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ORIGINAL RESEARCH

Prevalence of Insomnia and Related Factors Among Cancer Outpatients in China

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Background: The incidence of insomnia in cancer patients is significantly higher than in the general population. Chronic insomnia imposes pronounced physical and psychological burdens on cancer patients, affecting their quality of life and survival rate. This study aims to investigate insomnia in cancer patients and further analyze potentially related factors.

Methods: Oncology outpatients treated at Fudan University Shanghai Cancer Center were consecutively recruited. Demographic information and clinical features, such as type of cancer and treatment status, were collected. Insomnia was assessed using the Insomnia Severity Index (ISI).

Results: A total of 146 patients participated in the study, with the majority suffering from breast tumors (40.4%), gastrointestinal tract tumors (18.5%), and endocrine tumors (5.8%). Among these patients, 25 (17.1%) did not report insomnia, 69 (47.3%) had subclinical insomnia, and 52 (35.6%) reached the level of clinical insomnia. Older patients aged 41–50 years (Estimate = −3.49, 95% CI, −6.99 to 0.00, p = 0.05) and those with higher education levels (Estimate = −2.72, 95% CI, −4.88 to −0.55, p = 0.01) were less likely to have higher ISI total scores. In contrast, undergoing chemotherapy (Estimate = 3.86, 95% CI, 0.53 to 7.19, p = 0.02) was associated with higher ISI total scores. Gender, age, education, treatment modalities correlated with ISI subitem scores.

Conclusion: The prevalence of insomnia is higher in oncology patients and is associated with gender, age, education, tumor type, and treatment modality. Screening and interventions for insomnia should be emphasized in the whole-course management of oncology patients.

Keywords: cancer, outpatient, treatment, insomnia, insomnia severity index

Introduction

Cancer is one of the leading causes of death in the Chinese population and a main economic burden of Chinese patients.[1] Adequate sleep is essential for a better quality of life; however, 29–75% of cancer patients suffer from insomnia.[2–5] The course of the disease and cancer treatments, such as chemotherapy, radiotherapy, and surgery, negatively impact individuals' physical and psychological status; thus, sleep disturbances plague patients throughout the course of the disease and treatment. Research suggests that the incidence of sleep disorders in cancer patients ranks second in the oncology symptom groups, right after cancer fatigue.[6] Chronic sleep problems lead to poor surgical wound recovery, increased chances of tumor recurrence, cognitive function impairment, substance abuse, and increased healthcare cost.[7] Insomnia in oncology settings remains insufficiently assessed and managed despite its high prevalence and long-term persistence without a specific treatment. Therefore, understanding the influencing factors of insomnia is essential to guide effective management strategies. In this study, we investigated the insomnia of outpatients at Fudan University Shanghai Cancer Center to determine the influencing factors and enhance the whole-course comprehensive management to improve the life quality of cancer patients.

Subjects and Methods

Subjects

Outpatient cancer patients were randomly selected from Fudan University Shanghai Cancer Center between October 2021 and March 2022. Participants were recruited by members of the research team, who provided written information outlining the

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study's objectives, procedures, voluntary participation, and confidentiality assurances. All participants signed informed consent forms before completing the questionnaire. To ensure confidentiality, all responses were anonymized, and patients' identity information was not disclosed to anyone outside the research team. Eligibility criteria included a cancer diagnosis, normal cognitive function, and voluntary participation in the survey. Exclusion criteria included patients with a severe cognitive or mental disorder who could not complete the questionnaire. These disorders were assessed by a psychiatrist using the International Classification of Diseases, 10th Revision (ICD-10) diagnostic criteria. The evaluation was based on a review of medical history and a clinical examination.

Instrument

The questionnaire included demographic information such as gender, age, and education level. Clinical characteristics such as type of tumor, treatment status, and insomnia status (as assessed by the Insomnia Severity Index, ISI) were collected by trained research staff who were part of the study team. These staff members ensured the accuracy and consistency of data collection through standardized procedures. ISI is a brief self-report tool that measures patients' perceptions of their insomnia. This questionnaire consists of seven items that assess patients' difficulty falling asleep and staying asleep, waking up too early, satisfaction with current sleep patterns, disturbance to daily functioning, impairment perception, and distress or worry associated with sleep problems. Each item is rated on a five-point Likert scale of 0 to 4, with a total score range of 0 to 28. Patients with higher scores indicate more severe insomnia and are categorized as follows: no clinically significant insomnia (0–7), which reflects normal sleep patterns without significant insomnia symptoms; subclinical insomnia (8–14), which indicates the presence of insomnia symptoms but at a mild level that does not significantly impair daily functioning; and clinical insomnia (≥15), which represents moderate to severe insomnia that impacts daily functioning and requires further intervention.[8–10] ISI has an internal consistency of 0.7 or higher and is a reliable and valid tool for screening and assessing insomnia severity, displaying great sensitivity to treatment.

Statistical Methods

Data from this study were analyzed by the "Statistical Program for Social Sciences" (SPSS) 22.0 version. The minimum required sample size was calculated using the single-proportion sample size formula, based on an estimated insomnia prevalence of 60%, a margin of error of 10%, and a 95% confidence level. This calculation indicated that at least 93 participants were needed. Categorical variables between groups were examined using the chi-square test. We then conducted linear regression analyses, treating the ISI total score and subitems as dependent variables, while demographic information and clinical characteristics were included in the model as independent variables. Statistical tests were two-sided, and p-values <0.05 indicated significance.

Results

Demographic and Clinical Factors Associated with the Severity of Insomnia

Among the 152 patients initially screened, 6 were excluded due to undetermined tumor diagnosis, leaving 146 participants eligible for the study. The majority of participants were women (78.7%, n = 105), with more in the 50+ age group (34.9%). In addition, 25 (17.1%) of the patients who did not report insomnia, 69 (47.3%) had subclinical insomnia, and 52 (35.6%) reached the level of clinical insomnia. The severity of insomnia was higher in women compared to men ($p < 0.01$). Regarding cancer types, 59 patients had breast cancer, 27 had gastrointestinal tract tumors, 8 had endocrine tumors, and 52 had other types of tumors. The level of insomnia varied significantly among patients with different cancer types ($p = 0.01$), as detailed in Table 1.

Regression Analysis of Factors Influencing ISI Scores and Subitems

Linear regression analysis was conducted to explore associations between patients' demographic and clinical characteristics with the ISI total score and its subitems. Significant findings are detailed in Tables 2 and 3, while a heatmap visualizing β values and their significance for all ISI subitems is presented in Figure 1. For the ISI total score, older patients aged 41–50 years (Estimate = −3.49, $p = 0.05$, 95% CI = −6.99 to 0.00) and patients with higher education levels

Table 1 Univariate Analysis of Factors Affecting the Severity of Insomnia in Cancer Patients

		Without Insomnia	Subclinical Insomnia	Clinical Insomnia	Cardina-lity	*p*
Influencing factors [n (%)]						
Gender	Men	11 (35.5)	14 (45.2)	6 (19.4)	10.70	<0.01
	Women	14 (12.2)	55 (47.8)	46 (40.0)		
Age (years)	<30	3 (13.0)	10 (43.5)	10 (43.5)	4.00	0.68
	31–40	6 (19.4)	17 (54.8)	8 (25.8)		
	41–50	6 (14.6)	22 (53.7)	13 (31.7)		
	>50	10 (19.6)	20 (39.2)	21 (41.2)		
Educational level	High School or less	10 (13.3)	33 (44.0)	32 (42.7)	3.79	0.15
	College or above	15 (21.1)	36 (50.7)	20 (28.2)		
Cancer type	Breast cancer	4 (6.8)	31 (52.5)	24 (40.7)	11.61	0.02
	Digestive tract cancer	9 (33 0.3)	10 (37.0)	8 (29.7)		
	Endocrine cancer	2 (25.0)	2 (25.0)	4 (50.0)		
	Others	10 (19.2)	26 (50.0)	16 (30.8)		
Prior surgery	Yes	14 (14.7)	41 (43.2)	40 (42.1)	5.08	0.07
	No	11 (21.6)	28 (54.9)	12 (23.5)		
Prior chemotherapy	Yes	7 (10.0)	34 (48.6)	29 (41.4)	5.30	0.07
	No	18 (23.7)	35 (46.1)	23 (30.3)		
Prior radiotherapy	Yes	3 (9.7)	12 (38.7)	16 (51.6)	4.71	0.09
	No	22 (19.1)	57 (49.6)	36 (31.3)		
Prior immunotherapy	Yes	1 (8.3)	7 (58.3)	4 (33.3)	0.94	0.62
	No	24 (17.9)	62 (46.3)	48 (35.8)		
Prior targeted therapy	Yes	1 (5.3)	9 (47.4)	9 (47.4)	2.64	0.26
	No	24 (18.9)	60 (47.2)	43 (33.9)		
Prior treatment	No	11 (27.5)	21 (52.5)	8 (20.0)	7.74	0.10
	Monotherapy	4 (11.1)	17 (47.2)	15 (41.7)		
	Combination therapy	10 (14.3)	31 (44.3)	29 (41.4)		
Perioperative period	Yes	7 (29.2)	11 (45.8)	6 (25.0)	3.35	0.18
	No	18 (14.8)	58 (47.5)	46 (37.7)		
Undergoing chemotherapy	Yes	3 (10.3)	12 (41.4)	14 (48.3)	2.86	0.23
	No	22 (18.8)	57 (48.7)	38 (32.5)		
Undergoing radiotherapy	Yes	2 (20.0)	3 (30.0)	5 (50.0)	1.35	0.50
	No	23 (16.9)	66 (48.5)	47 (34.6)		
Undergoing immunotherapy	Yes	2 (15.4)	6 (46.2)	5 (38.5)	0.61	0.97
	No	23 (17.3)	63 (47.4)	47 (35.3)		
Undergoing targeted therapy	Yes	1 (9.1)	4 (36.4)	6 (54.5)	1.94	0.37
	No	24 (17.8)	65 (48.1)	46 (34.1)		
Undergoing treatment	No	14 (18.2)	36 (46.8)	27 (35.1)	6.13	0.19
	Monotherapy	7 (13.0)	30 (55.6)	17 (31 5)		
	Combination therapy	4 (26.7)	3 (20.0)	8 (53.3)		

Notes: n: frequencies; *p*: p-values (2-tailed).

(Estimate = −2.72, p = 0.01, 95% CI = −4.88 to −0.55), reported lower scores. In contrast, undergoing chemotherapy was associated with higher scores (Estimate = 3.86, p = 0.02, 95% CI = 0.53 to 7.19).

For difficulty falling asleep (ISI-1), older age groups such as 31–40 years (Estimate = −0.74, p = 0.02, 95% CI = −1.34 to −0.13), 41–50 years (Estimate = −1.05, p < 0.01, 95% CI = −1.65 to −0.44), >50 years (Estimate = −0.72, p = 0.02, 95% CI = −1.30 to −0.31), as well as patients with higher education levels (Estimate = −0.47, p = 0.01, 95% CI =−0.85 to −0.10), were protective factors, while a history of prior surgery was associated with higher scores (Estimate = 0.71, p = 0.01, 95% CI = 0.16 to 1.26). For difficulty staying asleep (ISI-2), higher education levels (Estimate = −0.39, p = 0.03, 95% CI = −0.74 to −0.05) and the perioperative period (Estimate = −0.49, p = 0.05, 95% CI = −0.99 to −0.00) were protective, whereas prior radiotherapy was

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Table 2 Linear Regression Analysis of ISI Sub-Items and Total Score with Demographic and Clinical Factors

Variables		ISI-1			ISI-2			ISI-3			ISI-4		
		E	p	95% CI	E	p	95% CI	E	p	95% CI	E	P	95% CI
Gender (vs Women)	**Men**	−0.27	0.28	(−0.78, 0.23)	−0.17	0.48	(−0.63, 0.30)	−0.09	0.73	(−0.60, 0.42)	−0.04	0.87	(−0.55, 0.46)
Age (vs <30)	**31–40**	−0.74	0.02*	(−1.34, −0.13)	−0.44	0.12	(−0.99, 0.12)	0.11	0.71	(−0.50, 0.72)	−0.57	0.06	(−1.18, 0.03)
	41–50	−1.05	0.00*	(−1.65, −0.44)	−0.20	0.47	(−0.76, 0.35)	−0.02	0.96	(−0.63, 0.59)	−0.60	0.05*	(−1.21, 0.00)
	>50	−0.72	0.02*	(−1.30, −0.13)	−0.09	0.75	(−0.63, 0.46)	0.51	0.09	(−0.09, 1.10)	−0.68	0.02*	(−1.27, −0.09)
Educational level (vs High School or less)	**College or above**	−0.47	0.01*	(−0.85, −0.10)	−0.39	0.03*	(−0.74, −0.05)	−0.46	0.02*	(−0.84, −0.08)	−0.47	0.01*	(−0.85, −0.09)
Cancer type (vs Breast cancer)	**Digestive tract cancer**	−0.38	0.21	(−0.99, 0.22)	−0.46	0.11	(−1.01, 0.10)	−0.43	0.16	(−1.04, 0.18)	−0.43	0.16	(−1.04, 0.17)
	Endocrine cancer	−0.06	0.89	(−0.92, 0.80)	0.27	0.49	(−0.52, 1.06)	0.26	0.56	(−0.61, 1.12)	−0.12	0.79	(−0.98, 0.75)
	Others	0.16	0.53	(−0.35, 0.67)	0.02	0.92	(−0.44, 0.49)	0.01	0.97	(−0.50, 0.52)	−0.17	0.50	(−0.68, 0.34)
Prior surgery (vs No)	**Yes**	0.71	0.01*	(0.16, 1.26)	0.35	0.17	(−0.15, 0.85)	0.28	0.31	(−0.27, 0.83)	0.12	0.67	(−0.43, 0.67)
Prior chemotherapy (vs No)	**Yes**	0.18	0.54	(−0.41, 0.78)	0.23	0.42	(−0.32, 0.78)	0.40	0.19	(−0.2, 1.00)	0.05	0.86	(−0.55, 0.65)
Prior radiotherapy (vs No)	**Yes**	0.46	0.10	(−0.09, 1.02)	0.64	0.01*	(0.13, 1.15)	0.18	0.52	(−0.38, 0.74)	0.13	0.65	(−0.43, 0.69)
Prior immunotherapy (vs No)	**Yes**	0.55	0.19	(−0.27, 1.37)	0.45	0.24	(−0.30, 1.20)	0.09	0.83	(−0.74, 0.91)	0.34	0.41	(−0.48, 1.16)
Prior targeted therapy (vs No)	**Yes**	−0.29	0.46	(−1.08, 0.49)	0.01	0.99	(−0.72, 0.73)	0.16	0.68	(−0.63, 0.95)	0.15	0.71	(−0.64, 0.93)
Prior treatment (vs No)	**Combination therapy**	−0.42	0.28	(−1.17, 0.34)	−0.52	0.14	(−1.22, 0.17)	−0.34	0.38	(−1.10, 0.42)	0.04	0.92	(−0.72, 0.80)
Perioperative period (vs No)	**Yes**	−0.17	0.53	(−0.71, 0.37)	−0.49	0.05*	(−0.99, −0.00)	0.20	0.46	(−0.34, 0.75)	0.00	0.99	(−0.54, 0.54)
Undergoing chemotherapy (vs No)	**Yes**	0.39	0.18	(−0.19, 0.96)	0.37	0.18	(−0.16, 0.89)	0.48	0.11	(−0.10, 1.06)	0.56	0.06	(−0.02, 1.14)
Undergoing radiotherapy (vs No)	**Yes**	−0.08	0.86	(−0.9, 0.75)	−0.15	0.71	(−0.90, 0.61)	0.41	0.33	(−0.42, 1.25)	0.33	0.44	(−0.50, 1.15)
Undergoing immunotherapy (vs No)	**Yes**	−0.46	0.28	(−1.29, 0.38)	−0.30	0.43	(−1.07, 0.46)	−0.01	0.99	(−0.85, 0.83)	−0.38	0.37	(−1.22, 0.45)
Undergoing targeted therapy (vs No)	**Yes**	0.42	0.37	(−0.51, 1.35)	0.37	0.39	(−0.48, 1.23)	0.04	0.94	(−0.90, 0.98)	0.26	0.58	(−0.67, 1.20)
Undergoing treatment (vs No)	**Combination therapy**	−0.20	0.67	(−1.11, 0.72)	0.14	0.74	(−0.70, 0.99)	−0.20	0.68	(−1.12, 0.73)	−0.40	0.39	(−1.32, 0.52)

Notes: *: p-value<0.05.

Abbreviations: ISI, Insomnia Severity Index; CI, confidence interval; E, estimate; p, p-values (2-tailed),

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Table 3 Linear Regression Analysis of ISI Sub-Items and Total Score with Demographic and Clinical Factors

Variables		ISI-5			ISI-6			ISI-7			ISI-total		
		E	p	95% CI	E	p	95% CI	E	p	95% CI	E	p	95% CI
Gender (vs Women)	**Men**	−0.48	0.05*	(−0.97, 0.00)	−0.01	0.97	(−0.51, 0.49)	−0.20	0.47	(−0.74, 0.34)	−1.26	0.39	(−4.17, 1.65)
Age (vs <30)	**31–40**	−0.44	0.15	(−1.03, 0.15)	−0.05	0.86	(−0.65, 0.55)	−0.50	0.13	(−1.15, 0.15)	−2.62	0.14	(−6.12, 0.88)
	41–50	−0.76	0.01*	(−1.35, −0.17)	−0.31	0.31	(−0.91, 0.29)	−0.55	0.09	(−1.2, 0.10)	−3.49	0.05*	(−6.99, 0.00)
	>50	−0.47	0.11	(−1.05, 0.1)	−0.18	0.55	(−0.76, 0.41)	−0.50	0.12	(−1.14, 0.13)	−2.13	0.22	(−5.53, 1.28)
Educational level (vs High School or less)	**College or above**	−0.27	0.15	(−0.63, 0.1)	−0.40	0.04*	(−0.77, −0.03)	−0.26	0.21	(−0.66, 0.14)	−2.72	0.01*	(−4.88, −0.55)
Cancer type (vs Breast cancer)	**Digestive tract cancer**	−0.20	0.50	(−0.79, 0.39)	−0.33	0.27	(−0.93, 0.27)	−0.50	0.13	(−1.15, 0.15)	−2.74	0.12	(−6.25, 0.77)
	Endocrine cancer	−0.16	0.71	(−1, 0.68)	0.63	0.14	(−0.22, 1.49)	0.67	0.15	(−0.25, 1.59)	1.50	0.55	(−3.47, 6.48)
	Others	0.35	0.16	(−0.14, 0.85)	0.10	0.70	(−0.40, 0.60)	0.17	0.53	(−0.37, 0.72)	0.65	0.66	(−2.29, 3.58)
Prior surgery (vs No)	**Yes**	0.36	0.18	(−0.17, 0.89)	0.38	0.17	(−0.16, 0.92)	0.47	0.12	(−0.12, 1.05)	2.67	0.10	(−0.49, 5.83)
Prior chemotherapy (vs No)	**Yes**	0.01	0.97	(−0.57, 0.6)	−0.21	0.48	(−0.80, 0.38)	0.04	0.91	(−0.6, 0.68)	0.70	0.69	(−2.76, 4.16)
Prior radiotherapy (vs No)	**Yes**	0.36	0.19	(−0.18, 0.91)	0.46	0.10	(−0.09, 1.01)	0.45	0.13	(−0.14, 1.05)	2.69	0.10	(−0.53, 5.91)
Prior immunotherapy (vs No)	**Yes**	−0.07	0.87	(−0.86, 0.73)	0.36	0.38	(−0.45, 1.17)	0.33	0.45	(−0.54, 1.21)	2.06	0.39	(−2.67, 6.79)
Prior targeted therapy (vs No)	**Yes**	0.02	0.95	(−0.74, 0.79)	−0.22	0.58	(−1.00, 0.56)	0.58	0.17	(−0.26, 1.42)	0.42	0.86	(−4.12, 4.95)
Prior treatment (vs No)	**Combination therapy**	−0.32	0.39	(−1.06, 0.42)	−0.16	0.67	(−0.91, 0.59)	−0.36	0.38	(−1.17, 0.45)	−2.08	0.35	(−6.45, 2.29)
Perioperative period (vs No)	**Yes**	−0.39	0.15	(−0.91, 0.14)	−0.50	0.06	(−1.04, 0.03)	−0.14	0.64	(−0.72, 0.44)	−1.50	0.34	(−4.62, 1.62)
Undergoing chemotherapy (vs No)	**Yes**	0.56	0.05*	(0.00, 1.13)	0.61	0.04*	(0.04, 1.18)	0.90	0.00*	(0.29, 1.52)	3.86	0.02*	(0.53, 7.19)
Undergoing radiotherapy (vs No)	**Yes**	−0.12	0.77	(−0.93, 0.69)	−0.13	0.75	(−0.95, 0.69)	0.28	0.53	(−0.6, 1.17)	0.55	0.82	(−4.22, 5.32)
Undergoing immunotherapy (vs No)	**Yes**	−0.12	0.76	(−0.94, 0.69)	−0.30	0.47	(−1.13, 0.53)	−0.10	0.83	(−0.99, 0.79)	−1.67	0.49	(−6.49, 3.15)
Undergoing targeted therapy (vs No)	**Yes**	0.25	0.59	(−0.66, 1.15)	0.03	0.95	(−0.89, 0.95)	−0.45	0.37	(−1.45, 0.54)	0.92	0.74	(−4.46, 6.29)
Undergoing treatment (vs No)	**Combination therapy**	−0.11	0.81	(−1, 0.79)	0.00	0.99	(−0.91, 0.91)	−0.35	0.48	(−1.33, 0.63)	−1.12	0.68	(−6.42, 4.19)

Notes: *: p-value<0.05.

Abbreviations: ISI, Insomnia Severity Index; CI, confidence interval; E, estimate; p, p-values (2-tailed),

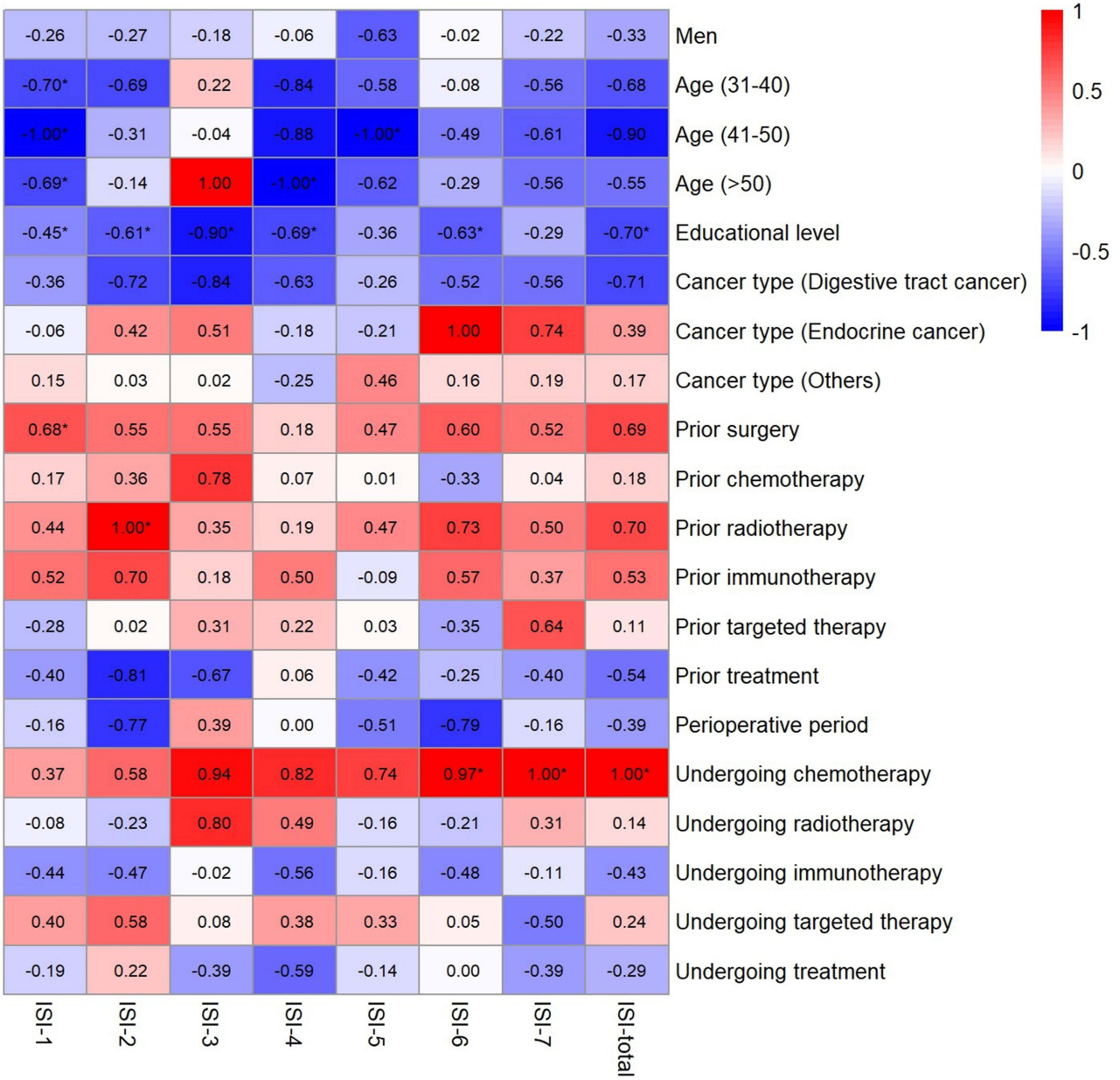

Figure 1 Heatmap of Regression Coefficients (β Values) for Influencing Factors Across ISI Subitems and Total Scores. ISI: Insomnia Severity Index. The heatmap shows β values from linear regression analyses, with ISI subitems on the horizontal axis and influencing factors on the vertical axis. Red represents positive β values, blue represents negative values, and darker shades indicate stronger effects. Asterisks (*) mark significant associations ($p \leq 0.05$).

linked to higher scores (Estimate = 0.64, p = 0.01, 95% CI = 0.13 to 1.15). For waking up too early (ISI-3), patients with higher education levels scored lower (Estimate = −0.46, p = 0.02, 95% CI = −0.84 to −0.08).

For sleep dissatisfaction (ISI-4), older patients aged 41–50 years (Estimate = −0.60, p = 0.05, 95% CI = −1.21 to 0.00) and >50 years (Estimate = −0.68, p = 0.02, 95% CI = −1.27 to −0.09), as well as those with higher education levels (Estimate = −0.47, p = 0.01, 95% CI = −0.85 to −0.09), reported lower scores. For interference with daily functioning (ISI-5), men (Estimate = −0.48, p = 0.05, 95% CI = −0.97 to −0.00) and patients aged 41–50 years (Estimate = −0.76, p = 0.01, 95% CI = −1.35 to −0.17) reported lower scores, while undergoing chemotherapy was associated with higher scores (Estimate = 0.56, p = 0.05, 95% CI = 0.00 to 1.13). For detriment to life quality (ISI-6), higher education levels (Estimate = −0.40, p = 0.04, 95% CI = −0.77 to −0.03) were protective, whereas undergoing chemotherapy was positively

correlated (Estimate = 0.61, p = 0.04, 95% CI = 0.04 to 1.18). For feelings of distress (ISI-7), undergoing chemotherapy was a significant risk factor (Estimate = 0.90, p< 0.01, 95% CI = 0.29 to 1.52).

Discussion

This study found a high prevalence of insomnia among cancer outpatients, with 47.3% of participants experiencing subthreshold insomnia and 35.6% suffering from clinical insomnia. Insomnia was associated with demographic factors, such as gender and education level, and clinical factors, such as tumor type and treatment modality. Women, patients undergoing chemotherapy or radiotherapy, and those with lower education levels were particularly vulnerable to severe insomnia. These findings align with previous research highlighting the significant burden of sleep disturbances among cancer patients.

Considering the high prevalence and complexity of insomnia, a reliable and practical assessment tool is crucial for its accurate identification and management. There are many advantages to adopting ISI as an insomnia assessment scale in this study. First, the ISI is a validated and reliable tool for detecting insomnia across both general and clinical populations, including cancer patients. Its brevity, consisting of only seven questions, makes it convenient for participants to complete, especially in outpatient settings. Additionally, the ISI focuses on patients' subjective perceptions, aligning well with the goal of screening for insomnia severity and prevalence in cancer patients.[11] The prevalence observed in this study is comparable to the 59.9% average reported in previous ISI-based studies, though slight variations may arise due to differing cutoff scores.[4] For instance, while some studies have suggested a threshold score of 8 to maximize sensitivity and specificity,[12] Morin et al recommended a cutoff score of 11 for distinguishing clinical insomnia in cancer patients.[10] These findings underscore the necessity of adopting practical and validated tools like the ISI to address insomnia effectively in clinical practice.

While the ISI was chosen for its practicality and suitability in this study, alternative tools, such as the Pittsburgh Sleep Quality Index (PSQI), measure broader aspects of sleep disturbances, including somnolence and circadian rhythm disorders. However, given its longer format and multiple dimensions, the PSQI was not considered practical for this study's focus on insomnia in outpatient cancer patients.[13] Similarly, semi-structured interviews or objective assessments like polysomnography (PSG) offer high diagnostic accuracy but are resource-intensive and not feasible for brief outpatient screenings. These tools could be explored in future studies to complement subjective measures and validate clinical findings.[14]

Similar to the general population, women were at a higher risk of developing insomnia among cancer patients, while higher education served as a protective factor.[15] Women's greater susceptibility to insomnia, especially in breast or gynecologic cancers under treatment, may be linked to hormonal fluctuations. Altered vagal regulation and dysregulated cortisol rhythms in women with metastatic breast cancer have been strongly associated with sleep disruptions.[16] In contrast, lower levels of education may imply less awareness of the disease, affordability, and acceptance of mood and sleep interventions, thus increasing the incidence of insomnia. Most studies have suggested that physiological variations and changes in the sleep phase in older people contribute to the high prevalence of sleep disorders. Although age was not associated with overall insomnia in this study, younger patients were more likely to have difficulty falling asleep, felt dissatisfied with sleep quality, and reported less interference with daily functioning.[17] A similar conclusion was drawn in a follow-up study of postoperative patients with lung cancer. Researchers found a higher incidence of sleep disorders in younger patients, possibly associated with higher family and social stress and a more significant burden of symptoms.[18,19]

In terms of molecular mechanisms, the activation of the hypothalamic-pituitary-adrenal axis in tumor patients leads to the massive production of glucocorticoids. Upregulation of interleukin 1 beta (IL-1 b), interleukin 6 (IL-6), tumor necrosis factor-alpha (TNF-a), and dysregulation of serotonin, dopamine, gamma-aminobutyric acid, norepinephrine, and downregulation of melatonin play essential roles in the development of sleep disorders.[20,21] Additionally, different types of tumors have distinct effects on insomnia. Some studies have suggested that the prevalence of insomnia is the highest among breast tumors, possibly due to the decrease in estrogen levels after endocrine therapy such as aromatase inhibitors, which increases susceptibility to hot flashes and joint pain, inhibiting sleep.[22,23] Recent findings further reveal that breast cancer patients frequently experience coexisting sleep disorders, such as obstructive sleep apnea, highlighting the need for proactive sleep symptom screening in this population.[24] Similarly, In endometrial cancer survivors, biobehavioral

factors like mood disturbances, pain, and fatigue significantly predict insomnia, highlighting the multifactorial nature of sleep disturbances and the role of psychological and physical stressors across cancers.[25]

In this study, we found that insomnia was correlated with tumor category in univariate analysis. However, this factor was excluded in the multiple regression model. In addition, patients with GI tract tumors scored lower in most ISI subitems, which could be attributed to gender effect, since all patients with breast tumors were women and most patients with GI tract tumors were men ($p < 0.01$). However, Insomnia has also been studied in colorectal cancer survivors, where disrupted diurnal rest-activity rhythms (RAR) were found to correlate with persistent insomnia and reduced quality of life up to five years post-treatment.[26]

Aside from breast cancer, insomnia has been reported with notable prevalence among lung cancer patients in previous studies, likely due to the disease's direct impact on the respiratory system and associated psychological burden.[27] Similarly, patients with head and neck tumors have also been observed to experience insomnia, though less prominently.[28] Furthermore, prior research has indicated that insufficient or excessive sleep duration, insomnia symptoms, and evening chronotype significantly predict an increased risk of developing lung cancer, suggesting a complex interplay between sleep disturbances and cancer pathophysiology.[29] However, in our study, the small number of participants with lung and head and neck tumors did not provide sufficient data to support similar findings.

In addition to the type of tumor, the treatments patients received also significantly influenced sleep. Our study suggests that patients receiving any cancer treatments are prone to insomnia, especially after surgery, radiotherapy, and chemotherapy. These treatments may impair all aspects of sleep. It has also been suggested that the more types of treatment a patient receives, the more severe insomnia can become, which is consistent with our findings.[30] Prolonged chemotherapy will impair nocturnal melatonin secretion, and insomnia symptoms are particularly prevalent and persistent during the first two cycles of chemotherapy, with rates significantly higher than those in the general population.[31,32] In addition, adverse effects such as pain, nausea, and fatigue that develop during radiotherapy contribute to a significant reduction in total sleep time, decreased sleep efficiency, and prolonged sleep latency.[33] Another study found that cancer patients are prone to developing insomnia in the perioperative period due to stress, pain, and the different surgical procedures they choose. Patients also have chronic insomnia after surgery or during the recovery process of anti-cancer treatment that requires excessive bed rest.[34] Nevertheless, perioperative oncology patients scored lower on ISI subitems in this study, possibly associated with feeling relaxed after completing the surgery. The same result was found in Josée et al's research.[35] There was no correlation between immunotherapy and insomnia in this study, potentially due to the limited representation of patients in this treatment group. Yet some investigators have suggested that immunotherapy may cause insomnia in cancer patients by impairing thyroid function. Moreover, recent evidence highlights that sleep and circadian rhythm disturbances during immunotherapy may stem from immune-mediated adverse events and disruptions in the tumor microenvironment, impacting patient quality of life and treatment outcomes.[36] The drug toxicity of targeted therapies may also impair sleep quality, which has been less studied and should be considered by clinicians.

Even though insomnia is a common symptom among oncology patients, anti-cancer treatment often takes precedence in research and clinical practice. Additionally, the understanding of sleep-related disorders among healthcare professionals tends to be empirical rather than evidence-based. This can lead to insufficient awareness of the condition and a lack of motivation for follow-up treatment by both healthcare providers and patient.[37] Therefore, screening and monitoring of sleep status should be routinely incorporated into the clinical management of cancer patients. Standardized assessment instruments and normative processes should be applied, along with systematic training for oncologists and nurses. Given the demanding nature of clinical work, intelligent systems could provide significant assistance. Patients could undergo screening for insomnia and other psychological issues through electronic devices under the guidance of artificial intelligence, which would assess the severity and report the findings to healthcare providers for further action.[38,39] In addition to assessing insomnia prevalence and related factors, patients in this study were offered sleep hygiene tips and informed about available medical resources to address their sleep issues.

Comprehensive management approaches are also critical to addressing insomnia in cancer patients. Pharmacological interventions may follow treatment principles for the general population, including the use of benzodiazepines, benzodiazepine receptor agonists, low-dose sedating antidepressants, and orexin receptor antagonists.[9] However, in cancer patients, special considerations must be given to potential drug-drug interactions and physical conditions, such as the presence of respiratory suppression, delirium, or impaired liver and kidney function. Non-pharmacological interventions should prioritize

cognitive-behavioral therapy for insomnia (CBT-I) as the first-line treatment, given its strong evidence base and efficacy.[40] Additional complementary approaches, such as light therapy and exercise interventions have also demonstrated benefits in improving sleep quality in cancer patients.[41]

Participants in this study were outpatients at Fudan University Shanghai Cancer Center, resulting in a relatively small and limited sample size. Further, this was a cross-sectional survey of voluntary participants, lacking a control group or follow-up studies. Demographic information, including economic status, was incomplete, and clinical data lacked details on tumor stage, past sleep history, and prevalence of depression and anxiety. These limitations may have introduced potential confounding biases. Despite these constraints, our study contributes to the growing body of evidence on insomnia in oncology patients and highlights the need for more comprehensive assessments in future research.

Conclusion

In conclusion, this study highlights the high prevalence of insomnia among oncology patients, with significant associations identified between insomnia and demographic factors such as gender and education level, as well as clinical and treatment-related factors. Despite its high prevalence, insomnia remains underrecognized and inadequately managed in oncology settings. Routine screening and timely interventions are essential, with tools like the ISI offering a practical and effective option for assessment.

This study underscores the importance of integrating insomnia management into cancer care through pharmacological and non-pharmacological approaches such as CBT-I and light therapy. Although limited by a small sample size and cross-sectional design, the findings provide valuable insights into cancer-related insomnia. Future research with larger, longitudinal studies is needed to refine interventions and improve quality of life and treatment outcomes for patients.

Data Sharing Statement

The original contributions presented in the study are included in the article files, further inquiries can be directed to the corresponding author.

Ethical Approval Statement

Ethics approval was obtained from Medical Ethics Committee, Fudan University Shanghai Cancer Center (Approval No. 2112247-5), and informed consent was obtained from the study participants prior to study commencement. The study was conducted in accordance with the principles of the Declaration of Helsinki.

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Disclosure

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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