RESEARCH ARTICLE

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The Relationship between Unmet Need, Physical Symptoms, Psychological Well-Being and Health-Related Quality of Life in Cholangiocarcinoma Survivors

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Abstract

Background: Cholangiocarcinoma (CCA) survivors continue to face challenges that affect their health-related quality of life (HRQOL) along the survivorship trajectory. **Objective:** This study intends to investigate the association and to create a model for explaining the link between unmet needs, physical symptoms, psychological well-being, and HRQOL in CCA survivors. Method: This cross-sectional study consecutively recruited 231CCA survivors from an oncology unit of a university hospital in Khon Kaen, Thailand. Cancer-related unmet need, physical symptoms, psychological well-being and HRQOL were all assessed using the questionnaire, and medical records were used to acquire demographic and clinical data. We use a path analysis to create a hypothesized model in which symptoms, unmet need, anxiety, and depression, support care need predicting HRQOL. **Results:** The mean total of HRQOL score was 75.59±6.24 (95%CI: 74.78-76.39) indicated that the subjects had a low level of HRQOL as a whole. The hypothesis model was found to fit the actual data and explained 39.8% of the variance of HRQOL. Symptoms and anxiety had a significant negative effect on HRQOL ($\beta = -0.62$, $p< 0.001$) and ($\beta=-0.18$, $p<0.001$), respectively. However, the relationship between HRQOL and other mediators was not found significant association. **Conclusion:** According to our findings, the research model can be used to investigate how symptoms affect HRQOL. It also means that cancer care providers should be aware of these factors while caring for CCA survivors in order to enhance their HRQOL.

Keywords: Cholangiocarcinoma survivors- health-related quality of life- unmet needs- physical symptoms- psychological

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Introduction

Despite overall dropping age-standardized incidence rates in men and stable rates in women, the number of cancer survivors in the United States continues to rise (Siegel et al., 2019). This reflects a rise in new cancer diagnoses as a result of a rising and aging population, as well as gains in cancer survival as a result of advances in early detection and treatment. including CCA patients (Pongthavornkamol et al., 2019). Because these patients may be troubled with both the disease and the negative effects of CCA treatment affecting their physical, psychological, and unmet needs in terms of health-related quality of life (HRQOL) (Subramaniam et al., 2018; Erdoğan Yüce et al., 2021). HRQOL is one of the main indicators for health care assistants to provide supportive care commitments. Many previous studies reported that HRQOL is associated with common physical symptoms of CCA such as abdominal pain, indigestion, anorexia (Sun et al., 2008; Somjaivong et al., 2011) since these symptoms cause patients to confront social problems and inhibit their routine activities by decreasing the ability to work that further influence their social and family connection (Zeng et al., 2016; Wee et al., 2020). Moreover, these problems may be considerably increased because of the occurring symptoms (Willems et al., 2016). Furthermore, CCA survivors frequently experience psychological issues, anxiety, and sadness as a result of the onset of physical symptoms (Subramaniam et al., 2018; Erdoğan Yüce et al., 2021). A prior study reported that HRQOL after hepatic resection in patients with the benign disease was better than in those with malignant disease, but HRQOL in both groups trend to decline after surgery (Wee et al., 2020).

In addition, cancer survivors describe a need for support in numerous aspects of their illness that influenced physical and psychological results (Hansen et al., 2013; Hasegawa et al., 2016). As they had little understanding about the health intake adjustment and self-care before

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and after these processes, these patients with unmet needs would be apprehensive and concerned about illness development and adverse events (pain, etc.) before the start of treatments.; likewise, they cannot manage their uncontrolled physical symptoms. Anxious patients have a high level of unmet physical, psychological, healthcare, and information demands, as evidenced by various researches (Liao et al., 2011; Uchida et al., 2011). Patients need both health-related information and medical information to support their medical decision-making (Abu-Helalah et al., 2014).

Furthermore, caregivers, the person who takes care of the CCA survivors, experience many unmet needs during the time caring for them (Chen et al., 2016). While patients suffering from anxiety, despair, or poor physical performance had a high degree of unmet demands, these caregivers also had a high number of unmet needs (Cheng et al., 2016). A larger caregiver burden was connected with a lower functional level of the patient, as well as a higher degree of sadness and anxiety (Liu et al., 2017).

The existence of correlations between these parameters linked with HRQOL has been compared among a variety of cancer survivors in Thailand (Pongthavornkamol et al., 2019). Few studies have been paid to investigate support care needs among CCA survivors (Somjaivong et al., 2011), and has been reported the effect of symptoms, as well as other factors influencing HRQOL among CCA patients. Hence, the goals of this study were to assess HRQOL and create a model to explain the impact of symptoms, unmet needs, anxiety, and physical well-being on HRQOL in CCA survivors. The ability to create particular functional nursing treatments to preserve and enhance the HRQOL of CCA survivors will be aided by a firm understanding of the elements that influence this outcome.

Materials and Methods

Study design and population

This cross-sectional study was included 231 CCA survivors who were recruited from the Srinagarind Hospital, Khon Kaen, Thailand. The questionnaire was administered from February 2021 to April 2021 to participants aged at least 40 years old diagnosed with CCA by board certificated specialists, were able to communicate in the Thai language, and were willing to participate in the study. Participants with cognitive impairment were excluded.

Also, we included 231 CCA caregivers who were 18 years old or older, a family member of a CCA patient, competent to converse in Thai, and able to give written informed consent to attend the hospital.

Study instrument

Participants addressed their baseline characteristics including gender, age, education level, and marital status, and researchers achieved additional information from the medical record on comorbidities, CCA stage at diagnosis, and metastasis.

The Functional Assessment of Cancer Therapy-Hepatobiliary (FACT-Hep) was used for evaluation HRQOL. This particular measurement is most widely used for hepatobiliary cancer patients (Banales et al., 2016). It is divided into two sections: the first concerns cancer patients' overall QOL (Functional assessment of cancer therapy-general: FACT-G) and includes four subscales including physical well-being, social/family well-being, emotional well-being, and functional well-being each with 27 items. The second section has 18 items that relate to the unique QOL related to CCA patients for the hepatobiliary subscale. The Thai version of FACT-G was utilized (Glangkarn et al., 2011). FACT-Hep items are graded on a 5-point Likert scale. The question about "happiness in sex life" was left blank because none of the patients wanted to answer. The raw FACT-Hep score was calculated according to the standards, ranged from 0 to 176, with higher scores indicating improved HRQOL. Because each domain of QOL differed in a number of questions, the average mean scores were used to compare them in this study. All domains and overall FACT-Hep score variables were dichotomized using the median to yield "good (high)" or "poor (low)" scores (Woradet et al., 2016) for evaluating the level of HRQOL.

The CaSUN, a translated version of the original CaSUN, is a self-administered scale comprising of 35 items that were developed to evaluate the unmet needs of patients consisting of 6 components (Hodgkinson et al., 2007). All items are scored based on whether the needs mentioned by the items are not applicable, met, or unmet by the participants. If an unmet need is indicated, it is assessed as weak (scoring 1), moderate (score 2), or strong (score 3). The overall score was calculated by adding all of the need items together, with higher scores indicating more unmet requirements.

The Thai version of the Memorial Symptom Assessment Scale – Short Form (MSAS-SF), a translated version of the MSAS-SF, evaluates physical symptoms on a 5-point Likert-type scale. Its goal is to measure the frequency, severity, and discomfort associated with 32 different multidimensional symptoms that patients experience (Chang et al., 2000). The MSAS-SF has been used to diagnose a wide spectrum of conditions and can be utilized in both clinical and research contexts (Wookey and McKean, 2016; Menezes et al., 2017).

Psychological well-being was evaluated by the Mental health questionnaire for psychological well-being, the Hospital Anxiety and Depression Scale (HADS) has been developed by Zigmond and Snaith in 1983 (Zigmond and Snaith, 1983). It is widely utilized to screen for anxiety and depressive symptoms. It was also used in the study of cancer survivors in Thailand (Villoria and Lara, 2018). It consisted of 14 questions, divided into 7 questions for measuring anxiety symptoms, all of which were odd numbers, and for the other seven depressive symptoms, all of which were even numbers. Each response was scored on a Likert scale ranging from 0 to 3 points. The scores for anxiety and depressive episodes were divided into sections ranging from 0 to 21, categorized as the score range is on three scales: 0-7 points are considered to be non-anxiety and depression 8-10 points are considered anxiety and depression but are not considered doubtful cases 11–21 points: Anxiety and depression are considered psychiatric disorders.

The SCNS-P&C (Supportive Care Needs Survey for Partners and Caregivers) was created to measure the multi-dimensional supportive care needs of cancer caregivers at various stages of their illness (Girgis et al., 2011). In our study, the SCNS-P&C items were translated from English to Thai. This tool developed to assess cancer caregivers' multidimensional supportive care needs at various phases of their illness. This tool contains 45 items divided into four categories: communication and relationships (10 things), health care and information (16 items), social and work (11items), and psychological (8 items). A five-point rating scale is used for all the items. The overall score was calculated by adding all of the need items together, with higher scores indicating more unmet requirements.

Data Collection

Data collection was conducted. All eligible volunteers were informed about the study's objective, process, potential benefits, and ability to withdraw also, were collected until the data collection was finished of all participants' self-report after acquiring permission and executing an informed consent. Participants were invited to complete the questionnaire on their own within 30 to 40 minutes. However, if necessary, an interviewer was always accessible if the respondents, for example, participants aged above 60 years, or had low visual acuity or another impairment. The interviewers went over the returned questionnaires and asked the respondents to fill in any blanks.

Sample size

The sample size for parameters estimated in the hypothesized model was determined. For each calculated free parameter, an optimum ratio was 10 to 20 responders (Kline RB,2005). The hypothesized model in this investigation has 10 free parameters; a sample size of 100-200 was required. As a result, all of 231 CCA survivors who enrolled at the time of data collection were recruited.

Statistical Analysis

The primary outcome of this study was the HRQOL scores, the continuous variable, that was calculated by a total mean score of FACT-Hep that yielded a range of scores from 1 to 176, with higher scores inflecting better HRQOL.

Pearson correlation was conducted to estimate the association between HRQOL symptoms, unmet need, anxiety and depression, and support care need. A p-value of 0.05 or less was considered a statistically significant association. A path analysis was conducted to estimate direct effect (DE) and indirect effect (IE) among HRQOL symptoms, unmet need, anxiety and depression, and support care need of caregivers.

We created a hypothesized model in which symptoms, unmet need, anxiety, and depression, support care need predicting HRQOL, and all these factors were mediators of symptoms and HRQOL. We perform path analyses, add and alter components based on the modification index, examine the goodness of fit, and look into the relationships between parameters in the HRQOL of CCA survivors. (Figure 1)

To evaluate model fitting, we used multiple fit indices to evaluate model fit as follow: Chi-square statistics [relative $\chi^2(\chi^2/df)$] <3.0, the goodness of fit index (GFI), comparative fit index (CFI) >0.90, root mean square error of approximation (RMSEA) <0.08, and non-normed fit index (NNFI>0.90) (Tabachenik and Fidel, 2012). IBM SPSS Statistical version 26.0 and Amos version 25.0 were used for all statistical analyses.

Ethical considerations

The research ethics committee of Khon Kaen University in Thailand accepted this study (HE631628). Eligible participants were addressed at their regular medical appointments by nurses or at patient advocacy group meetings by the study researcher. We received signed informed consent from all participants after a brief explanation of the study design.

Results

The questionnaire was completed by 231 CCA survivors. Sixty-six participants were males (66.7%) and the average age was 66.85±8.65 SD years. The majority of participants were married (75.8%) and had primary school education (69.4%). Seventy-one participants (71.9%) were classified in stage III-IV with metastasis (61.9%) (Table 1).

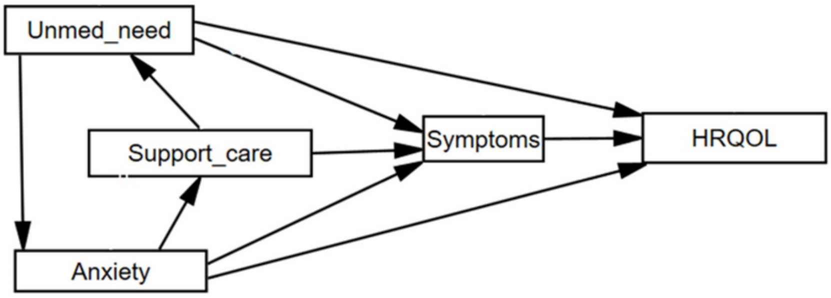

Figure 1. Path Diagram for the Hypothesized Model

Table 1. Baseline Characteristics of the Participants (n=231)

Characteristics	Number	Percent
Gender		
Male	154	66.7
Female	77	33.3
Age		
Less than 50	8	3.5
50-59	43	18.7
>=60	180	77.9
Mean (±SD)	66.85 (±8.65)	
Education level	(n=229)	
Primary	159	69.4
Secondary	53	23.1
Bachelor	17	7.4
Marital status		
Married	175	75.8
Unmarried	56	24.2
Comorbidity	(n=230)	
No	127	55.2
Yes	103	44.8
Cancer stage at diagnosis		
I	21	9
II	28	12.1
III	96	41.6
IV	70	30.3
Unknown	16	7
Metastasis		
No	88	38.1
Yes	143	61.9

Health-related quality of life (HRQOL)

The HRQOL total score ranged from 3 to 108, with a mean of 75.59 ±6.24 SD (95%CI: 74.78-76.39) showing that the individuals as a group had a low level of HRQOL. Because each category of HRQOL had a different number of questions, the average mean score was used to compare in this study. The domain of HRQOL with the greatest scores (average score=3.25) was social/family well-being, whereas the domain with the lowest scores was physical well-being (average score=1.36) (Table 2).

Summary Statistics of the 32 Symptoms by the MSAS-SF

The symptom prevalence revealed that all subjects reported at least one symptom, with prevalence ranging from 5.3 percent to 53.8 percent. The top five most physical prevalence included changes in the way food tastes (61.37%), pain (61.05%), weight loss (58.87%), feeling bloated (57.32%), and lack of appetite (54.21%). Likewise, the most common psychological symptoms were irritability (71.33%), worrying (70.72%), feeling sad (69.78%), and feeling nervous (66.67%), respectively. Symptoms with the highest scores included changes in the way of food tastes, pain, weight loss, feeling bloated, and lack of appetite and the mean symptom scores were 1.08±0.69 SD, 1.34±0.99 SD, 1.11±0.85 SD, and 1.32±1.04) SD, respectively.

Unmet need by the CaSUN

Unmet supportive care needs were indicated by a total of 80.1% expressed unmet need in at least one area, survivors, and unmet need in several areas were frequent with an average of 6.53 needs. However, the total score of unmet needs is low (mean=58.86±6.96 SD, score range 30–74), with the subscale scores of intensive cares domain (mean=27.35±4.54 SD), information domain (mean=10.14±2.04SD), relationship

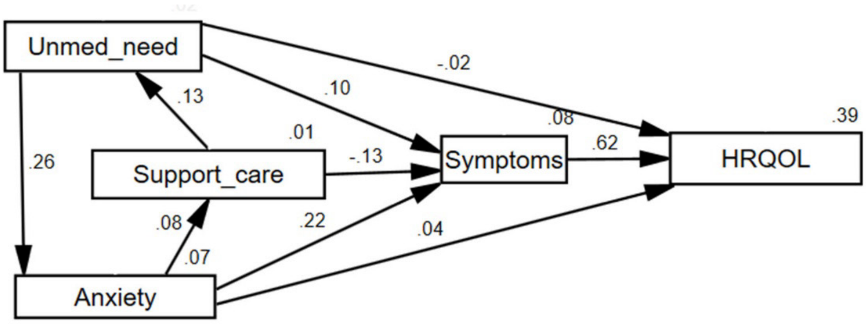

Figure 2. Our Hypothesized Model Testing to Predict HQOL in CCA Survivors

Table 2. FACT-Hep Assessed the Baseline HRQOL Score of CCA Survivors.

FACT-Hep	Mean±SD	Median	Min: max	Average score (0-4)
Physical well-being (0-28)	9.48±313	8	0:22	1.36
Social/family well-being (0-24)	19.48±1.68	19	15:28	3.25
Emotional well-being (0-24)	9.55±2.10	9	3:17	1.59
Functional well-being (0-28)	15.77±2.69	17	3:25	2.25
Hepatobiliary cancer subscale (0-72)	25.3±3.78	24	5:28	1.41
Total (overall HRQOL) (0-176)	75.59±6.41	78	58:108	1.81

Table 3. Bivariate Relationship among Unmet Need, Symptoms, Psychological Well-Being, and HRQOL.

Variable	Symptoms	Support care need	Unmet need	Anxiety
Symptoms	1	-0.89	0.138*	0.232**
Support care need	-0.089	1	0.146*	0.11
Unmet need	0.138*	0.146*	1	0.271**
Anxiety	0.232**	0.11	0.271**	1
HRQOL	-0.625**	0.023	-0.089	-0.180**

**Significant at 0.01 level. *Significant at 0.05 level.

domain (mean=4.99±2.59 SD), and medical care domain (mean=16.32±2.11 SD).

Anxiety and depression

The results of HADS, for both anxiety and depression (96.54% for anxiety and 98.27% for depression) of these 5.19% were within the normal range (0–7) (3.46% for anxiety and 1.73% for depression). The mean anxiety and depression scores were 16.77±3.23 SD and 15.54 ±2.96 SD, respectively.

SCNS of the caregiver of CCA survivors

The overall unmet needs scores of CCA caregivers were considered high (mean=154.63±20.36 SD, score range 92–197), with the subscale scores of communications and relationship (mean=31.14±5.86 SD), health care and information (mean=65.49±7.42 SD), social and work (mean=36.22±7.72 SD), and psychological (mean=24.47±4.61 SD).

Bivariate correlation between unmet need, symptoms, phycological well-being, support care need and HRQOL

Pearson correlation coefficient was used to estimate the relationships among unmet needs, physical symptoms, anxiety, support care need, and HRQOL. The HRQOL demonstrated a significantly negative correlation with symptom occurrences and anxiety with the range of correlation was from -0.180 to -0.625 whereas the relationship between HRQOL and other mediators including unmet need and support care need was not found significant association. Likewise, HRQOL also shown the strongest negative correlation with symptoms (r=-0.625, p< 0.001) (Table 3).

Testing and modification of the hypothesized model on the HRQOL of CCA survivors

From our model, the support care needs of the caregiver, anxiety, symptoms, and HRQOL served as endogenous variables, while the exogenous variable was an unmet need. The linear structural relationship result demonstrated that this model fits with our empirical data (χ^2/df=2.293, P=0.130, CFI=0.991, GFI=0.971, NNFI=0,999 and RMSEA=0.075), and the path analysis can explain 39.8% of the variance of HRQOL. The total (TE), direct (DE), and indirect effect (IE) among the variables were reported in Table 4. The results of model testing were depicted in Figure 2.

The path analytic model to examine the structure relationship among the study variables was shown in Figure 2 and Table 4. Symptom (the total score of MSAS-SF) revealed a significant negative effect on the total score of HRQOL (β =-0.628, p< 0.001) and IE of -0.105, -0.067, on HRQOL through unmet need and support care need of caregivers (p<0.001). Similarly, anxiety and depression (the total score of HADS) has a weak significant negative correlation on HRQOL (β = -0.18, p < 0.001). However, the relationship among HRQOL unmet need and support care need was not significant. The final model explained 39.8% of the HRQOL of CCA survivors. This finding suggested that CCA survivors with a higher level of symptoms may have a lower level of HRQOL. The result also indicated that these patients with more anxiety and depression may have poorer HRQOL.

Discussion

This research evaluated the mediating effects and relevance of HRQOL, unmet need, support care needs of caregivers, anxiety, and depression in the cortex of the relation between HRQOL and symptoms of CCA survivors. This research showed that the CCA survivors had a low level of HRQOL, which indicated that most of the participants were in stages III and IV and were receiving palliative care for at least 3 months. Regarding the HRQOL scores in every parameter, our findings were lower than those of a previous study (Woradet et al., 2016).

Table 4. Summary Table, Direct and Indirect Effects of Causing Variables on Affecting Variables (n=231)

Causal	Anxiety			Support care need		Unmet need			Symptoms		
	TE	DE	IE	TE	DE	TE	DE	IE	TE	DE	IE
Anxiety	0.033	-	0.033	0.033	-	0.263	0.262	0.001	-	-	-
Support care need	0.078	0.078	-	0.033	-	0.02	-	0.02	-	-	-
Unmet need	0.01	-	0.01	0.126	0.126	-	-	-	-	-	-
Symptoms	0.211	0.22	-0.008	-0.108	-0.127	0.153	0.097	0.055	-	-	-
HRQOL	-0.181	-0.041	-0.14	0.067	-	-0.089	-0.016	-0.105	-0.618	-0.618	-

Abbrevuation: TE, total effects; DE, direct effects; IE, indirect effects; HRQO, health-related quality of life.

The contrast to our study, this previous study enrolled 171 newly diagnosed CCA patients and HRQOL had been confirmed to decline after treatment (Wee et al., 2020). Likewise, our result illustrated that CCA survivors have the maximum score in Social/family well-being domain and the minimum score in physical well-being domain. These results could be explained by the fact that in the Thai cultural context, these individuals received excellent social and emotional support from their family, friends, and healthcare providers, resulting in a high sense of social and family well-being. The finding is similar to that of the study of CCA patients in the Northeastern region of Thailand in which the highest HRQOL of these patients were in the social family well-being domain (Woradet et al., 2015). In physical well-being domain, changes in food tastes and abdominal pain were common symptoms (61.37% and 61.05%), since participants reduce their sense of emotional well-being and functional well-being. In addition, the pain reduces the social and functional well-being of CCA patients, according to a prior study (Wu et al., 2012).

Furthermore, our participants in this study exhibited at least one common symptom. Many of these symptoms are common to cancer patients in general and some unique to their disease. Especially symptoms related with obstructive jaundice such as malaise, itching and dehydration (Heffernan et al., 2002). Despite the fact that the individuals exhibited mild to severe symptoms, 98.7% of cases reported that they felt distressed from their symptom occurrences, both physical and psychological symptoms. It is feasible that most of them have recently been diagnosed and undergoing the cancer treatment process, these symptoms were a combination of pathology and treatment-related side effects. Furthermore, the current study shows that the cancer survivor's symptoms had a significant direct impact on HRQOL; hence, CCA survivors with a higher level of symptom occurrence had a poorer HRQOL score. This result was supported by a study of breast cancer patients (Wu et al., 2012). Moreover, our findings indicate the cancer symptoms having an IE on HRQOL through anxiety and depression. Surprisingly, participants with high levels of anxiety and depression had a DE on HRQOL. It's possible that CCA survivors' symptoms were linked to the unpredictability of the disease's progression. This result indicated that rising symptoms are the cause of anxiety and depression when the pattern of symptoms cannot be predicted. In addition, our result revealed that the unmet need of CCA survivors and the support care need of caregivers of CCA patients had an IE on HRQOL through anxiety and depression. The relationship between higher unmet needs is linked to higher levels of anxiety and depression levels in our study result were supported by a previous study (Ferrari et al., 2019). Before starting cancer therapy, we assumed that patients would be concerned and frightened about disease progression and side effects (pain, etc.) since they had no idea about the health care process and self-care during and after treatment also, they cannot manage physical symptoms, therefore, we believe that meeting unmet needs may be considered as important for HRQOL. Also, Patients were given insufficient information to suit their demands, causing psychological and emotional suffering (Ferrari et al., 2019). In addition, patients need health-related information and medical information to support their medical decision-making if they little know about the information that can affect HRQOL (Abu-Helalah et al., 2014). Our study also showed the influence of supportive care needs of CCA survivors having an indirect effect on HRQOL through anxiety and depression. In our situation, most carers were family members who were virtually full-time caretakers and had little time for themselves; as a result, a poorer cancer patient's functional status was linked to increased caregiver effort and stress. As a result of the increased caregiver burden, poor QOL was linked to poorer life satisfaction and higher levels of sadness and anxiety (Liu et al., 2017).

In this study, Unmet need, support care need and anxiety showed weak correlation with HRQOL. This result may be explained that some CCA survivors with symptoms and decreased functioning of psychological well-being were most likely placed in the group 'no unmet needs.' Some of these patients may have been content with their care, did not consider their symptoms or limits to be unpleasant, or did not need professional assistance (Steele and Fitch, 2008). This could have weakened the results of our study.

There are a few flaws in this study. First, the current investigation was conducted in only one university hospital, the findings may not be completely applicable to patients attending various types of medical facilities. Second, the HRQOL concept model had a high goodness of fit, but the coefficient of determination was 0.38, and it is probable that the remaining 0.62 was due to some other factors. Identifying this potential component is a future research issue.

The current research is a theoretical framework for carrying out a path model to test the action by which symptoms influence HRQOL. Our results recommend that symptoms have both direct and indirect effects on the HRQOL of CCA survivors. It also suggests that cancer care providers address characteristics such as unmet need, anxiety, and support care need in their care for improving CCA survivors' HRQOL.

Author Contribution Statement

MS., PR., BP. envisioned the research idea. US. and MT. analyzed, interpreted the data, and helped to draft the manuscript. That was also discussed with MS and US. who supervised the research project. All authors revised the manuscript critically and approved the final version to be published.

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Ethical Approval

This research was approved by the research ethics committee of Khon Kaen University, Thailand (HE631628). The informed written consent was obtained from each of the study participants of this study. Besides, every participant was assured about the confidentiality of his personal information.

Availability of the data

Data can be provided on a duly justified request to the corresponding author.

Conflicts of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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