

# A comparison of psychological well-being and quality of life between spouse and non-spouse caregivers in patients with head and neck cancer: a 6-month follow-up study

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**Objective:** The caregivers of patients with head and neck cancer (HNC) may suffer from impaired psychological well-being and a decreased quality of life (QOL) related to the chronic burden of caring for patients' physical conditions and their mood changes. In this study, we aimed to compare the psychological well-being and QOL between spouse caregivers and non-spouse caregivers of patients with HNC over a 6-month follow-up period.

**Patients and methods:** This study was conducted using a prospective design with consecutive sampling. We recruited study subjects from the outpatient combined treatment clinic of HNC at a medical center in Southern Taiwan. The Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition was carried out by a trained senior psychiatrist to diagnose caregivers. Furthermore, one research assistant collected the caregivers' demographic characteristics, clinical data, and clinical rating scales, including the Short Form 36 (SF-36) Health Survey, Hospital Anxiety and Depression Scale (HADS), and Family Appearance, Pulse, Grimace, Activity, and Respiration index at the patients' pretreatment, as well as their 3- and 6-month follow-up appointments.

**Results:** Of the 143 subjects that successfully completed the study, two-thirds of caregivers were spouses. During the 6-month follow-up period, spouse caregivers demonstrated significantly higher rates of depression diagnosis ( $p=0.032$ ), higher scores in the depression subscale of HADS (HADS-D) ( $p=0.010$ ), and lower SF-36 mental component summary (MCS) scores ( $p=0.007$ ) than non-spouse caregivers. Furthermore, during those 6 months, HADS-D ( $p=0.007$ ) and the anxiety subscale of HADS scores ( $p<0.001$ ) significantly decreased, while SF-36 MCS scores significantly increased ( $p=0.015$ ).

**Conclusion:** The mental health of spouse caregivers of HNC patients was more severely affected than that of non-spouse caregivers during the observed 6-month follow-up period. Therefore, clinicians need to pay more attention to caregivers' psychological distress during patient care, especially for spouse caregivers.

**Keywords:** spouse caregiver, psychological well-being, quality of life, head and neck cancer, follow-up study

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## Introduction

Head and neck cancer (HNC) is among the 10 most common cancers in the world, with ~540,000 new cases and 271,000 deaths every year worldwide and a 5-year mortality rate of ~50%.<sup>1</sup> The caregivers of cancer patients may suffer from impaired psychological well-being (including anxiety, depression, or family support) and a

decreased quality of life (QOL) related to the chronic burden of caring for patients' physical conditions and their mood changes.<sup>2,3</sup>

In the past, studies that generally used self-rated questionnaires have reported that the prevalence of depression in caregivers for cancer patients varied from 4.5% to 82.2%.<sup>4-7</sup> However, few studies have investigated the morbidity of depression in caregivers of HNC patients, which has been found to range from 9.7% to 14.7%.<sup>4,8</sup> Compared to studies of the morbidity of depression in cancer caregivers, epidemiological studies of anxiety in cancer caregivers are quite rare. Park et al conducted a nationwide survey of patient-family caregiver dyads in Korea and found that the prevalence of anxiety in family caregivers reached 38.1%.<sup>7</sup>

Previous studies have also shown that caregivers that experienced depression demonstrated impaired family support compared to nondepressed caregivers.<sup>9,10</sup> Our prospective study followed caregivers of HNC patients for 6 months and revealed that impaired family support is a risk for depression among cancer caregivers.<sup>11</sup> Yeh et al<sup>12</sup> explored the psychological well-being, quality of caregiver-patient relationship, and family support on the health of family caregivers for cancer patients, observing that a lack of family support had a significant negative correlation with caregivers' health. These studies suggest that family support not only affects caregivers' moods but also has an influence on their physical health.

Several researchers have reported the impact that providing care to HNC patients has on the QOL of those caregivers.<sup>4,13,14</sup> Furthermore, some cross-sectional studies have even confirmed the correlation between depression and QOL in these caregivers.<sup>4,8</sup> A study of 897 cancer family caregivers from Korea found that the QOL of caregivers is associated with anxiety.<sup>7</sup> In our longitudinal study, we followed depression, anxiety, and QOL, and their interaction in caregivers of HNC patients and found that the caregivers' QOL significantly improved over the 6-month follow-up period, and we observed a lower mental component of the Short Form 36 (SF-36) Health Survey score at baseline to be a predictor of depressive disorders after 6 months.<sup>11</sup>

Spouses are often the primary and most valuable source of support and care for cancer patients.<sup>15</sup> The cancer experience is not only a stressful event for patients but also for their spouses.<sup>16</sup> When faced with the patient's exasperating disease, ongoing caregiving responsibilities, and the fear of losing their loved ones, spouses can tend to feel quite distressed.<sup>17</sup> Previous studies have demonstrated that spousal caregivers of cancer patients are at greater risk of depression and various physical conditions (eg, coronary heart disease

and stroke) when compared to the general population.<sup>18-20</sup> These prior studies have suggested that medical professionals should pay close attention to the mental health and QOL of the spouses of cancer patients. However, few studies have conducted a spouse/non-spouse caregiver comparison of QOL and psychological well-being in HNC patients.

Based on the aforementioned literature review, some studies have detected correlations among depression, anxiety, family support, and QOL in caregivers of HNC patients.<sup>4,8,11,13,14</sup> Nevertheless, prospective studies comparing those same factors between spouse caregivers and non-spouse caregivers of HNC patients are rare. The aim of this present study was to compare the psychological well-being (depression, anxiety, family support) and QOL between spouse caregivers and non-spouse caregivers of HNC patients during a 6-month follow-up period.

## Patients and methods

### Subjects

The study protocol was approved by the institutional review board of Chang Gung Hospital in Taiwan (reference number: 99-3723B). All procedures performed in this study involving participants were in accordance with the ethical standards of the institutional and/or national research committee and with the Declaration of Helsinki. We obtained written informed consent from the patients and their caregivers.

In this prospective study, we adopted a consecutive sampling design and recruited subjects from the outpatient combined clinic for HNC from Kaohsiung Chang Gung Memorial Hospital (KCGMH). Of the four medical centers in Southern Taiwan, KCGMH is the largest, and provided services to 5,000 cancer patients between February 2012 and January 2013. The caregivers had to meet the following inclusion criteria: 1) taking care of patients with newly diagnosed, untreated HNC; 2) aged 20 years or over; 3) living with the patients and taking care of their daily needs; and 4) able to verbalize and write. Exclusion criteria for the patients were as follows: 1) a previous history of malignancy or 2) recurrent HNC, while the exclusion criterion for caregivers was a previous history of malignancy.

### Assessments

**Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV), clinician version (SCID-CV)**

Psychiatric diagnoses were performed using the SCID-CV interview, a structured diagnostic interview based on DSM-IV criteria.<sup>21</sup> This interview was carried out by a clinician or mental health professional with the relevant

professional training. The diagnosis was supplemented by the DSM-IV criteria for primary insomnia (which was not included in the SCID). The SCID interview carried out by a trained psychiatrist is considered a “gold standard” of psychiatric diagnosis.

### Hospital Anxiety and Depression Scale (HADS)

HADS is a 14-item self-administered questionnaire that assesses the severity of anxiety and depression.<sup>22</sup> It is commonly used in hospital practices (including cancer patients) and primary care, as well as for the general population.<sup>23</sup> Seven items are used to evaluate anxiety, and seven other items are used to evaluate depression. Each item has four possible responses (scored from 0 to 3); the anxiety (HADS-A) and depression (HADS-D) subscales of HADS—each have independent measures.<sup>22</sup> In this study, HADS was carried out by a trained research assistant.

### SF-36

SF-36 was designed to evaluate functional health, well-being, and QOL in population surveys.<sup>24</sup> It consists of eight health domains: physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health. A standard scoring algorithm combines scores into two summary scores for the physical component summary (PCS) and the mental component summary (MCS).<sup>25</sup> The Taiwanese version of SF-36 was validated by Lu et al<sup>26</sup> and has been widely adopted to measure QOL in studies in Taiwan, as well as those of other Asian countries.<sup>27</sup> In the present study, SF-36 was performed by a trained research assistant.

### Family Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) index

The family APGAR index, which was developed by Smilkstein,<sup>28</sup> assesses a family member's perception of family function by examining his/her satisfaction with family relationships. It includes five parameters of adaptation, partnership, growth, affection, and resolution with a three-point scale that ranges from 0 (hardly ever) to 2 (almost always). Total scores range from 0 to 10, where a higher score represents a higher level of family functioning. A trained research assistant administered the family APGAR index.

### Procedures

The human research ethics committee of Chang Gung Memorial Hospital approved this study. The study procedures were as follows: 1) patients referred from the HNC outpatient

clinic and their caregivers were asked to provide written informed consent; 2) caregivers attended the appointment with their related patients and were identified as fulfilling the inclusion criteria; 3) SCID was used by a senior psychiatrist (Dr Y Lee) to reach a psychiatric diagnosis; and then 4) a trained research assistant collected the patients' demographic and clinical data, the caregivers' demographic data, and clinical rating scales data, including HADS, SF-36, and the Family APGAR index using in-person interviews. Furthermore, the above questionnaires and psychiatric diagnostic interviews were repeated at the 3- and 6-month follow-up appointments.

### Statistical analyses

Data were analyzed using the Statistical Package for the Social Sciences for Windows (version 16.0; SPSS Inc., Chicago, IL, USA). Variables are presented as either mean  $\pm$  standard deviation (SD) or frequency. We adopted either a chi-square ( $\chi^2$ ) test or independent *t*-test to compare the characteristics of the spouse and non-spouse caregiver groups. All statistical tests were two-tailed, and differences of  $p < 0.05$  were considered statistically significant.

We analyzed longitudinal data using generalized estimating equations (GEEs) in which the maximum likelihood estimation method and auto-regression covariance matrix were the primary analytic strategies. When compared to traditional approaches (ie, repeated-measure analysis of variance), these techniques are more effective at handling missing data.<sup>29,30</sup> We used the GEE to examine the potential effects on the two caregiver groups (spouse vs non-spouse), the potential time effect, and the potential interaction effects of caregivers and time on caregivers' psychometrics during the 6-month treatment period. The diagnosis of depression and HADS, APGAR, PCS, and MCS of the SF-36 scores were set as dependent variables, and the caregiver groups and follow-up time were set as the independent variables. To control for the potential confounding effects of caregivers' age, gender, education levels, past history of depression, and patients' chemotherapy, we set these characteristics as covariates in the GEE models. Bonferroni correction was used to adjust multiple tests.

### Results

Of the 143 caregivers included in the study, 76.2% (N=109) were female. The average age of the subjects was  $47.0 \pm 11.4$  years, and their mean education level was  $10.5 \pm 3.9$  years. Of the included caregivers, 76.2% were married, and 58.7% were employed at the time (Table 1). Of the recruited subjects, 91 (63.6%) caregivers were the patients' spouse, while the

**Table 1** Demographic and clinical characteristics between spouse and non-spouse caregivers in patients with head and neck cancer

Variables	Spouse (N=91)	Non-spouse (N=52)	Total (N=143)	$\chi^2$ / t-test <sup>a</sup>	p-value
Gender				31.007	<0.001***
Male	8 (8.8)	26 (50.0)	34 (23.8)		
Female	83 (91.2)	26 (50.0)	109 (76.2)		
Age, years, mean $\pm$ SD	49.9 $\pm$ 8.9	41.7 $\pm$ 13.3	47.1 $\pm$ 11.4	4.417	<0.001***
Age demarcated				14.713	<0.001***
$\geq 50$	53 (58.2)	13 (25.0)	66 (46.2)		
<50	38 (41.8)	39 (75.0)	77 (53.8)		
Education				13.042	0.001***
Under elementary school	27 (29.7)	6 (11.5)	33 (23.1)		
High school	54 (59.3)	29 (55.8)	83 (58.0)		
College or above	10 (11.0)	17 (32.7)	27 (18.9)		
Education, years, mean $\pm$ SD	9.6 $\pm$ 3.8	12.0 $\pm$ 3.7	10.4 $\pm$ 3.9	-3.715	0.001**
Unemployment	38 (41.8)	21 (40.4)	59 (41.3)	0.026	0.872
Combine other medications	32 (35.2)	12 (23.1)	44 (30.8)	2.270	0.132
Comorbid diseases	45 (49.5)	17 (32.7)	62 (43.4)	3.784	0.052
Hypnotics use	12 (13.2)	4 (7.7)	16 (11.2)	1.005	0.316
Alcoholism	7 (7.7)	8 (15.4)	15 (10.5)	2.085	0.149
Smoking	10 (11.0)	16 (30.8)	26 (18.2)	8.703	0.003**
Betel nut	3 (3.3)	7 (13.5)	10 (7.0)	5.257	0.037**
Past history of depression	8 (8.8)	1 (1.9)	9 (6.3)	2.647	0.156
Family history of depression	8 (8.8)	2 (3.8)	10 (7.0)	1.244	0.328
Time since cancer diagnosis (weeks)	3.7 $\pm$ 1.6	3.5 $\pm$ 0.9	3.6 $\pm$ 1.4	1.011	0.314
Depressive disorder	16 (17.6)	5 (9.6)	21 (14.7)	1.696	0.195
Psychiatric disorder	36 (39.6)	8 (15.4)	44 (30.8)	9.079	0.003**
Patient treatment					
Operation	54 (59.3)	27 (51.9)	81 (56.6)	0.741	0.389
Chemotherapy	51 (56.0)	38 (73.1)	89 (62.2)	4.085	0.043*
Radiotherapy	55 (60.4)	39 (75.0)	94 (65.7)	3.115	0.078
CCRT	48 (52.7)	34 (65.4)	82 (57.3)	2.160	0.142
Patient cancer stage				0.631	0.427
Early (stage I and II)	43 (47.3)	21 (40.4)	64 (44.8)		
Advance (stage III and IV)	48 (52.7)	31 (59.6)	79 (55.2)		
Patients' cancer sites				0.094	0.759
Nasopharynx	19 (20.9)	12 (23.1)	31 (21.7)		
Others	70 (79.1)	40 (76.9)	112 (78.3)		

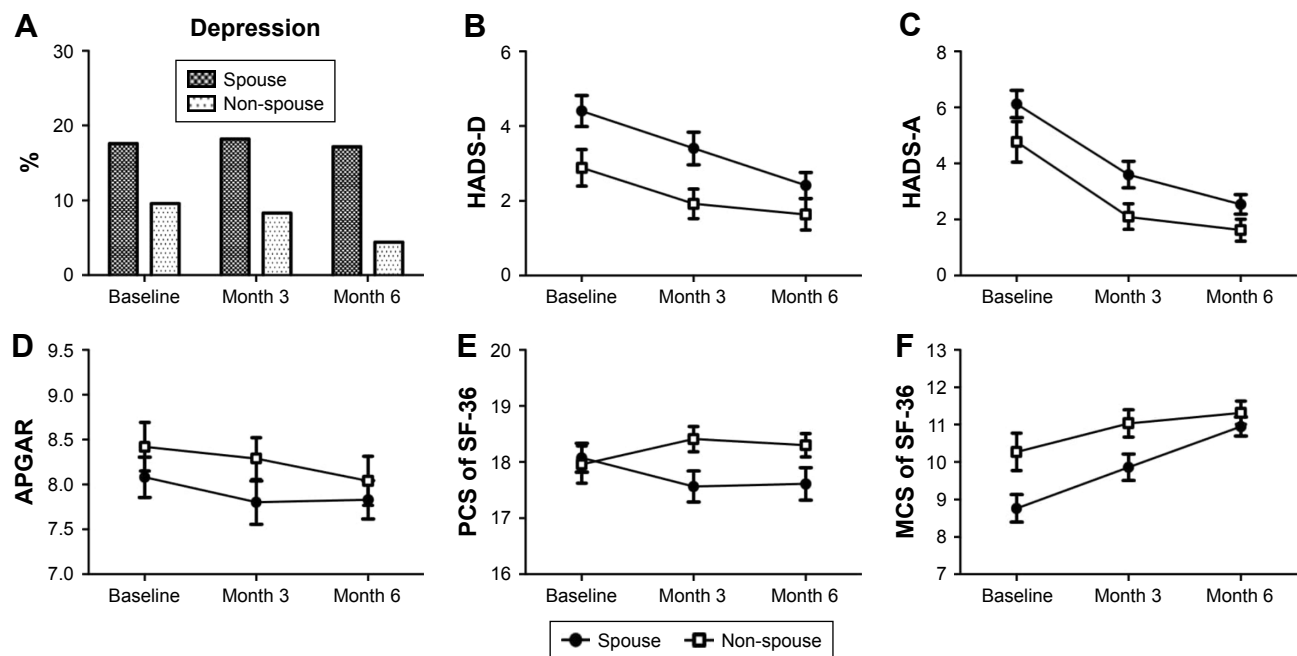
Notes: \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$ . <sup>a</sup>Independent t-test.

Abbreviation: CCRT, concurrent chemoradiotherapy.

other 52 (36.4%) caregivers were not spouses of the patients. Spouse caregivers were more likely to be female ( $p < 0.001$ ), elderly ( $p < 0.001$ ), with lower education levels ( $p = 0.001$ ), tobacco users ( $p = 0.003$ ), betel nut users ( $p = 0.037$ ), and with a higher rate of a psychiatric disorder ( $p = 0.003$ ) than the non-spouse caregivers. The psychiatric disorders of caregivers considered in this study include depressive disorders, adjustment disorder, alcohol abuse, anxiety disorder not otherwise specified, and primary insomnia. The majority of caregivers had a psychiatric disorder after taking care of the cancer patients. The course of experiencing these psychiatric disorders ranged from 1 to 6 months. Although many caregivers suffered from a psychiatric disorder, most of them were still capable of caring for the patient without

significant impairment to their functioning. Furthermore, patients cared for by non-spouse family members had higher rates of receiving chemotherapy ( $p = 0.043$ ). The most common familial relationship among the caregivers in our study was wives (58.0%), followed by children (23.1%), parents (6.3%), and husbands (5.6%).

Figure 1 demonstrates the trends of depression diagnosis, HADS, APGAR, PCS, and MCS of the SF-36 scores of caregivers during the 6-month follow-up period. The effects of the two different caregiver groups and time on the aforementioned psychometrics are provided in Table 2. After controlling for the confounding effects of caregivers' age, gender, education levels, history of depression, and patients' chemotherapy, spouse caregivers had significantly elevated



**Figure 1** Trends of depression (A), HADS-D score (B), HADS-A score (C), APGAR score (D), PCS of SF-36 score (E) and MCS of SF-36 score (F) in caregivers of patients with head and neck cancer during a 6-month follow-up.

**Abbreviations:** APGAR, Appearance, Pulse, Grimace, Activity, and Respiration; HADS, Hospital Anxiety and Depression Scale; HADS-D, depression subscale of HADS; HADS-A, anxiety subscale of HADS; SF-36, Short Form 36; PCS, physical component summary; MCS, mental component summary.

rates of being diagnosed with depression ( $p=0.032$ ), greater HADS-D scores ( $p=0.010$ ), and lower SF-36 MCS scores ( $p=0.007$ ) than non-spouse caregivers during the 6-month follow-up period. Regarding the time effects, HADS-D ( $p=0.007$ ) and HADS-A ( $p<0.001$ ) scores significantly decreased, while SF-36 MCS scores significantly increased ( $p=0.015$ ). Furthermore, caregivers and time had a significant interaction effect on SF-36 PCS scores ( $p=0.045$ ). After the Bonferroni correction, spouse caregivers had significantly lower SF-36 MCS scores than non-spouse caregivers, and HADS-D and HADS-A scores significantly decreased during the 6-month follow-up.

## Discussion

This prospective study is among the first to examine the psychological well-being and QOL differences between spouse caregivers and non-spouse caregivers in HNC patients. We found that spouse caregivers were more likely to be female and elderly, less educated, and prone to psychiatric disorders than non-spouse caregivers. Spouse caregivers also demonstrated a significantly higher morbidity of depressive disorder, a greater severity of depression, and a worse mental component of QOL than non-spouse caregivers. The severity of depression and anxiety significantly decreased while the QOL mental component significantly improved over time.

**Table 2** Main effects of caregiver (spouse vs non-spouse) and time, and the interaction effect of caregiver and time on psychological well-being during a 6-month follow-up

Psychological well-being	Spouse vs non-spouse		Time		Caregiver * time	
	B (95% CI)	p-value	B (95% CI)	p-value	B (95% CI)	p-value
Depression	1.00 (0.08, 1.92)	0.032	-0.44 (-1.19, 0.31)	0.247	0.43 (-0.37, 1.23)	0.292
HADS-D	2.22 (0.52, 3.92)	0.010	-0.66 (-1.14, -0.18)	0.007*	-0.34 (-0.97, 0.29)	0.291
HADS-A	1.95 (-0.35, 4.25)	0.096	-1.59 (-2.27, -0.92)	<0.001*	-0.21 (-1.05, 0.63)	0.626
APGAR	-0.42 (-1.38, 0.53)	0.385	-0.17 (-0.48, 0.14)	0.287	0.02 (-0.36, 0.39)	0.927
PCS of the SF-36	0.24 (-0.83, 1.31)	0.656	0.15 (-0.13, 0.42)	0.290	-0.37 (-0.74, -0.01)	0.045
MCS of the SF-36	-2.28 (-3.93, -0.64)	0.007*	0.54 (0.10, 0.97)	0.015	0.56 (-0.04, 1.15)	0.067

**Notes:** Data were analyzed using generalized estimating equations models, controlling for age, gender, education levels, past history of depression, and patients' chemotherapy.

\*Significant correlation remains after Bonferroni correction ( $p=0.05/6=0.0083$ ).

**Abbreviations:** APGAR, Appearance, Pulse, Grimace, Activity, and Respiration; HADS, Hospital Anxiety and Depression Scale; HADS-D, depression subscale of HADS; HADS-A, anxiety subscale of HADS; SF-36, Short Form 36; PCS, physical component summary; MCS, mental component summary.



Furthermore, caregivers and time had a significant interaction effect on the physical component of QOL.

Of our subjects, most of the spouses were wives (wife: husband =10:1), while most of the non-spouse subjects were children (children: parents =3.7:1). Such demographic data can explain why spouse caregivers are more elderly and less educated than non-spouse caregivers. In regard to psychiatric diagnosis, the depressive disorder morbidity of spouse caregivers was 17.0% at both the index and the 6-month follow-up; meanwhile, the depressive disorder morbidity of non-spouse caregivers at the index and the 6-month follow-up was 10.3% and 4.5%, respectively. The adjustment disorder morbidity of spouse caregivers at the index and the 6-month follow-up was 20.2% and 1.1%, respectively, whereas the adjustment disorder morbidity of non-spouse caregivers at the index and the 6-month follow-up was 6.9% and 0, respectively. Therefore, we can suppose that spouse caregivers were more concerned for and distressed by their partner's physical and even mental conditions and thus experienced more psychiatric disorders than non-spouse caregivers.

Wang et al<sup>31</sup> carried out a meta-analytic study to examine the female preponderance in depressive disorders and discovered that women in the nonclinical population reported higher levels of depressive symptoms than men. Other studies have previously reported that unemployed adults were at an elevated risk of developing major depression.<sup>26</sup> Therefore, being female and being unemployed are two risk factors for developing depressive disorder.<sup>31,32</sup> Among our spouse caregivers, 91% were females and 42% were unemployed. This demographic characteristic of spouse caregivers can partially explain why spouse caregivers had a significantly higher morbidity of depressive disorders, as well as a greater severity of depression than non-spouse caregivers.

In comparing spouse caregivers and non-spouse caregivers, we also found that spouse caregivers' QOL mental component was significantly worse than that of non-spouse caregivers. Prior studies have shown that the degree of QOL was inversely correlated to the severity of depression in the caregivers of cancer patients.<sup>11,33</sup> Therefore, it is not unexpected that the QOL of our caregivers, both spouse and non-spouse, negatively correlated to their depression severity. However, few studies have reported that the QOL of spouse caregivers was worse than that of non-spouse caregivers when caring for patients, especially in regard to the mental component of QOL. More large-scale studies should be performed in the future to confirm our findings.

Regarding the time effect, our results indicate that caregivers' depression and anxiety symptoms were inversely correlated to the QOL mental dimension in HNC caregivers during the 6-month follow-up period. Caregivers of newly diagnosed HNC patients face various treatment options during the first 6 months after diagnosis, and their resulting anxiety and depression symptoms are subsequently reduced through stress coping techniques and cognitive reconstruction.<sup>11,33</sup> The physical component of QOL in non-spouse caregivers was significantly better than that of spouse caregivers during the 6-month follow-up period (Figure 1). Although spouse caregivers' QOL mental component improved after the 6-month follow-up period, their QOL physical component decreased during the same time. This finding may indicate that the physical condition of spouse caregivers may deteriorate due to exhaustion after providing care for half a year. This hypothesis is understandable since most of the spouse caregivers in our sample were ~50 years old.

Sterba et al performed a systemic review based on QOL in HNC patient-caregiver dyads. Of the 12 studies they reviewed, only one study detected a correlation between the QOL of spouses and their depression/psychiatric diagnosis.<sup>4,13</sup> Furthermore, Zwahlen et al conducted a study to examine the mental health of 31 oral cancer patients and their wives. They found that 1) patients and their wives with a psychiatric diagnosis had a lower global QOL and 2) a higher marital quality in wives was associated with a higher QOL and lower rate of depression.<sup>4,34</sup> These studies imply that spouse caregivers' QOL is conversely correlated to the rate of depression in spouse caregivers of HNC patients. To the best of our knowledge, no studies have yet compared the psychological well-being and QOL between spouse caregivers and non-spouse caregivers of HNC patients. Additional studies in the future are necessary to confirm our results.

## Study strengths and limitations

The present study has several strengths, including its prospective study design, the use of a structured clinical interview by psychiatrists, and being the first study to compare psychological well-being and QOL between spouse caregivers and non-spouse caregivers of HNC patients. Nevertheless, this study also has certain limitations that need to be considered when interpreting these data. First, consecutive sampling may result in a sampling bias. Second, we recruited our samples from a general hospital, which may not be representative of the general population. Third, our sample size was relatively small, so larger and longer-term follow-up

studies with caregivers of patients with various types of cancer are needed in the future to better understand the psychological well-being and QOL between spouse caregivers and non-spouse caregivers. Fourth, we neither did evaluate the details of patients' psychological well-being, QOL, or regimen for their HNC after the baseline assessment, nor did we examine the financial status of the caregivers. Such factors may potentially be important regarding caregivers' psychological well-being and QOL.<sup>35</sup> Finally, if Bonferroni correction had been applied to adjust for multiple testing in the GEE models (Table 2), some of our significant findings (ie, depression and HADS-D) would no longer be significant, which indicates that our sample size may not be sufficient to detect differences in depression between spousal and non-spousal caregivers.

## Conclusion

Our findings suggest that depression and the mental component of QOL of spouse caregivers among HNC patients were more severe than that of non-spouse caregivers during the observed 6-month follow-up period. Clinicians should pay more attention to spouse caregivers' mental health when providing patient care.

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## Disclosure

The authors report no conflicts of interest in this work.

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