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PAPER

Sleep quality in individuals diagnosed with colorectal cancer: Factors associated with sleep disturbance as patients transition off treatment

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Abstract

Objective: To identify patient characteristics associated with sleep disturbance and worsening of sleep in individuals diagnosed with localized colorectal cancer and assess heterogeneity in these relationships.

Methods: Data were from the MY-Health study, a community-based observational study of adults diagnosed with cancer. Patient-Reported Outcomes Measurement Information System® Sleep Disturbance, Anxiety, Depression, Fatigue, and Pain Interference measures were administered. Participants self-reported demographics, comorbidities, and treatment information. Regression mixture and multiple regression models were used to evaluate the relationship between sleep disturbance and patient characteristics cross-sectionally at an average of 10 months after diagnosis (n = 613) as well as change in sleep disturbance over a 6-month period (n = 361).

Results: Pain, anxiety, fatigue, and the existence of multiple comorbid conditions had statistically significant relationships with sleep disturbance (B = 0.09, 0.22, 0.29, and 1.53, respectively; $P < 0.05$). Retirement (B = −2.49) was associated with sleep quality in the cross-sectional model. Worsening anxiety (B = 0.14) and fatigue (B = 0.20) were associated with worsening sleep disturbance, and more severe sleep disturbance 10 months after diagnosis (B = −0.21) was associated with improvement in sleep quality after diagnosis ($P < 0.05$). No evidence of latent subgroups of patients (heterogeneity) was present.

Conclusions: Pain, anxiety, fatigue, employment, and comorbid conditions were associated with sleep disturbance, but regression coefficients were small (< |2.5|). Results suggest that screening for anxiety, depression, fatigue, or pain is not sufficient for identifying sleep disturbance. Given the negative consequences of sleep disturbance, sleep disturbance screening may be warranted.

KEYWORDS

anxiety, cancer, chemotherapy, fatigue, oncology, pain, quality of life, retirement, sleep

1 | BACKGROUND

More than 1.1 million individuals in the United States (US) are currently living with colorectal cancer (CRC)[1] and, in a recent randomized trial, half of all participants with CRC reported experiencing decrements in sleep.[2] Consequences of sleep disturbance include decreased cognitive functioning,[3] fatigue,[4] loss of work productivity,[5] trouble keeping up with social activities, mood disturbance,[6] and increased visits to health professionals.[5] Sleep disturbance is also a risk factor for infectious and cardiovascular diseases.[7]

Chemotherapy, in particular, has been associated with disturbed sleep,[8] but there is little research confirming these findings in

individuals diagnosed with CRC, many of whom manage unique consequences of CRC treatment such as bowel control and stomas, as well as more general aspects of cancer and cancer treatment (eg, fatigue, anxiety, pain, nausea[9,10]), all of which have implications for sleep quality. Identifying patient-level factors associated with sleep disturbance (including worsening or improvement in sleep disturbance) may help to identify at-risk patients and facilitate symptom management of sleep disturbance and may inform the design of future randomized studies by identifying patients likely to benefit from an intervention for severe sleep disturbance.

The primary objective of this study was to identify patient, disease, and treatment characteristics associated with sleep disturbance in individuals diagnosed with stage I, II, or III CRC as they transition off treatment. We test the hypothesis that patients who were currently undergoing or had recently undergone chemotherapy would report worse sleep disturbance than patients who never had chemotherapy.

Consistent with the 3-P Behavioral Model of Sleep, the etiology and severity of sleep disturbance may vary from patient to patient.[11] Sleep disturbance may be caused by anxiety related to cancer diagnosis in 1 patient or physical symptoms such as pain or nausea in another. Therefore, the second objective was to investigate heterogeneity in the relationship between patient, disease, and treatment characteristics across levels of sleep disturbance severity and the magnitude of change in sleep disturbance after CRC diagnosis. We test the hypothesis that associations between these factors and sleep disturbance differ by *severity* of (or magnitude of change in) sleep disturbance using regression mixture models (RMMs).

2 | METHODS

2.1 | MY-Health study design

This secondary data analysis was conducted using data from Georgetown University's Measuring Your Health (MY-Health) study,[12] which included individuals diagnosed with cancer were from 1 of 4 Surveillance, Epidemiology, and End Results Program (SEER) cancer registries located in California (2), Louisiana, and New Jersey. Participants included in this secondary analysis had been diagnosed with stage I, II, or III CRC. Mail-in paper questionnaires were administered to patients twice: 10 and 17 months after diagnosis on average. The mean number of months since CRC diagnosis was 10 months (range, 5.5 to 21.3; standard deviation [SD], 1.6) and will be referred to Month 10*. At Month 10*, patients were transitioning off of cancer treatment and likely to still be experiencing the effects of treatment on quality of life. The data collected during the follow-up assessment, which was an average of 17 months after diagnosis (range, 12.8 to 26.4; SD, 2.0), represent a timepoint by which most patients had completed treatment and were experiencing less acute treatment impacts; Month 17* data. The MY-Health study oversampled black, Hispanic, and Asian patients and those under the age of 65. Details on the MY-Health study design and procedures have been published previously.[12] The MY-Health study was approved through Georgetown University's IRB (approval: 2009-436).

2.2 | Measures

2.2.1 | Dependent variable

Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance items were administered to patients at both study timepoints. PROMIS Sleep Disturbance includes a 7-day recall and measures staying asleep, getting enough sleep, restless sleep, satisfaction with sleep, refreshing sleep, and difficulty falling asleep. A custom 6-item short form was scored; the psychometric properties of the 6-item form were evaluated in individuals enrolled in the MY-Health study (Month 10* CRC sample Cronbach's $\alpha = 0.93$).[13] PROMIS Sleep Disturbance is a continuous variable scored on a T-score metric with a mean of 50 and SD of 10 based on the referent population (a mixture of clinical and the general US population),[14] with higher scores indicating worse sleep disturbance. Positive change in scores is indicative of worsening sleep. Leung et al[15] provided a cutpoint on PROMIS Sleep Disturbance indicative of clinically significant sleep disturbance (≥57 points; area under the curve, 0.92).

2.2.2 | Independent variables

The MY-Health data set contains information on patient, disease, and treatment factors associated with sleep disturbance. All information was self-reported except for age at diagnosis, sex, and diagnosis date, which were obtained via Surveillance, Epidemiology, and End Results Program registry data. Cancer treatment type (surgery,[16] chemotherapy[8]) and most recent date of treatment were categorized.[†] Four PROMIS domains were included as candidate independent variables to assess aspects of health-related quality of life (HRQOL) known to be associated with sleep disturbance[17-21]: Anxiety[22] (11 items), Depression[22] (10 items), Fatigue[23] (14 items), and Pain Interference (11 items).[22] These PROMIS measures were normed to the general US population,[14] and higher scores indicate worse anxiety, depression, fatigue, and pain interference, respectively. Nausea severity was measured using a 5-point nausea item from the FACT-G Physical Well-Being subscale[24] with a recall period of the "past 7 days" and response choices ranging from 0 = "not at all" to 4 = "very much".[‡] Other characteristics known to be associated with sleep disturbance were included in the models such as age at diagnosis,[8,25,26] sex,[27] time since diagnosis,[18] employment status,[28] comorbid conditions,[29] and an indicator for living with children under the age of 18.[28,30] Age at diagnosis and race were also included in the model to account for the oversampling of younger and minority persons.

2.2.3 | Analyses

The first set of analyses assessed data collected at Month 10*. The second set of analyses focused on *change* in sleep disturbance from the Month 10* to the Month 17* data collection (referred to as the Change analyses). Change in sleep disturbance after diagnosis was regressed on change in patient, disease, and treatment factors.

Relationships between candidate independent variables were evaluated for collinearity by calculating bivariate correlations and variance inflation factor (VIF) within multiple regression models (VIF ≥ 10). The VIF was less than 10 for PROMIS Anxiety and PROMIS Depression, but the correlation coefficient between PROMIS Anxiety and

TABLE 1 Patient characteristics at month 10*

Characteristic	Month 10* (*n* = 613)
Age at diagnosis	
Mean (SD), median, min-max	62.3 (12.3), 64.0, 22–84
Sex	
Female	323 (52.7%)
Race	
Other or multiple	163 (26.6%)
White	335 (54.6%)
Black	115 (18.8%)
Employment status	
Work	237 (38.7%)
Retired	264 (43.1%)
Unemployed or disabled	112 (18.3%)
Living status	
Live with child(ren) under 18 years old	99 (16.2%)
Number of relevant comorbidities[a]	
0	238 (38.8%)
1	163 (26.6%)
≥ 2	212 (34.6%)
Cancer stage	
I	178 (29.0%)
II	191 (31.2%)
III	244 (39.8%)
Months since most recent chemotherapy	
Never received	278 (45.4%)
Currently receiving	128 (20.9%)
1–2 months since last chemotherapy	107 (17.5%)
>2 months since last chemotherapy	100 (16.3%)
Months between most recent surgery and month 10 data collection*	
Never	53 (8.6%)
0–4 months	54 (8.8%)
More than 4 months	506 (82.5%)
Radiation	
Ever received radiation	112 (18.5%)
Months since diagnosis at month 10 data collection*	
Mean (SD), median, min-max	9.7 (1.6), 9.5, 6–21
PROMIS Sleep Disturbance T-score	
Mean (SD), median, min-max	50.6 (9.8), 51.4, 30–75
Clinically meaningful PROMIS Sleep Disturbance T-score[35]	
≥57	153 (25.0%)
PROMIS Anxiety T-score	
Mean (SD), median, min-max	49.5 (11.0), 49.6, 36–84
PROMIS Depression T-score	
Mean (SD), median, min-max	48.4 (10.7), 48.0, 36–81
PROMIS Fatigue T-score	
Mean (SD), median, min-max	52.2 (10.6), 51.8, 29–81
PROMIS Pain Interference T-score	
Mean (SD), median, min-max	53.1 (10.9), 54.9, 40–79
FACT-G Physical Well-being Nausea Item	
Mean (SD), median, min-max	0.6 (1.0), 0.0, 0–4
Survey language	
English	552 (90.0%)
Spanish	33 (5.4%)
Chinese	28 (4.8%)

Abbreviations: max, maximum; min, minimum; SD, standard deviation.

Note: Percent calculated out of non-missing responses.

[a]Includes heart failure, asthma, lung disease (eg, emphysema, chronic bronchitis, chronic obstructive pulmonary disease), joint diseases (eg, arthritis, rheumatism), anxiety, depression, stroke, mini-stroke, blood clot or bleeding in the brain, diabetes, sleep disorder, HIV or AIDS.

PROMIS Depression was strong (r = 0.87), suggesting collinearity between scores. Because anxiety is associated with disturbed sleep while depression is associated with both disturbed sleep and hypersomnia,[31] PROMIS Anxiety was included in the model and PROMIS Depression was excluded.

Regression mixture models (RMMs),[32] finite mixture models which show weighted combinations of multiple distributions (latent classes), were used to assess the relationship between sleep disturbance and other patient, disease, and treatment characteristics. Because RMMS—unlike multiple regression—do not assume that a single association pattern applies to the whole study population, they are preferable for assessing heterogeneity. When only 1 class of sleep disturbance was found, multiple regression (which assumes 1 common class of sleep disturbance and 1 common linear relationship between each independent variables and sleep disturbance) was used to model factors associated with sleep disturbance. RMMs were estimated using Dual Quasi-Newton optimization.[33] Models ranging from 1 to 4 classes were evaluated using SAS PROC FMM (SAS Institute Inc, Cary NC). The final models were chosen based on fit (smallest Bayesian Information Criterion Index [BIC] and Akaike information criterion [AIC])[34] and interpretability.

Patient attrition between survey administrations was high; factors associated with patient persistence in survey participation from Month 10* data collection to Month 17* data collection were evaluated using descriptive statistics and logistic regression. Patients who participated in both survey administrations (outcome = 1) were compared with patients who participated in the Month 10* data collection but not the Month 17 collection (outcome = 0) using logistic regression. The model included patient characteristics related to sleep disturbance and potentially associated with patient attrition.

Analysis conventions

An alpha of 0.05 or less was chosen as the criterion for statistical significance of the covariates in the models. All categorical and ordinal variables were entered in the models as dummy variables except the

nausea item which was entered as a continuous variable. Complete case analyses were conducted for all models. Analyses were performed using SAS software (SAS Institute Inc, Cary NC).

3 | RESULTS

Participant characteristics at Month 10* are presented in Table 1. Just over half of the sample had undergone chemotherapy by the first data collection (54.6%). At Month 10*, the mean PROMIS Sleep Disturbance score was similar to the average scores observed in the referent population, patients who went to sleep clinics and healthy sleepers (mean, 50.6), with 25.0% of patients classified as likely experiencing clinically significant sleep disturbance per Leung's cutpoint.

TABLE 2 RMM model fit statistics

	Month 10* Model		Change Model	
Number of Classes	BIC	AIC	BIC	AIC
1	4344.4	4251.6	2490.6	2405.0
2	4485.6	4295.6	2392.8	2217.8
3	4626.8	4339.6	2489.7	2225.2
4	4768.0	4383.6	--	--

On average, there was little improvement in mean PROMIS Sleep Disturbance scores from Month 10* to Month 17*, with a mean change of −0.1 points (Supplemental Table 1).

3.1 | RMM model fit and heterogeneity

Objective 2 (heterogeneity) was assessed first to determine the appropriate model type (RMMs or multiple regression). Table 2 presents BIC and AIC statistics for both models based on SAS-generated starting values.

For the Month 10* model, the smallest BIC and AIC were associated with the 1-class model; therefore, a multiple regression was used. Regarding the Change model, BIC and AIC were lowest for the 2-class model and the 4-class Change model did not converge. The 2-class model was uninterpretable with the smallest of the 2 classes composed of only 32 patients (out of 361). Regression coefficients for the smallest class were all statistically significant, suggesting that the smaller class modeled outliers instead of a meaningful group of patients. Therefore, a multiple regression was determined to be the most appropriate model for the Change model. Together, the model fit statistics do not provide evidence to support the hypothesis that meaningful subgroups (heterogeneity) of patient characteristics associated with different levels of sleep disturbance severity or magnitude of change in sleep disturbance were present.

TABLE 3 Relationship between sleep disturbance and patient, disease, and treatment characteristics at month 10* (n = 613)

Effect	Categories	Estimate	Standard Error	Z	P Value
Intercept		22.364	3.88	5.77	<0.0001
Months since most-recent chemotherapy treatment	Currently receiving	0.050	0.92	0.05	0.9562
	1–2 months	−1.271	0.90	−1.42	0.1558
	> 2 months	−0.219	0.92	−0.24	0.8114
	Never received	Ref	-	-	-
Months between surgery and month 10* data collection	0–4 months	0.090	1.52	0.06	0.9530
	More than 4 months	0.101	1.12	0.09	0.9276
	Never	Ref	-	-	-
Race	Black	1.094	0.83	1.32	0.1880
	Other or multiple[a]	−0.136	0.74	−0.18	0.8535
	White	Ref	-	-	-
Number of relevant comorbidities[b]	1	1.446	0.79	1.84	0.0659
	≥ 2	1.532	0.77	1.99	0.0461
	0	Ref	-	-	-
Sex	Female	0.324	0.62	0.52	0.6028
	Male	Ref	-	-	-
Live with child under 18 years old	Checked	1.050	0.92	1.14	0.2525
	Unchecked	Ref	-	-	-
Employment	Retired	−2.488	0.87	−2.85	0.0044
	Unemployed or disabled	−0.628	0.93	−0.68	0.4974
	Working full time, part time or student	Ref	-	-	-
Months between diagnosis and month 10* data collection		−0.028	0.19	−0.15	0.8836
Age at diagnosis (years)		−0.038	0.04	−1.02	0.3098
PROMIS Anxiety at month 10* data collection		0.218	0.04	5.46	<0.0001
PROMIS Fatigue at month 10* data collection		0.287	0.05	6.16	<0.0001
PROMIS Pain Interference at month 10* data collection		0.093	0.04	2.39	0.0167
FACT-G Physical Well-being Nausea item at month 10* data collection		0.067	0.41	0.16	0.8706
Variance		56.226	3.21	_	_

[a]Includes patients who categorized themselves as Asian, American Indian or Alaska Native, Asian Hawaiian or Pacific Islander, Other, or a combination of races.

[b]Includes heart failure, asthma, lung disease, joint diseases, anxiety, depression, stroke, mini-stroke, blood clot or bleeding in the brain, diabetes, sleep disorder, HIV, or AIDS.

3.2 | Month 10* model

Table 3 presents the results of the Month 10* multiple regression model addressing objective 1. The chemotherapy hypothesis was not supported; the relationship between chemotherapy and sleep disturbance was not statistically significant. Being diagnosed with 2 or more relevant comorbid conditions, anxiety, fatigue, or pain interference was found to be statistically significantly related to sleep disturbance. Retirement was associated with quality sleep.

3.3 | Change model

The chemotherapy hypothesis was not supported; the relationship between chemotherapy and sleep disturbance was also not statistically significant in the change model. Also addressing objective 1, worsening anxiety and fatigue and PROMIS Sleep Disturbance at Month 10* were statistically significant in the Change model (Table 4). The negative coefficient on PROMIS Sleep Disturbance at Month 10* indicates that poorer sleepers at Month 10* had greater improvement in sleep from Month 10* to Month 17* data collection.

3.4 | Patient attrition

Retirement (OR = 1.6) was associated with continued participation in the survey, and identification as non-white, non-black, or multiple races (OR = 0.63) was associated with patient attrition/missing responses (OR = 0.53) (Supplemental Table 2).

4 | DISCUSSION

In this large sample of patients with CRC, a quarter of the sample likely experienced clinically meaningful sleep disturbance at an average of 10 months after CRC diagnosis.[35] The Month 10 RMM analyses showed that there were no latent classes driving the relationship between sleep disturbance and other patient, disease, and treatment characteristics. Statistically significant factors related to sleep disturbance in the Month 10 model were 2 or more comorbid conditions, non-retirees, anxiety, pain interference, and fatigue.

Average change in sleep disturbance from Month 10* to Month 17* hovered around 0 change. Multiple classes were not found in the Change analyses, supporting the notion that correlates of sleep disturbance do not vary by magnitude of change in sleep disturbance. However, change scores ranged from 25-point improvement to 19-point worsening, highlighting the variability of patients' experiences with sleep disturbance as they transition off treatment. The Change analyses show that poorer sleepers at Month 10* had greater improvement in sleep disturbance from Month 10* to Month 17* data collection. These results are important for future clinical trial research because

TABLE 4 Relationship between change in sleep disturbance and change in patient, disease, and treatment factors at month 17* (n = 361)

Effect	Categories	Estimate	Standard Error	Z	P Value
Intercept		10.385	4.91	2.11	0.0345
Months since most-recent chemotherapy treatment	Currently receiving	1.480	1.76	0.84	0.3994
	1–2 months	0.710	1.80	0.40	0.6928
	> 2 months	−0.064	0.75	−0.09	0.9321
	Never received	Ref	-	-	-
Months between surgery month 17 data collection	0–4 months	−1.714	1.77	−0.97	0.3339
	More than 4 months	0.042	1.25	0.03	0.9729
	Never	Ref	-	-	-
Race	Black	−0.192	0.92	−0.21	0.8341
	Other or multiple[a]	−0.295	0.90	−0.33	0.7420
	White	Ref	-	-	-
Number of relevant comorbidities[b]	1	1.591	0.88	1.82	0.0694
	≥ 2	−0.074	0.85	−0.09	0.9306
	0	Ref	-	-	-
Sex	Female	−0.166	0.68	−0.24	0.8075
	Male	Ref	-	-	-
Live with child under 18 years old	Checked	−0.729	1.11	−0.66	0.5121
	Unchecked	Ref	-	-	-
Employment	Retired	−0.578	0.96	−0.60	0.5482
	Unemployed or disabled	−0.440	1.12	−0.39	0.6944
	Worked full time, part time or student	Ref	-	-	-
Months between diagnosis and month 17 data collection		0.091	0.17	0.53	0.5956
Age at diagnosis (years)		−0.018	0.05	−0.38	0.7026
PROMIS Anxiety change		0.135	0.04	3.07	0.0021
PROMIS Fatigue change		0.203	0.05	4.17	<0.0001
PROMIS Pain Interference change		−0.025	0.04	−0.62	0.5358
FACT-G Physical Well-being Nausea item change		0.100	0.40	0.25	0.8049
PROMIS Sleep Disturbance at month 10*		−0.209	0.04	−5.59	<0.0001
Variance		40.544	3.02	_	_

[a]Includes patients who categorized themselves as Asian, American Indian or Alaska Native, Asian Hawaiian or Pacific Islander, Other, or a combination of races.

[b]Includes heart failure, asthma, lung disease, joint diseases, anxiety, depression, stroke, mini-stroke, blood clot or bleeding in the brain, diabetes, sleep disorder, HIV, or AIDS.

they suggest that some patients will improve more than others based on the quality of their sleep disturbance as they transition off treatment.

Although previous research has shown detrimental effects of cancer treatment on sleep,[25] the results of our analyses did not support this finding in patients transitioning off of CRC treatment. It is possible that the factors driving sleep disturbance due to treatment are already included in the model, such as pain interference and fatigue. It is also possible that more significant longitudinal changes in sleep disturbance occur for patients with CRC at different timepoints than those assessed in this study. Future research should evaluate sleep disturbance at different points during the survivorship trajectory to provide a clearer picture of what patients may experience, allowing clinicians to anticipate and prepare patients for sleep disturbance issues.

4.1 | Clinical implications

Results of these analyses show a link between sleep disturbance and anxiety, depression, fatigue, and pain interference at Month 10*. Interestingly, the correlation coefficients on the HRQOL-related variables were small, suggesting that although there was a statistically significant relationship between sleep disturbance and other aspects of HRQOL, screening for or treating clinically significant anxiety, depression, fatigue, or pain may not facilitate the identification or improvement of sleep disturbance. Although sleep disturbance is prevalent in patients with cancer, most individuals diagnosed with cancer do not discuss sleep difficulties with their clinicians.[36] These results suggest that screening for sleep disturbance may be warranted, supporting recommendations from Clinical Practice Guidelines in Oncology.[37]

4.2 | Limitations

Relationships among anxiety, depression, pain interference, fatigue, and sleep disturbance may be bidirectional and endogeneity limits the conclusions that can be drawn from regression analyses to *associations* instead of *causation*. Another limitation of this study was patient attrition between data collections. Minorities were less likely to participate in the follow-up survey, and retirees were more likely to participate in both study data collections. Sleep management interventions (eg, use of sleep aids) were not captured in the patient survey, introducing possible bias in the models.

Although lab-based sleep measures are considered the gold standard, they may not adequately characterize sleep disturbances at home or sleep disturbances over time.[7] PROMIS Sleep Disturbance underwent rigorous development and psychometric evaluation.[6,13,22,38] By utilizing PROMIS Sleep Disturbance, a larger sample of patients with CRC was assessed than would have been possible with lab-based measures. As a community-based observational study, the MY-Health data provided information on experiences from a very diverse sample of patients who were evaluated during the course of usual care.

Future analyses should evaluate factors associated with clinically significant sleep disturbance at various timepoints throughout patients' survivorship.

5 | CONCLUSION

The results of this study confirm relationships between sleep disturbance and other aspects of HRQOL found in studies evaluating other cancer sites.[16,18-21,39] Results suggest that knowledge of clinically significant anxiety, depression, fatigue, or pain may not be sufficient for identifying and improving sleep disturbance in patients with CRC. Given the negative consequences of sleep disturbance on health outcomes, sleep disturbance screening may be warranted in individuals diagnosed with CRC.

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NOTES

† Categories were based on relevant physical recovery periods post-treatment and data availability: Currently receiving chemotherapy, 1 to 2 months since chemotherapy, >2 months since chemotherapy, never received chemotherapy.

‡ Although the nausea item has not been psychometrically evaluated as a single measure of nausea, the entire FACT-G PWB scale, which has been evaluated extensively in cancer patients, covers concepts that overlap with PROMIS measures such as Pain Interference and Fatigue. Therefore, only the nausea item was included in the models as a continuous variable.

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SUPPORTING INFORMATION

Additional Supporting Information including supplemental tables may be found online in the supporting information tab for this article.

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