory of unpleasant symptoms (TOUS) was developed to understand the experience of symptoms in different contexts and multidimensional factors contributing to each symptom (Lenz, Suppe, Gift, Pugh, & Milligan, 1995). In 1997, an updated version of TOUS was published that integrated existing knowledge of a range of symptoms and found similarities between symptoms to guide research through those similarities (Lenz, Pugh, Milligan, Gift, & Suppe, 1997). In terms of content, TOUS describes the relationship between three main components: symptoms patients are experiencing, influencing factors affecting the experience of symptoms, and performance outcome or effects of symptoms on patients' daily living activities (Lenz et al., 1997).

Symptoms, the starting point of the theory, represent a change in normal, healthy functioning for an individual. For the purpose of this theory, they are realistic and subjective feelings of the patient specifically measured through four characteristics: duration, intensity, quality, and distress. Duration is defined as the time when symptoms occur or the frequency of symptoms. Intensity describes the severity of symptoms. Meanwhile, quality is understood as the patient's personal feeling about symptoms that are occurring. Finally, distress is interpreted as the impact of symptoms on the patient's daily life (Lee, Vincent, & Finnegan, 2017). Although there are patients who experience the same symptoms, each person will interpret these four characteristics differently

according to their feelings and tolerance levels. On the other hand, based on the description of the theory, symptoms often occur at the same time in clusters instead of separately and independently (Lenz et al., 1997).

The following influencing factors were the second component mentioned in the TOUS content: physiologic, psychologic, and situational. Physiologic factors include anatomical, physiological abnormalities or physical impairment, or other genetic and disease-related factors. Psychologic factors include the individual mental state of the patient or how they react to the disease. Lastly, situational factors related to the surrounding environment could affect symptom experiences including physical and social environments (Lenz & Pugh, 2014).

Performance outcome is the last component in the TOUS, which is simply defined as the result of symptoms' experiences. In other words, performance outcome is the level to which symptoms have affected the patient's ability to physically, cognitively, and socially in everyday life (Lee et al., 2017). Figure 1 illustrates the original middle-range theory of unpleasant symptoms and Figure 2 presents an updated version of the middle-range theory of unpleasant symptoms (Lenz et al., 1997).

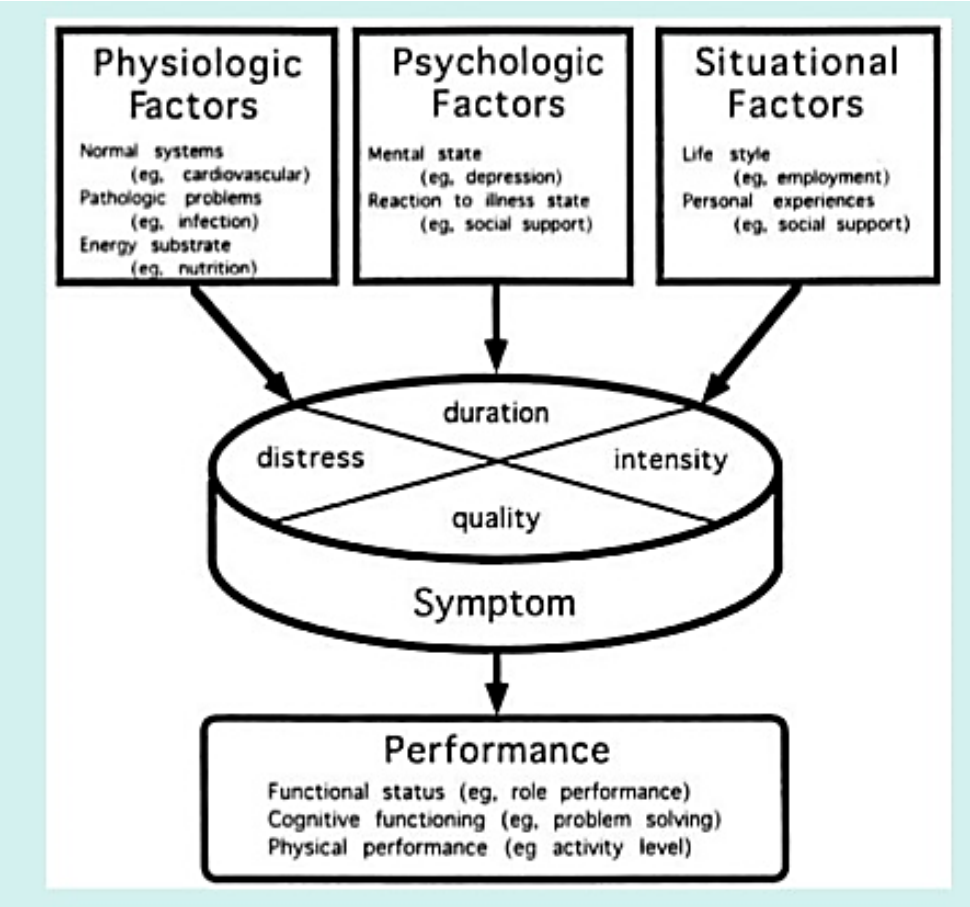

Figure 1. Original diagram of the middle-range theory of unpleasant symptoms (Lenz et al., 1997).

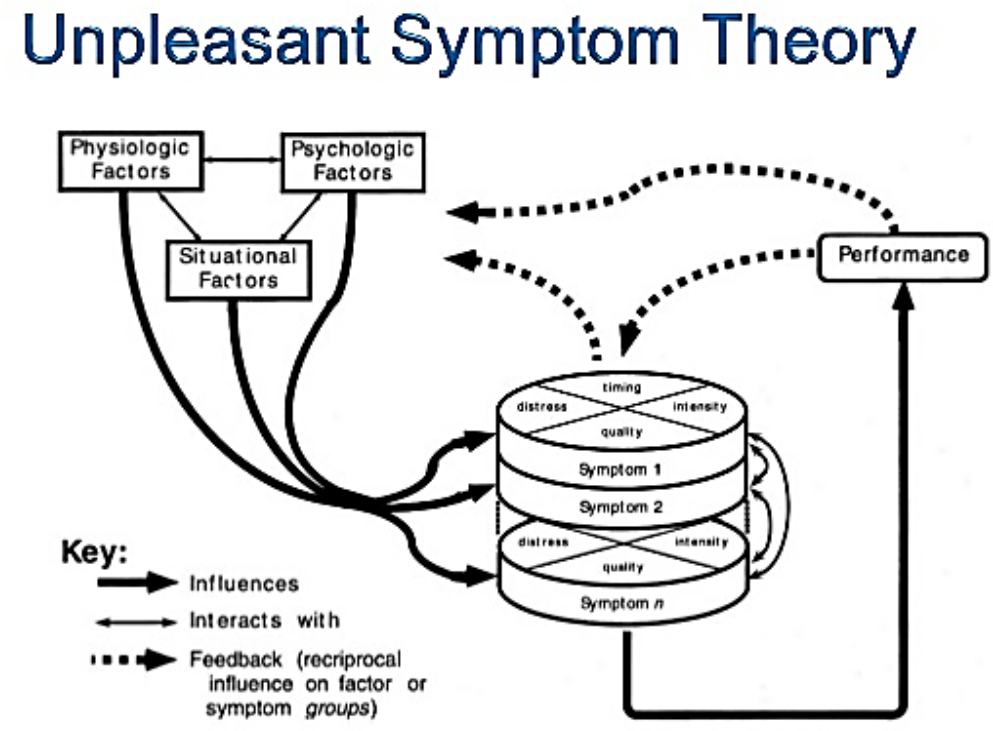

Figure 2. Updated version of the middle-range theory of unpleasant symptoms.

Assumptions

As mentioned, the CD receives and treats about 25,000 people every year. In the course of treatment, aspects related to HRQoL of patients such as nutrition, psychology, social relationships, etc., receive less attention. Although chemotherapy might be effective in preventing cancer cell growth, it would help if patients felt more comfortable by reducing symptoms of the disease. Therefore, the assumption of this paper was some aspects of HRQoL related to symptoms of the disease would be improved while other aspects of HRQoL related to the side effects of chemotherapy drugs would be reduced.

CHAPTER II

LITERATURE REVIEW

Colorectal Cancer

Colorectal cancer ranks fourth in the top five most common cancers and the second most deadly cancer in the world. On the other hand, many studies have demonstrated that CRC-induced symptoms and side effects during CRC treatment reduce patients' HRQoL. Therefore, it was necessary to evaluate QoL for CRC patients throughout the process. This study was conducted to investigate QoL of CRC patients during chemotherapy. To get an overview of the QoL situation of CRC patients, many research documents were synthesized, analyzed, and evaluated. Using the keywords quality of life, colorectal patient, and chemotherapy for searching reliable databases such as Medline, PsychInfo, Cumulative Index Nursing Allied Health Literature (CINAHL), and Researchgate, a literature review was conducted to understand existing knowledge and gaps in QoL management of CRC patients.

In 2017, a systematic review was conducted by Cabilan and Hines to understand the effects of CRC treatment on physical activity, functional status, and QoL. Regarding the method of searching documents, articles and studies searched on databases—CINAHL, Embase, MEDLINE, OpenGrey and ProQuest—were those written in English, and had been implemented since February 2015 until the time of conducting the search. As a result, 23 studies met the criteria and were reviewed in terms of relevance, validity, and methodological quality. These studies used the QLQ-C30 questionnaire of the

European Organization for Research and Treatment of Cancer (EORTC, 1995) to synthesize data. The results of the literature review showed the physical and functional status of patients with CRC tended to decrease after six months of treatment. However, after one year of treatment in terms of QoL, the score returned to the baseline level. In the conclusion, Cabilan and Hines commented on the implications for practice and research. In terms of the implications for practice, it would be necessary to have appropriate interventions to improve the physical capacity and functional status of CRC patients. When considering the implications for research, the reviewers paid attention to the consistency of the results between studies. In addition, they also suggested a separate analysis between colon cancer patients and rectal cancer patients, ostomates, and non-ostomates patients (Cabilan & Hines, 2017).

Dunn et al. (2003) conducted a systematic review to describe the general knowledge about QoL of CRC patients, reviewed what improvements had been made, and identified gaps in the Australian system. By looking for materials on reliable databases such as Medline, PsychInfo, CINAHL and Sociological Abstracts, the authors reviewed a total of 41 articles. In the articles, three main aspects related to QoL of patients with CRC were synthesized from the review: QoL definition and measurement, QoL prediction, and the relationship between QoL and survival. However, the results of these studies were not consistent, which might have been due to small sample sizes and limitations in research methods. Specifically, the concepts related to QoL in these studies were not similar because QoL is a complex, subjective, and difficult concept to quantify. Discussing the method of evaluation of QoL, many tools were available for evaluation. However, some questionnaires were used for a variety of diseases while others were used

for specific diseases. Therefore, the use of different tools in these studies made it difficult to compare results. Additionally, not all widely used tools met validity and reliability requirements as they were still being revised and updated. On the other hand, it was difficult to compare and summarize the content related to the factors identified as predictors or correlation of quality of life in patients with CRC, i.e., demographic characteristics and illness, time since diagnosis, social support, and physical activity. Reason included a limitation in the methodology of the studies and no theoretical basis for modeling the predictors of quality. Finally, there was little evidence to show a relationship between QoL and survival (Dunn et al., 2003).

Studies Using the Quality of Life C30 Questionnaire

In 2015, Teker, Kemal, and Yucel conducted a study in Turkey with the aim of understanding the QoL of CRC patients during chemotherapy. The authors presented three main objectives of the study: evaluate QoL of CRC patients during chemotherapy, describe the relevant factors, and assess the relationship between QoL and different chemotherapy regimens. This study was performed at the chemotherapy departments of two hospitals with the following sampling criteria: CRC at any stage, Eastern Cooperative Oncology Group (ECOG) performance status 0-2, age 18 years or older, and received chemotherapy for at least three months. There were 101 selected study participants who were instructed to answer the EORTC (1995) QLQ-C30 questionnaire. Based on the tool description in the article, the EORTC QLQ-C30 has a total of 30 questions corresponding to three scales: global health status, functional, and symptom scales. Therefore, the research results were analyzed and discussed mainly based on those scales. According to statistical data analysis, demographic characteristics such as

education, income, age, and type of chemotherapy affected the global health status scale while other characteristics did not. Additionally, age also affected functional status ($p < .05$). On the other hand, palliative chemotherapy affected the perception of appetite and nausea/vomiting so it had a negative impact on symptom scales by reducing the score of this scale ($p < .05$). Finally, the authors concluded QoL might be affected by some demographic characteristics and different chemotherapy regimens (Teker et al., 2015).

Another study conducted by Lee et al. in 2016 also explored QoL of cancer patients and used the EORTC (1995) QLQ-C30 questionnaire to understand the changes related to QoL of patients with colon cancer during chemotherapy treatment in Korea. In the preamble of the study, the authors mentioned the development in oncology surgery and chemotherapy helped to increase the survival rate of colon cancer patients. Specifically, chemotherapy drugs reduced tumor growth and prevented metastasis. However, the side effects of the drugs might affect the patient's QoL so QoL evaluation was necessary. Discussing the methodology, 56 post-operative patients who were being treated with chemotherapy at Chungbuk National University Hospital were invited to participate in the study. In the study, the EORTC QLQ-C30 questionnaire was used to collect data. Survey results demonstrated the two most adverse side effects for patients were nausea and peripheral neuropathy. Specifically, 71.4% of patients were reported to have nausea and 55.4% of patients had signs of peripheral neuropathy. In addition, one patient had to end chemotherapy after 11 cycles due to severe effects on peripheral neuropathy and another patient manifested an allergy shortly after the infusion. The results of the study also analyzed some of the QoL-related factors and noted that age specifically had a significant impact on the global health scale ($p = .004$), weight gain had

a significant impact on the symptom scale (P = 0.033), peripheral neuropathy also significantly affected symptoms (p = .042), and delayed chemotherapy had a significant effect on the functional scale (p = .041). However, in the conclusions, the authors reported the study had shown no significant difference in changing QoL during chemotherapy. Healthcare workers need to have proper awareness regarding reassurance and health education for the patient (Lee et al., 2016).

For the purpose of evaluating QoL of CRC patients during complex treatment, a study was conducted on 30 patients diagnosed with CRC at the University Hospital in Trnava, Slovakia (Martina, Miroslav, & Lubica, 2017). Although with the same purpose as other studies, this one used a combination of two EORTC (1995) questionnaires: EORTC QLQ-C30 and QLQ-CR29 (EORTC, 2006). A unique aspect of this study was the authors analyzed the data within various categories such as type of cancer, demographic, and treatment characteristics. Martina et al. (2017) concluded there was a correlation between QoL and type of treatment. Specifically, in this study, neoadjuvant chemoradiotherapy and stoma formation had a more negative impact than radical resection with adjuvant chemotherapy (Martina et al., 2017).

Through the review and analysis of previous studies related to QoL of CRC patients, it could be seen the EORTC (1995) QLQ-C30 questionnaire had been applied in many studies. In addition, the EORTC (2006) QLQ-CR29 has also been applied in some studies in recent times. Therefore, further description of these two questionnaires is needed. First, both questionnaires were developed by the EORTC (1995, 2006). The QLQ-C30 could be considered the first questionnaire of the EORTC (1995) built to assess cancer patients' QoL. The reliability of the QLQ-C30 has been established as

evidenced by the use of QLQ-C30 in many studies with more than 100 translated versions in many languages including the Vietnamese version. In addition to the QLQ-C30, the EORTC has also developed additional questionnaires to assess patients' QoL with different types of cancer including the QLQ-CR38 (Sprangers, Velde, & Aaronson, 1999), which is used to assess QoL of CRC patients. In the 1990s, QLQ-CR38 was translated into many languages and applied in many studies worldwide. However, during this period, many new methods of cancer treatment were developed including radiotherapy, new chemotherapy, etc. and they have had a clear effect on reducing symptoms caused by cancer. Therefore, some questions in QLQ-CR38 relating to the symptoms of cancer and the side effects of current treatments are no longer appropriate. In addition, the QLQ-CR38 was not only judged to be lacking in detail and complexity but was also accused of being tested only in the Netherlands and not internationally.

Therefore, in 2006, the EORTC released an updated version of QLQ-CR38—the QLQ-CR29. This updated process had a total of four phases. Specifically, in Phase II, a temporary module was developed and conducted on 79 CRC patients (from the United Kingdom, Germany and France) and 11 healthcare professionals (specialists, nurses, surgeon, and oncologist). After Phase II, 15 items were removed due to duplication (seven items) or low relevance (eight items). After Phases I and II, 29 items were synthesized into the QLQ-CR29 and pre-tested on 120 patients in France and Germany during Phase III. Finally, in Phase IV, the QLQ-CR29 proceeded to international field testing for reliability, clinical, and psychometric validity. Specifically, the QLQ-CR29 was tested on 120 CRC patients in Germany and France. Test results showed patients could understand and accept the questionnaire content. In addition, according to the

comments suggested after the testing, the items for patients with and without stoma had been separated while still making sure the items were the same for both groups (Gujral et al., 2007). Additionally, in 2009, Whistance et al. examined the clinical and psychometric validity and reliability of the EORTC's (2006) QLQ-R29 questionnaire in a study involving 351 CRC patients of seven different countries (United Kingdom, France, Taiwan, Italy, Germany, Spain, and the United States). The study found correlations between the EORTC's (1995) QLQ-C30 and the QLQ-CR29 were below the coefficient of 0.40 for all scales, demonstrating the core questionnaire and supplementary module did not overlap in topics (Whistance et al., 2009). In general, QoL problems of CRC patients were of interest and have been studied by many researchers. Currently, the tool has been widely used in the evaluation of QoL of CRC patients and shown to be highly reliable.

In Chapter I, the researcher summarized the content of the theory and physiologic, psychologic, and situational factors affecting cancer patients. This chapter provided a literature review that clearly related these factors in other studies. In addition, the QLQ-C30 questionnaire was evaluated according to sociodemographic factors and clinical characteristics consistent with the theory framework.

CHAPTER III

METHOD

Research Design and Sample

The aim of this study was to evaluate factors related to HRQoL of CRC patients undergoing chemotherapy. To achieve this goal, the study used descriptive cross-sectional methods. A convenience sampling method was applied and based on a statistical list of patients who had been diagnosed with CRC and were participating in chemotherapy at the UMC's Chemotherapy Department. In addition, study participants were selected according to the following criteria:

- CRC patients were receiving chemotherapy at UMC's Chemotherapy department.
- The patient agreed to participate in the study after hearing the explanation of the study's purpose.
- The patient had the ability to perceive and read Vietnamese.
- The patient was healthy enough to participate.
- The patient had no mental illness.

Exclusion criteria in the sample collection process resulted in the removal of the following participants:

- The patient stopped participating in the study;
- The patient was having health concerns and refused participation.
- The patient did not follow the instructions in the survey questionnaire;

- The patient was incapable of understanding or unable to answer (old, hearing impaired, or suffering from mental illnesses).

For patients who met the sampling criteria, the researcher explained the purpose of the study, how to participate in the study, and the benefits/risks involved in the study. If the patient agreed after the explanation, the patient signed the Vietnamese version of the University of Northern Colorado's (UNC) informed consent form (see Appendix A). After that, the patient answered the questions in the survey before joining chemotherapy during the day (see Appendix B). The purpose of the timing of the survey was to reduce the impact of answering questions because patients treated after chemotherapy are often tired of the side effects of the drugs. While the patient answered the questionnaire, the researcher was next to the patient to answer any questions.

In this study, the sample size was expected to be 60 patients. According to 2018 statistics, the Chemotherapy Department had about 630 colon cancer patients and 350 rectal cancer patients participating in chemotherapy. With the cancer treatment regimen, they undergo six to eight phases; each phase is two to three weeks apart with clinical tests to ensure eligibility for chemotherapy. In six months of 2019, the number of patients with colorectal cancer participating in chemotherapy increased on average 10-12 people per day. Therefore, during a relatively short time period, this study enrolled a sample of 60 people.

To conduct the survey, the questionnaire in this study was the EORTC's (1995) QLQ-C30. In particular, the QLQ-C30 was developed to assess the quality of life of cancer patients. It has been translated and validated into more than 100 languages including Vietnamese and is used every year in more than 5,000 studies worldwide. The

completed questionnaire in this study had a total of 30 questions, which was tested by at least two experts before the patient was tested and was adjusted to ensure the relevance to the research subjects (if any). The questionnaire in Vietnamese was printed on paper and distributed to participants.

Ethical Considerations

Regarding medical ethics, this study was conducted with the approval of UNC's Institutional Review Board (see Appendix C) and the Scientific Council of UMC where the study was conducted (see Appendix D). Additionally, the researcher explained that participation was voluntary and refusal to participate in the research would not affect the quality of treatment and care of participants. Furthermore, the information provided by the patient was for research purposes only and would be kept completely confidential. Information requested by the questionnaire was not offensive and did not affect the patient mentally or physically.

Data Analysis

Data were entered and processed by SPSS software 20.0 and presented by frequency, percentage (quantitative variable), and average value ± standard deviation. Data analysis involved descriptive statistics related to the variables. In addition, Cronbach's alpha was determined for the instrument. The *p* value of .05 was set for statistical significance. Researchers must ensure the clarity and accuracy in the information and instructions for answering questions for study participants. Incomplete survey forms regarding study variables were removed and not used.

This chapter presented important steps to carry out a study. Sections included the research design, criteria of sample, population, instrument, collection, research ethics, and analysis of the data.

CHAPTER IV

RESULTS

Introduction

To answer the research questions, responses to the EORTC (1995) QLQC30 were analyzed. The demographic and clinical characteristics of the participants were described and related to the TOUS (Lenz et al., 1997) theory of the patient's experience of symptoms. Results of the QLQC30 questionnaire are presented as the mean value of the global health status, functional scales, social function, the cognitive function, financial difficulties, and symptom scales. Data were collected from August 18 to 29, 2019 and 60 consecutive patients with CRC undergoing chemotherapy were included. All patients were diagnosed and treated at University Medical Center.

Patient Characteristics

The mean age among patients was 57.38±11.07 (see Table 1); the maximal age was 82-years-old and the minimal age was 32-years-old (see Figure 3). The mean age for males was higher than the female mean age but no significant difference was found (58.38 and 55.78, respectively; $p = .382 > .05$).

Table 1

Mean Age Among Patients

Gender	Minimal Age	Maximal Age	*M* ± *SD*	*p*-value
Male	32	82	58.38±10.88	$p = 0.382$
Female	36	71	55.78±11.41	
Total	32	82	57.38±11.07	

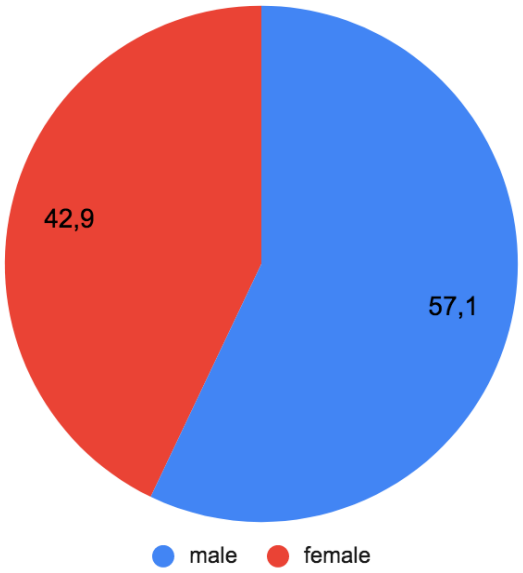

Figure 3. Gender distribution.

Other baseline characteristics among the research subjects included education level and insurance status (see Table 2). Forty percent of research participants had

completed high school; 23.3% had attended college or university, and 36.7% had only a primary-secondary school education. All patients interviewed had health insurance.

Table 2

Background Characteristics Among the Subjects

Characteristics	*n*	%
Level of Education		
Primary-Secondary School	22	36.7
High School	24	40.0
College/University	14	23.3
Health Insurance		
Yes	60	100
No	0	0

N = 60

Clinical Characteristics

The clinical characteristics of patients are shown in Table 3. More than half of the patients (75%) had colon cancer and the remaining (25%) had rectal cancer. The majority of the patients (83.3%) were receiving Xelox protocol and the remaining patients were receiving Xeliri and others (11.7% and 5%, respectively). Almost all patients (16.7%) had undergone Phase 4 and Phase 5 of therapeutic processes. The prevalence of ostomates and non-ostomates patients was 21.7% and 78.3%, respectively.

Table 3

Clinical Data for Study Subjects

Characteristics	*n*	%
Diagnosis		
Colon cancer	45	75.0
Rectal cancer	15	25.0
Protocol		
Xelox	50	83.3
Xeliri	7	11.7
Others	3	5.0
Phase		
1	3	5.0
2	9	15.0
3	8	13.3
4	10	16.7
5	10	16.7
6	3	5.0
7	8	13.3
8	4	6.7
>8	5	8.3
Stoma		
Yes	13	21.7
No	47	78.3

N = 60

Results of the Quality of Life Questionnaire

The mean value of the global health status/QoL was 69.17±19.90 points standard deviations (SD). Within the functional scales, social function (SF) was rated lowest with a mean score of 80.83±22.51 points, whereas the cognitive function (CF) was rated highest with a mean of 88.06±14.09 points. Reported financial difficulties (FI) had a mean value of 30.0±28.59 points; the lowest was diarrhea with a mean value of 10.56±17.88 points. Figure 4 presents a visual representation of the survey results.

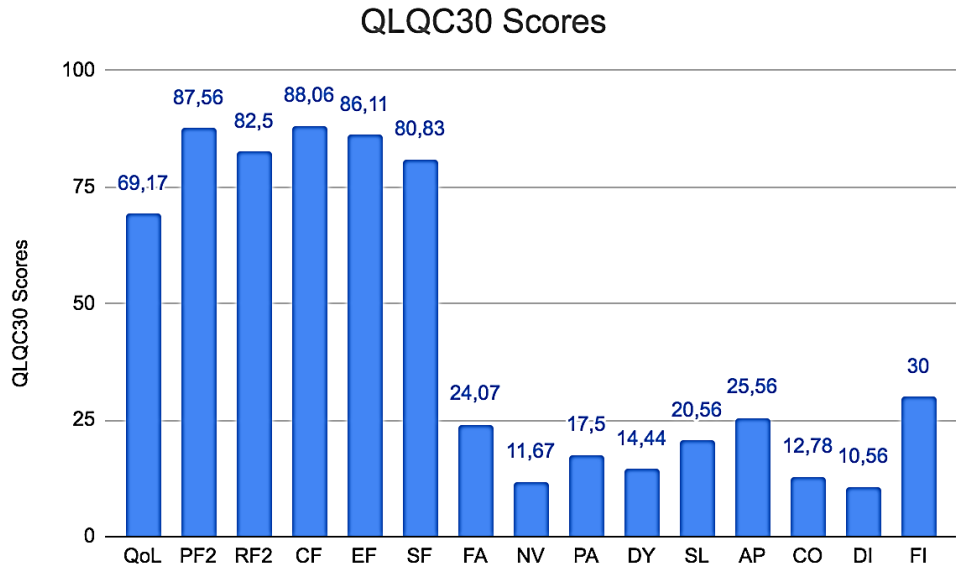

Figure 4. Results of the survey (European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire, version 3.0). Indicated values are the mean of all pooled patients (*N* = 60). QoL: quality of life, PF2: physical functioning, RF2: role functioning, EF2: emotional functioning, CF2: cognitive functioning, SF2: social functioning, FA: fatigue, NV: nausea and vomiting, PA: pain, DY: dyspnea, SL: insomnia, AP: appetite loss, CO: constipation, DI: diarrhea, FI: financial difficulties.

Quality of Life in Colorectal Cancer Patients

The patients were evaluated according to age and were divided into two groups (<60 years and >60 years). The age of 60 was used as cut off according to the WHO's (2020) definition of an older person (see Table 4). There was no significant difference in global health status and functional scales by age (67 and 75, respectively; $p = .516$) but financial difficulties were lower in older than in younger patients (20 and 40, respectively; $p < .05$).

Table 4

Quality of Life Survey Scores by Age Groups

Global Health Status	Age < 60 years	Age 60+ years	*p*-value
QoL (*M*±*SD*) Median (Q1/Q3)	67.24±21.35 66.67 (62.5/83.3)	70.97±18.62 75.0 (66.67/83.33)	0.516
	Functional Scales		
Physical functioning (PF2)	88.74±13.81 93.33 (80.00/100)	86.45±12.94 86.67 (80.0/100)	0.415
Role functioning (RF2)	81.03±20.28 83.33 (66.67/100)	83.87±16.93 83.33 (66.67/100)	0.737
Cognitive functioning (CF)	86.21±11.84 83.33 (83.33/100)	89.78±15.91 100.00 (83.33/100)	0.089
Emotional functioning (EF)	83.62±16.74 91.67 (66.67/100)	88.44±17.57 91.67 (83.33/100)	0.175
Social functioning (SF)	80.46±21.40 83.33 (66.67/100)	81.18±23.86 83.33 (66.67/100)	0.734
	Symptom Scales/Items		
Fatigue (FA)	25.29±22.20 22.22 (5.56/38.89)	22.94±17.67 22.22 (11.11/33.33)	0.780
Nausea and vomiting (NV)	13.22±24.14 0 (0/16.67)	10.22±16.49 0 (0/16.67)	0.937
Pain (PA)	18.97±19.27 16.67n(0/33.33)	16.13±22.15 0 (0/33.33)	0.315
Dyspnea (DY)	18.39±26.10 0 (0/33.33)	10.75±21.75 0 (0/0)	0.156
Insomnia (SL)	14.94±26.10 0 (0/33.33)	25.81±25.40 33.33 (0/33.33)	0.051
Appetite loss (AP)	24.14±29.41 33.33 (0/33.33)	26.88±29.08 33.33(0/33.33)	0.659
Constipation (CO)	8.05±17.03 0 (0/0)	17.20±22.56 0 (0/33.33)	0.075
Diarrhea (DI)	8.05±17.03 0 (0/0)	12.90±18.61 0 (0/33.33)	0.227
Financial difficulties (FI)	40.23±25.79 33.33(33.33/66.67)	20.430±28.12 0 (0/33.33)	0.003*

*Mann Whitney test

The mean score for global health status among males was significantly high compared to females (73.65 and 61.96, respectively; $p < .05$). In contrast, the mean scores for nausea and vomiting (NV) and constipation (CO) in male patients were lower than for females (7.66 and 18.12, respectively; 9.01 and 18.84, respectively) with $p < .05$. There was no significant difference in functional and other symptom scales (see Table 5).

Patients were also divided into groups according to the level of education. The results showed no difference in global health status but there were some differences in the functional and symptom scales (see Table 6). For instance, lower scores were obtained from primary-secondary level patients with respect to role functioning (RF2), emotional functioning (EF), and social functioning (SF) than from higher education groups ($p < .05$). The fatigue (FA) and financial difficulties (FI) scores were worse in the lower educational level group than in the others ($p < .05$).

Patients who were receiving different protocols (Xelox, Xeliri, or Others) were compared on QoL functional and symptom scores. Table 7 depicts the results of this analysis. No statistical difference was found in scores among the patients who were experiencing different protocols ($p > .05$).

Finally, with respect to the comparison between ostomates ($n = 13$) and non-ostomates patients ($n = 47$), there was no significant difference in global health status and functional scales (see Table 8). However, for the symptom scales, the NV was worse in the non-ostomates patient group than in the ostomates patient group ($p < .05$).

Table 5

Association Between Quality of Life Survey Scores and Gender

Global Health Status	Male	Female	*p*-value
QoL (*M*+-*SD*) Median (Q1/Q3)	73.65±20.08 83.33 (66.67/83.33)	61.96±17.74 66.67 (50.0/75.0)	0.004*
	Functional Scales		
Physical functioning (PF2)	88.47±13.67 93.33 (80.0/100)	86.09±12.86 86.67 (80.0/100)	0.372
Role functioning (RF2)	82.88±19.84 83.33 (66.67/100)	81.88±16.6 83.33 (66.67/100)	0.613
Cognitive functioning (CF)	90.09±13.87 100 (83.33/100)	84.78±14.14 83.33 (83.33/100)	0.095
Emotional functioning (EF)	88.06±16.14 91.67 (83.33/100)	82.97±18.72 91.67 (66.67/100)	0.223
Social functioning (SF)	81.08±21.58 83.33 (66.67/100)	80.43±24.44 83.33 (66.67/100)	0.981
	Symptom Scales/Items		
Fatigue (FA)	21.62±20.45 83.33 (66.67/100)	28.02±18.61 22.22 (11.11/44.44)	0.163
Nausea and vomiting (NV)	7.66±18.67 0 (0/8.33)	18.12±21.85 16.67 (0/33.33)	0.019*
Pain (PA)	17.57±21.14 16.67 (0/33.33)	17.39±20.4 16.67 (0/33.33)	0.942
Dyspnea (DY)	9.91±19.03 0 (0/16.67)	21.74±29.49 0 (0/33.33)	0.093
Insomnia (SL)	18.02±24.34 0 (0/33.33)	24.64±28.81 0 (0/66.67)	0.416
Appetite loss (AP)	22.52±28.39 0 (0/33.33)	30.43±30.01 33.33 (0/66.67)	0.267
Constipation (CO)	9.01±18.67 0 (0/0)	18.84±22.08 0 (0/33.33)	0.043*
Diarrhea (DI)	9.01±16.94 0 (0/16.67)	13.04±19.43 0 (0/33.33)	0.384
Financial difficulties (FI)	27.93±29.93 33.33 (0/33.33)	33.33±26.59 33.33 (0/66.67)	0.357

*Mann Whitney test

Table 6

Quality of Life Survey Scores Distributed by Educational Levels

Global Health Status	Primary-Secondary School	High School	Colleges/ University	*p*-value
QoL (*M*+-*SD*)	61.90±18.98	70.83±19.35	71.97±20.82	0.155
		Functional Scales		
Physical functioning (PF2)	86.19±11.54	88.61±15.66	87.27±11.98	0.462
Role functioning (RF2)	67.86±17.86	83.33±17.72	90.91±14.30	0.001
Cognitive functioning (CF)	83.33±13.07	87.50±14.12	91.67±14.32	0.080
Emotional functioning (EF)	76.19±18.16	87.50±16.11	90.91±15.83	0.017
Social functioning (SF)	69.05±19.46	81.94±20.21	87.12±24.63	0.013
		Symptom Scales/Items		
Fatigue (FA)	35.71±19.58	21.76±19.79	19.19±17.877	0.040
Nausea and vomiting (NV)	14.29±21.54	14.58±25.69	6.82±11.10	0.662
Pain (PA)	23.81±21.40	15.28±21.38	15.91±19.57	0.276
Dyspnea (DY)	26.19±35.03	13.89±19.45	7.58±17.61	0.164
Insomnia (SL)	21.43±24.83	20.83±29.18	19.70±24.47	0.952
Appetite loss (AP)	30.95±35.72	27.78±30.56	19.70±22.20	0.667
Constipation (CO)	21.43±24.83	9.72±18.33	10.61±18.93	0.211
Diarrhea (DI)	16.67±25.32	9.72±15.48	7.58±14.30	0.569
Financial difficulties (FI)	47.62±31.25	27.78±27.22	21.21±24.22	0.031

*Kruskal-Wallis test

Table 7

Association Between Quality of Life Survey Scores and Protocols

Global Health Status	Xelox	Xeliri	Others	*p*-value
QoL (*M*+-*SD*)	68.50±21.12	72.62±10.45	72.22±19.25	0.936
		Functional Scales		
Physical functioning (PF2)	88.93±10.83	81.90±23.64	77.78±19.25	0.560
Role functioning (RF2)	82.33±17.63	76.19±25.2	100±0.0	0.161
Cognitive functioning (CF)	88.67±13.65	85.71±11.50	83.33±28.87	0.708
Emotional functioning (EF)	86.50±16.95	83.33±20.97	86.11±17.35	0.992
Social functioning (SF)	80.00±23.57	83.33±16.667	88.89±19.25	0811
		Symptom Scales/Items		
Fatigue (FA)	24.00±18.83	28.57±28.59	14.81±16.97	0.715
Nausea and vomiting (NV)	10.00±17.17	28.57±35.64	0.0±0.0	0.118
Pain (PA)	16.67±20.20	19.05±24.40	27.78±25.46	0.655
Dyspnea (DY)	15.33±24.48	14.29±26.23	0.0±0.0	0.488
Insomnia (SL)	20.00±24.28	28.57±40.50	11.11±19.25	0.820
Appetite loss (AP)	24.67±28.42	33.33±38.49	22.22±19.25	0.875
Constipation (CO)	12.67±20.08	9.52±16.27	22.22±38.49	0.900
Diarrhea (DI)	11.33±18.58	4.76±12.60	11.11±19.25	0.668
Financial difficulties (FI)	28.67±29.36	38.10±23.00	33.33±33.33	0.578

*Kruskal-Wallis test

Table 8

Quality of Life Survey Scores in Ostomate and Non-Ostomate Patients

Global Health Status	Ostomates Patients	Non-Ostomates Patients	*p*-value
QoL (*M*+-*SD*)	73.08±25.04	68.09±18.42	0.122
	Functional Scales		
Physical functioning (PF2)	87.18±11.37	87.66±13.90	0.657
Role functioning (RF2)	82.05±24.019	82.62±17.01	0.762
Cognitive functioning (CF)	88.46±14.25	87.94±14.20	0.930
Emotional functioning (EF)	89.74±13.24	85.11±18.14	0.395
Social functioning (SF)	82.05±18.59	80.50±23.65	0.992
	Symptom Scales/Items		
Fatigue (FA)	22.22±14.34	24.59±21.23	0.949
Nausea and vomiting (NV)	2.56±9.25	14.18±21.97	0.028
Pain (PA)	16.67±19.25	17.73±21.25	0.962
Dyspnea (DY)	7.69±14.618	16.31±25.89	0.352
Insomnia (SL)	10.26±16.01	23.40±27.73	0.141
Appetite loss (AP)	15.38±22.01	28.37±0.28	0.168
Constipation (CO)	7.69±19.97	14.18±20.55	0.202
Diarrhea (DI)	5.13±12.52	12.06±18.94	0.230
Financial difficulties (FI)	28.21±26.69	30.50±29.35	0.879

*Mann Whitney test

In summary, Chapter IV provided the results of a detailed analysis of the quality of life of colorectal cancer patients participating in this study. The results of the EORTC (1995) QLQC30 questionnaire were presented as the means of all pooled patients: quality of life, physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning, fatigue, nausea and vomiting, pain, dyspnea, insomnia,

appetite loss, constipation, diarrhea, and financial aspects. The results of the analysis indicated significant differences in several areas of QoL in colorectal cancer patients, which are discussed more specifically in Chapter V.

CHAPTER V

DISCUSSION

Introduction

Although gastrointestinal tumors represent a major healthcare problem worldwide, data for the QoL for patients suffering from this kind of cancer are rare, especially data deriving from routine clinical practice (Benoist, Tournigand, Andre, & de Gramont, 2011). According to Testa and Simonson (1996), QoL has become more important in healthcare practice and clinical research. Despite the importance of QoL evaluations, standardized methods have not applied in most oncology centers in Vietnam. Traditionally, the effect of treatment has been evaluated by the frequency or intensity of a given symptom measured by physicians. In this study, a single, well-established and reliable assessment tool--the EORTC (1995) QLQ-C30 (version 3)—was used instead of several different specific questionnaires for patients to describe quality of life of CRC patients being treated at UMC's oncology center in Vietnam.

General Characteristics

In general, for the colorectal cancer patients at UMC, the mean value of the global health status/QoL was 69.17 ± 19.90 points. Within the functional scales, social function was rated lowest with a mean score of 80.83 ± 22.51 points, whereas the cognitive function was rated highest with a mean of 88.06 ± 14.09 points. The most notable symptom was financial difficulties with a mean value of 30.0 ± 28.59 points and the lowest was diarrhea with a mean value of 10.56 ± 17.88 points.

There were some differences in this study compared with the research results of Teker et al. (2015), which was a study conducted to assess the QoL in colorectal cancer patients during chemotherapy in the era of monoclonal antibody therapies at the Department of Medical Oncology in Samsun, Turkey. The mean value of the global health status was 56.0 ± 26.6 points compared with 69.17 in this study. Within the functional scales, physical function was rated lowest (versus social function in the current study) whereas the cognitive function was rated highest, which was similar to this study. The most distinctive symptom was fatigue and the lowest was dyspnea. These differences might have been due to differences in the subjects, place, and type of chemotherapy regimen.

Correlation of the Factors

In comparing QoL in colorectal cancer patients between elderly and younger patients, the two groups showed similar QoL in global health status and functional scales; however, elders reported better outcomes regarding financial difficulties. Care for the elderly, their needs for financial assistance, and health services are critical problems. In Vietnam, there is increasing financial support from the state health system for the elderly by providing more support for medical services for older people and their families. On July 1, 2010, Law number 39/2009/QH12 was adopted (Vietnam National Assembly, 2009); the law defines the rights and responsibilities of elderly people, responsibilities of institutions, organizations, families and individuals in relation to the elderly, as well as a foundation for the care and financial support of the elderly (Ngoc, Baryshevab, & Lyubov, 2016). The Ministry of Health plans to publish a circular "Standardization of Geriatric Departments at Hospitals" to meet the growing demand for protecting the health

of the elderly in accordance with Law No. 39/2009/QH12 (Vietnam National Assembly, 2009).

This study also indicated a variety of significant differences in the QoL in colorectal cancer patients by gender. The mean score of global health status for males was significantly higher than for females (73.65 and 61.96, respectively; $p < .05$). The mean scores for nausea and vomiting and constipation in male patients were significantly lower ($p < .05$) than for females (7.66 and 18.12, respectively; 9.01 and 18.84, respectively). A possible explanation of gender differences in QoL was women might exaggerate their health conditions more than men or women might have a higher rate of self-perceived health regarding general health and symptoms/signs, which might explain why women had a lower level QoL. Also, they are referred to physicians and health centers more than men. The symptoms and signs related to postmenopausal comorbidities in women might also partially explain the gender differences in HRQoL.

Although no relationship was demonstrated between education and QoL scores in several studies, a variation was observed in the current study at different levels of education. Role functioning, emotional functioning, and social functioning scores were higher in university graduate patients than in others. Fatigue and financial difficulties scores were found to be significantly lower (better and higher scores represented a greater degree of symptoms) than those of patients with lower educational levels. This might be because patients develop certain social and other skills and become more functional as their level of education rises. Fatigue, financial difficulties, and limitations in role functioning might be related to emotional problems.

In the current study, there was no difference among different chemotherapy protocols of CRC patients ($p > .05$), which meant different chemotherapy protocols did not negatively affect QoL (Wintner et al., 2013). Chemotherapy might have actually maintained the QoL. When deciding on further chemotherapy protocols, health professionals usually use the ECOG performance status and ask a few brief questions to understand the tolerability potential of the patient. Actually, applying a QoL questionnaire to every new patient would provide more detailed information about the patient.

This was the first reported study about the effects of different chemotherapy protocols on QoL in patients with CRC in Vietnam. Conditions affecting the QoL could be related to stoma (Teker et al., 2015). The nausea/vomiting scores were lower in ostomate patients than in others. Patients with a stoma were usually more aware of the effects of treatment and might use antiemetics more regularly.

Limitations

Convenience sampling at a single hospital in Vietnam limited the generalization of this study. The time collecting the sample was also short. Since some patients might have been experiencing adverse effects from their treatment, the concentration needed to answer the questionnaire might have reduced the accuracy of the results.

Recommendations

According to the results, the following recommendations are made related to improving the quality of life for CRC patients undergoing treatment:

1. For each stage of colorectal cancer, patients have different influencing factors. A mental health plan and health education are needed at every

stage. This is necessary to prepare them for the changes in their health condition. Patient knowledge would help them with self-care and to identify abnormal signs related to chemotherapy. Assessing this information would be helpful to medical staff to monitor the side effects of the drug. In addition, patients could learn to detect abnormal signs early and reduce those symptoms. Patients could control daily activities and work better when they understand their health status.

2. Nurses need to pay more attention to the mental and economic status of patients to reduce anxiety during treatment. The cost of treatment should be disclosed and explained before the patient participates in treatment. The cost of each protocol at each stage is different and patients are attempting to control their finances and prepare for the regimen. Health providers in Vietnam should encourage patients to use health insurance, especially government insurance that provides high benefits for a low cost.

Application of Theoretical Framework

In the theory of unpleasant symptoms, three categories of factors were identified as influencing the occurrence, intensity, timing, distress level, and quality of symptoms: physiologic, psychologic, and situational factors (Lenz et al., 1997). In the Vietnam context, this study drew a picture about real experiences and patient issues. The results showed colorectal cancer patients did not demonstrate differences in clinical characteristics among protocols of chemotherapy. The data analyzed 60 colorectal cancer patients to find the influence of factors utilizing the EORTC's (1995) QLQ-C30 tool. Factors such as economy, educational level, gender, and morale affect the quality of life

of patients. Young people have a lack of economic stability compared to older people. Women are more resistant to side effects of drugs. Patients with knowledge are better able to control symtoms. Using health insurance brings benefits and convenience during chemotherapy. Patients are more informed about hospital costs for protocols. Clinical characteristics when undergoing certain protocols have been improved. The quality of life of colorectal cancer patients is increased based on both small and necessary factors. Improved awareness of patients about ways to manage themselves and their symptoms helps them to feel more confident about their life.

Conclusion

The aim of this study was to discover factors that affect colorectal cancer patients, which could improve their quality of life. Research into the QoL of CRC patients was important in the world and in Vietnam. A review of literature related to studies of QoL for this patient population was documented and compared. In addition, the tool used to gather the data was the EORTC's (1995) QLQ-C30 questionnaire—a reliable and valid questionnaire that has been used in many studies. This study was based on the TOUS theoretical framework that dealt with patient experiences and included three factors: physiologic, psychologic, situational. The level of influence depended on the stage of the disease and the health status of each patient. The analysis showed most clinical symptoms did not vary significantly among the treatment regimens. The results also demonstrated the financial and emotional/mental factors of patients must be considered. Colorectal cancer patients in Vietnam are often concerned with clinical symptoms and social and mental needs; however, there has been little regard for these concerns. Vietnamese patients also do not understand the problems they experience during

chemotherapy because they have little knowledge of their treatment and disease characteristics and depend on the guidance of the physician and a nurse. Different patients experience different symptoms and problems. Therefore, they need a detailed care plan that is appropriate for each stage of cancer.

This study was conducted at the UMC Hospital, which is a modern hospital in Vietnam. Thus, there is a need to gather a larger sample in various settings to uncover many other aspects and factors that influence colorectal cancer patients. Research results could help nurses understand their patients as well as improve their quality of life. When care is more evidence based, colorectal cancer patients in Vietnam will also receive better care and attention.

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APPENDIX A

INFORMED CONSENT FOR PARTICIPATION IN HUMAN SUBJECTS RESEARCH IN ENGLISH AND VIETNAMESE

UNIVERSITY OF
NORTHERN COLORADO

INFORMED CONSENT FOR PARTICIPATION
IN HUMAN SUBJECTS RESEARCH

Project Title: Quality of life among colorectal cancer patients during chemotherapy
Student Researcher: Chau Than Minh
Research Advisor: Jeanette McNeill DrPH, RN, ANEF, CNE, School of nursing
Purpose: The purpose of this project is a survey the quality of life and related factors affecting the quality of life of colorectal cancer patients participating in cancer chemotherapy for the first time at UMC hospital
Objective: This project plans to

- Determining the relation between demographic clinical characteristics and the quality of life scores among colorectal cancer patients at Chemotherapy Department, UMC hospital;
- Determining the mean score of health-related quality of life and related factors among colorectal cancer patients with C30 questionnaire.

All responses will be kept confidential and anonymous. All questionnaires will be scanned into a password protected computer and then "shredded" (permanently destroyed). All study data and information will then be kept on a thumb drive in a locked drawer in a locked cabinet. There are no anticipated risks by participation in this survey. If you complete the survey, it will be assumed that you have communicated consent for your participation. You may keep this form for future reference.

If you agree to participate in this study you will be asked to complete the attached 30 question survey. It should take you 5-10 minutes to complete.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled.

Having read the above and having had an opportunity to ask any questions in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact the Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

Please give this informed consent and the completed questionnaire to the researcher (the one who gave you the form).

Committee Contact information:

Student Researcher: Chau Than Minh – MSN Student
Email: than0389@bears.unco.edu or chau.tm@umc.edu.vn

Research Advisor: Jeanette McNeill, DrPH, RN, ANEF, CNE
Professor, University of Northern Colorado, School of nursing, Greeley, CO
Email: jeanette.mcneill@unco.edu
Phone: 970-351-1704

UNIVERSITY OF
NORTHERN COLORADO

THÔNG TIN ĐỒNG Ý DÀNH CHO ĐỐI TƯỢNG THAM GIA NGHIÊN CỨU

Tên đề tài: Chất lượng cuộc sống của người bệnh ung thư đại trực tràng trong quá trình hoá trị liệu

Nghiên cứu sinh: Thân Minh Châu

Giảng viên hướng dẫn: Jeanette McNeill, Tiến sĩ Điều dưỡng, Đại học Northern Colorado

Mục đích: Mục đích của dự án này là khảo sát chất lượng cuộc sống và các yếu tố liên quan ảnh hưởng đến chất lượng cuộc sống của người bệnh ung thư đại trực tràng tham gia hóa trị ung thư lần đầu tiên tại bệnh viện Đại học Y Dược thành phố Hồ Chí Minh (UMC).
Mục tiêu:

- Xác định mối quan hệ giữa các đặc điểm lâm sàng nhân khẩu học và chất lượng cuộc sống giữa các người bệnh ung thư đại trực tràng tại Khoa Hóa trị ung thư, bệnh viện UMC;
- Xác định điểm trung bình của chất lượng cuộc sống liên quan đến sức khỏe và các yếu tố liên quan ở người bệnh ung thư đại trực tràng với bảng câu hỏi QLQ-C30.

Việc tham gia là tự nguyện. Bạn có thể quyết định không tham gia nghiên cứu này và nếu bạn bắt đầu tham gia, bạn vẫn có thể dừng và rời đi vào bất cứ thời điểm nào. Sự quyết định của bạn luôn được tôn trọng và không ảnh hưởng đến quyền lợi mà bạn đang có.
Vui lòng đọc và có thể hỏi bất kỳ câu hỏi nào.

Nếu bạn đồng ý tham gia nghiên cứu bạn sẽ trả lời 30 câu hỏi khảo sát. Thời gian hoàn thành khảo sát từ 5-10 phút.

Một bản sao của giấy này sẽ được gửi bạn giữ tham khảo cho tương lai. Nếu bạn có bất kỳ mối quan tâm cho việc chọn lựa hay điều trị như một người tham gia nghiên cứu, vui lòng liên hệ Cơ Quan Nghiên Cứu, Kepner Hall, Trường Đại Học Northern Colorado Greeley, CO 80639; 970-351-1910.

Vui lòng cho thông tin đồng ý này và hoàn thành bảng câu hỏi nghiên cứu (người đưa bạn mẫu thông tin này)

Thông tin liên lạc của hội đồng:
Nghiên cứu sinh: Thân Minh Châu, Sinh viên lớp Thạc sĩ Điều dưỡng
Email: than0389@bears.unco.edu hoặc chau.tm@umc.edu.vn

Cố vấn nghiên cứu: Jeanett McNeill, Tiến sĩ Điều dưỡng, Đại học Northern Colorado
Email: jeanett.mcneill@unco.edu
Điện thoại: 970-351-1704

APPENDIX B

SURVEY

QLQC30 QUESTIONNAIRE

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

A. Question	Rating			
	Not at all	A little	Quite a bit	Very much
A1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
A2. Do you have any trouble taking a long walk?	1	2	3	4
A3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
A4. Do you need to stay in bed or a chair during the day?	1	2	3	4
A5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
During the past week:				
A6. Were you limited in doing either your work or other daily activities?	1	2	3	4
A7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
A8. Were you short of breath?	1	2	3	4
A9. Have you had pain?	1	2	3	4
A10. Did you need to rest?	1	2	3	4
A11. Have you had trouble sleeping?	1	2	3	4
A12. Have you felt weak?	1	2	3	4
A13. Have you lacked appetite?	1	2	3	4
A14. Have you felt nauseated?	1	2	3	4
A15. Have you vomited?	1	2	3	4
A16. Have you been constipated?	1	2	3	4
A17. Have you had diarrhea?	1	2	3	4

A18. Were you tired?	1	2	3	4
A19. Did pain interfere with your daily activities?	1	2	3	4
A20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
A21. Did you feel tense?	1	2	3	4
A22. Did you worry?	1	2	3	4
A23. Did you feel irritable?	1	2	3	4
A24. Did you feel depressed?	1	2	3	4
A25. Have you had difficulty remembering things?	1	2	3	4
A26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
A27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
A28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

A29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

A30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

B. General Information	
B1. Gender Ma ☐ Female ☐ le	B2. Year of birth: .....
B3. Education: Primary-Secondary School ☐ High School ☐ Colleges/University ☐ Post-graduate ☐	
B4. Diagnose: Colon cancer ☐ Rectal cancer ☐	
B5. Protocol: Xelox ☐ Xeliri ☐ Others ☐	
B6. Phase: 1 2 3 4 5 6 7 8 > 8	
B7. Stoma Yes ☐ No ☐	
B8. Insurance Yes ☐ No ☐	

QLQC30 BỘ CÂU HỎI NGHIÊN CỨU

Chúng tôi quan quan tâm đến một số thông tin về bạn và sức khỏe của bạn. Xin vui lòng trả lời các câu hỏi bởi chính bạn bằng cách khoanh tròn các con số thích hợp nhất đối với trường hợp của bạn. Không có câu trả lời "đúng" hay "sai". Thông tin mà bạn cung cấp sẽ được giữ kín hoàn toàn.

A. Câu hỏi	**Thang điểm**			
	Không có	Ít	Nhiều	Rất nhiều
A1. Bạn có thấy khó khăn khi thực hiện những công việc gắng sức, ví dụ như xách một túi đồ nặng hay một vali?	1	2	3	4
A2. Bạn có thấy khó khăn khi đi bộ một khoảng dài?	1	2	3	4
A3. Bạn có thấy khó khăn khi đi bộ một khoảng ngắn bên ngoài nhà mình?	1	2	3	4
A4. Bạn có cần nằm nghỉ trên giường hay trên ghế suốt ngày?	1	2	3	4
A5. Bạn có cần giúp đỡ khi ăn, mặc, tắm rửa hay đi vệ sinh?	1	2	3	4
Trong tuần vừa qua:				
A6. Bạn đã có bị hạn chế thực hiện trong việc làm của bạn hoặc trong các công việc hàng ngày khác?	1	2	3	4
A7. Bạn đã có bị hạn chế trong theo đuổi các sở thích của bạn hay trong các hoạt động giải trí khác?	1	2	3	4
A8. Bạn đã có bị thở nhanh không?	1	2	3	4
A9. Bạn đã bị đau gì không?	1	2	3	4
A10. Bạn đã cần phải nghỉ ngơi không?	1	2	3	4
A11. Bạn có bị mất ngủ?	1	2	3	4
A12. Bạn có cảm thấy yếu sức?	1	2	3	4
A13. Bạn có bị ăn mất ngon?	1	2	3	4

A14. Bạn có cảm giác buồn nôn?	1	2	3	4
A15. Bạn có bị nôn?	1	2	3	4
A16. Bạn có bị bón?	1	2	3	4
A17. Bạn có bị tiêu chảy?	1	2	3	4
A18. Bạn đã có bị mệt không?	1	2	3	4
A19. Cơn đau có cản trở sinh hoạt hàng ngày của bạn?	1	2	3	4
A20. Bạn đã có bị khó khăn khi tập trung vào công việc gì, như khi đọc báo hay xem truyền hình?	1	2	3	4
A21. Bạn đã có cảm thấy căng thẳng?	1	2	3	4
A22. Bạn đã có lo lắng?	1	2	3	4
A23. Bạn đã có cảm thấy dễ bực tức?	1	2	3	4
A24. Bạn đã có cảm thấy buồn chán?	1	2	3	4
A25. Bạn đã gặp khó khăn khi phải nhớ lại một sự việc?	1	2	3	4
A26. Tình trạng thể lực của bạn hoặc việc điều trị bệnh gây cản trở cuộc sống gia đình của bạn?	1	2	3	4
A27. Tình trạng thể lực của bạn hoặc việc điều trị bệnh gây cản trở cho các hoạt động xã hội của bạn?	1	2	3	4
A28. Tình trạng thể lực của bạn hoặc việc điều trị bệnh tạo ra khó khăn tài chánh của bạn?	1	2	3	4

Đối với những câu hỏi sau, vui lòng khoanh tròn con số trong khoảng từ số 1 đến số 7 mà phù hợp nhất đối với bạn.

A29. Bạn tự đánh giá như thể nào về sức khỏe tổng quát của bạn trong tuần qua?

1	2	3	4	5	6	7
Rất kém						Tuyệt hảo

A30. Bạn tự đánh giá như thế nào về chất lượng cuộc sống tổng quát của bạn trong tuần qua?

1	2	3	4	5	6	7
Rất kém						Tuyệt hảo

B. Thông tin cá nhân									
B1. Giới tính Nam ☐ Nữ ☐								B2. Năm sinh:	
B3. Trình độ học vấn: Tiểu học -THCS ☐ THPT ☐ Cao đẳng/Đại học ☐ Sau Đại học ☐									
B4. Chẩn đoán: Ung thư đại tràng ☐ Ung thư trực tràng ☐									
B5. Phác đồ điều trị hiện tại: Xelox ☐ Xeliri ☐ Khác ☐									
B6. Đợt hóa trị:	1	2	3	4	5	6	7	8	> 8
B7. Hậu môn nhân tạo Có ☐ Không ☐									
B8. Bảo hiểm y tế Có ☐ Không ☐									

APPENDIX C

INSTITUTIONAL REVIEW BOARD APPROVAL

UNIVERSITY OF
NORTHERN COLORADO

DATE:	August 12, 2019
TO:	Chau Than Minh
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[1465710-2] Quality of life among colorectal cancer patients during chemotherapy
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	August 12, 2019
EXPIRATION DATE:	August 12, 2023

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Nicole Morse at 970-351-1910 or nicole.morse@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX D

APPROVAL FROM UNIVERSITY MEDICAL CENTER

UNIVERSITY MEDICAL CENTER®

Ho Chi Minh City, 05 July, 2019

LETTER OF APPROVAL

Dear RN. Than Minh Chau,

This letter is to response to your request for approval to collect data for research entitled *"The quality of life among colorectal cancer patients during chemotherapy"* at the University Medical Center, Ho Chi Minh City, Vietnam (UMC). We are pleased to inform you that the application has been approved and data collection could be started at UMC in according to the following details:

- Study subject: The colorectal cancer patients at UMC
- Sample size: 60
- Department: Chemotherapy Department
- Duration: 06/Jul/2019 – 12/Jul/2019
- Authorized personnel: RN. Than Minh Chau

The researchers are required to comply with all conditions and regulations in data collection at University Medical Center, Ho Chi Minh City, Vietnam.

Sincerely yours,

BUI NGOC MINH TAM, MD.
Vice Manager, Training and Scientific Research Department
University Medical Center, Ho Chi Minh City

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