Supportive Care in Cancer (2019) 27:3777–3783
https://doi.org/10.1007/s00520-019-4662-2

ORIGINAL ARTICLE

Screening for clinical insomnia in cancer patients with the Edmonton Symptom Assessment System-Revised: a specific sleep item is needed

Josée Savard [1,2,3] · Hans Ivers [1,2,3]

Received: 10 September 2018 / Accepted: 16 January 2019 / Published online: 4 February 2019

Abstract

Objective We previously investigated the capacity of the original version of the Edmonton Symptom Assessment System-Revised (ESAS-r) and the Canadian Problem Checklist (CPP) to screen for clinical levels of insomnia in cancer patients. The original ESAS-r includes an item assessing drowsiness and an "other symptom" item, both of which are rated on a scale from 0 to 10, while the CPC has a sleep item, a box which is checked when this problem is present. Because none of these items showed an optimal screening capacity, we concluded that it would be best to add a specific 0–10 sleep item to the ESAS-r. This study assessed the capacity of this ESAS-r-sleep item to screen for clinical insomnia in patients with various cancer types.

Methods A total of 392 patients with mixed cancer sites completed the ESAS-r as part of a routine screening procedure implemented in the radio-oncology department of L'Hôtel-Dieu de Québec (CHU de Québec-Université Laval). They also filled out the Insomnia Severity Index (ISI).

Results Using a score of 8 or greater on the ISI as the standard criterion for clinical insomnia, a score of 2 or higher on the ESAS-r-sleep item (50.8% of the patients) was the one that showed the best screening indices: sensitivity of 86.7%, specificity of 75.3%, positive predictive value of 71.9%, and negative predictive value of 88.6%. An area under the curve of 0.89 was found, which is excellent.

Conclusions Adding a sleep item to the ESAS significantly improves screening of clinical insomnia in cancer patients.

Keywords Insomnia · Sleep · Screening · Tiredness · Fatigue · Cancer · ROC

Background

Insomnia is among the most prevalent psychological problems experienced by cancer patients. Studies evaluating several cancer symptoms have revealed that sleep disturbance was the first or at least among the first three burdensome symptoms reported by the patients [1–4]. A large-scale epidemiological study ($N = 962$) by our group showed that between 30 and 60% of patients had insomnia symptoms, a rate that included those meeting the criteria for an insomnia syndrome (from 21 to 28%), as assessed using a semi-structured interview [5, 6]. When left untreated, which is far too common, insomnia tends to become chronic especially at the syndrome level [6].

Despite the high prevalence of insomnia and its persistence, too often this problem is overlooked in routine care. Indeed, sleep disturbances are typically underdiagnosed and, as a consequence, undertreated [7, 8]. Sleep impairments tend to be trivialized both by patients and health care providers often because of the belief that these difficulties will fade away by themselves or will remit through the beneficial effect of a more general intervention [7, 8]. In addition, although patients believe that sleep problems should be better addressed, they are reluctant to report them to their oncology team because they do not want to complain and because they think they will only be prescribed sleeping pills anyway [9]. On their end, cancer care providers often do not ask about the sleep of their patients and are unaware of effective

✉ Josée Savard
josee.savard@psy.ulaval.ca

[1] School of Psychology, Université Laval, Québec, Canada

[2] CHU de Québec-Université Laval Research Center, Québec, Canada

[3] Université Laval Cancer Research Center, Québec, Canada

alternatives to hypnotic pharmacological agents [7, 8]. Yet, insomnia is associated with an array of negative impacts such as an increased risk for psychological disorders (e.g., depressive and anxiety disorders), impaired quality of life, a greater risk for infections, and a greater utilization of health care services, all of which being extremely costly for society [7, 10, 11].

Actively screening for insomnia on a routine basis is an essential first step to ensure that it is appropriately dealt with and in order to prevent such consequences. Systematic screening for psychological distress has become a standard of care in several countries around the world [12, 13]. In Canada, the Edmonton Symptom Assessment System-Revised (ESAS-r) [14] and the Canadian Problem Checklist (CPC) [15, 16] are used along with the *Distress Thermometer* [17, 18] to screen for psychological distress and other psychological, physical, practical, information, and spiritual issues that cancer patients may experience.

Unfortunately, the original version of the ESAS-r includes no specific insomnia item. Given this, the pan-Canadian practice guidelines on sleep disturbances in cancer patients [19] recommended using the "other problem" item of the ESAS-r, rated on a "0" to "10" scale, or a positive answer on the CPC-sleep item for screening purposes. We recently conducted a study to assess the capacity of these two items to screen for insomnia using a score of 8 or greater on the *Insomnia Severity Index* (ISI) as the standard criterion [20]. Results showed that the ESAS-r-other problem item was ineffective to detect clinical levels of insomnia since none of the patients used this item to report their sleep difficulties. With regard to the CPC-sleep item, a box that can be checked if the problem is present, it was associated with a sensitivity of only 60.4% (specificity of 89.6%). This result may be, at least partly, attributable to the lack of discrimination of such a dichotomous assessment as compared to a Likert scale that better takes into account individual differences on the symptom severity. The ESAS-r also contains an item assessing drowsiness (0 to 10 scale). Although drowsiness can sometimes be a consequence of insomnia, this symptom is more specific to other sleep disorders (e.g., obstructive sleep apnea) and could be due to some medications (e.g., opioids). Not surprisingly, a sensitivity of only 61.5% (specificity of 75.4%) was found using a score of 2 or higher on this item in the same study [20]. A screening test should detect the largest number of possible cases, while providing the lowest false-positive rate [21]. Although no general rule exists of acceptable values for sensitivity and specificity, a screening test that misses nearly 40% of the patients likely to have the condition of interest obviously falls short this objective.

Alternatives used by other teams [22–24] are to replace the ESAS-other symptom item with a specific sleep item or to simply add a sleep item to the scale [23]. In the study by Hannon et al., it was found that a version of the ESAS-r which added a sleep item (along with an item assessing constipation) in outpatients with advanced cancer was valid and reliable [23]. To our knowledge, only the investigation by Delgado-Guay et al. [22] conducted in 101 patients with advanced cancer assessed the screening capacity of the ESAS-r-sleep item. They found that a score of 3 or greater on that item was associated with a sensitivity of 74% (specificity = 73%) to detect significant sleep disturbances, as determined by a score of 5 or greater on the Pittsburgh Sleep Quality Index (PSQI). Given that advanced cancer may influence the nature and severity of sleep disturbances [25], it is important to assess the extent to which the ESAS-r-sleep item makes it possible to detect insomnia specifically in patients with early-stage cancer and to determine the best cutoff score to use in that context.

The goal of this study was to assess the capacity of the ESAS-r-sleep item to screen for clinical insomnia in patients with various types of early-stage cancer. Because the ESAS-r also assesses tiredness, a common consequence of insomnia, the capacity of that item to screen for clinical insomnia was also ascertained.[1] It was hypothesized that the sleep item would lead to a more specific screening for insomnia, i.e., a significantly greater screening capacity than that of the tiredness item.

Methods

Participants

Participants were patients who were screened for psychological distress, from February to September 2017, as part of routine care in the radio-oncology department of L'Hôtel-Dieu de Québec (CHU de Québec-Université Laval). A total of 411 patients completed screening and provided us written consent to use their data, of whom 19 had incomplete data, leaving a sample of 392 participants (94.7%). The main participants' characteristics are presented in Table 1. The mean age was 62.1 years old, and 63.3% were females. The most common cancer type was breast cancer (49.2%). All participants were currently receiving radiotherapy. Comparisons on demographics and medical data between included ($n = 392$) and excluded ($n = 19$) participants revealed no significant differences on age (62.1 vs. 64.0 years old, $t(380) = 0.79$, $p = .43$), sex

[1] We are indebted to Dr. Barry Bultz for suggesting that we make this comparison.

Table 1 Participants' characteristics ($N = 392$)

Variables	% (*n*)	*M* (SD)
Age ($n = 360$)		62.1 (10.6)
Sex		
Female	63.3% (248)	
Male	36.7% (144)	
Cancer site		
Breast	49.2% (193)	
Prostate	16.3% (64)	
Head/neck	10.0% (39)	
Lung	3.8% (15)	
Digestive	7.9% (31)	
Other	12.8% (50)	
Cancer stage ($n = 205$)		
Localized	84.4% (173)	
Locoregional	15.6% (32)	

(63.3% of women vs. 63.6%, $\chi^2(1) = 0.01$, $p = .97$), cancer stage (localized 84.4% vs. 100.0%, $\chi^2(1) = 1.83$, $p = .18$), and cancer site (breast cancer 49.2% vs. 31.8%, $\chi^2(1) = 2.53$, $p = .11$; prostate cancer 16.3% vs. 27.3%, $\chi^2(1) = 1.78$, $p = .18$).

Measures

The health care professional (e.g., nurse, radio-oncology technologist) who administered the screening tool provided some demographic and medical information (i.e., age, sex, cancer site, cancer stage) on a form accompanying the study measures.

Edmonton Symptom Assessment System-Revised [14] The ESAS-r was originally designed to assess the severity of nine symptoms that are common in patients with advanced cancer (pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, lack of well-being, shortness of breath). It also contains an "other symptom" item. Respondents rate their symptoms on a numerical scale ranging from 0 (absence) to 10 (severe). The ESAS-r is the most commonly used screening tool in Canada [26], and its psychometric properties are well established, particularly in the context of palliative care [27–29]. Two items were assessed for their screening capacity in this study: the tiredness and sleep items. The tiredness item ranges from 0 (not tired) to 10 (worst possible tiredness). The sleep item that was added for the purpose of this study in replacement of the other symptom item was the one used by other authors [22–24]; it ranges from 0 (no trouble sleeping) to 10 (worst possible sleep).

Insomnia Severity Index [30] The ISI includes seven items that evaluate the perceived severity of (a) difficulties falling asleep, (b) difficulties maintaining sleep, (c) early morning awakenings, (d) the degree of dissatisfaction with current sleep, (e) the degree to which sleep difficulties interfere with daytime functioning, (f) the degree to which others notice the deterioration of functioning related to the sleep problem, and (g) the level of distress or worry caused by the sleep difficulties. The five-point Likert scale ranges from 0 (not at all) to 4 (extremely), for a total score ranging from 0 to 28 [31]. The French-Canadian version of the ISI was empirically validated among cancer patients [32], with psychometric properties similar to those found in the general population [30]. A cutoff score of 8 or greater was found to indicate the presence of clinical levels of insomnia in cancer patients [32], the criterion that was used as the gold standard in this study.

Procedure

Patients were administered the ESAS-r as part of their routine care. We did not have any control over when the measures were completed, nor access to this information, but they are usually given while patients are receiving their radiotherapy regimen in the department where the study was conducted. For the purpose of this study, the ISI was added and was always second in the package. Patients also had to fill in a brief informed consent form in which they were asked if they agreed that their data be shared with our research team. This study was approved by the research ethics committee of the CHU de Québec-Université Laval.

Statistical analyses

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were computed using 2×2 frequency tables for each criterion. Sensitivity was defined as the rate of patients with an ISI score ≥ 8 and scoring positively on a specific ESAS-r criterion, whereas specificity was the proportion of patients with an ISI score < 8 and scoring negatively on a specific ESAS-r criterion. The PPV corresponded to the rate of participants scoring positively on a specific ESAS-r criterion and having an ISI score ≥ 8, while the NPV was the proportion of patients scoring negatively on a specific ESAS-r criterion and having an ISI score < 8. In addition, to estimate the overall screening capacity of each criterion, (a) all four indices were averaged and (b) the trapezoidal area under each ROC curve (AUC) and its 95% confidence interval were computed using SAS 9.4 PROC LOGISTIC (SAS Institute, 2014).

Results

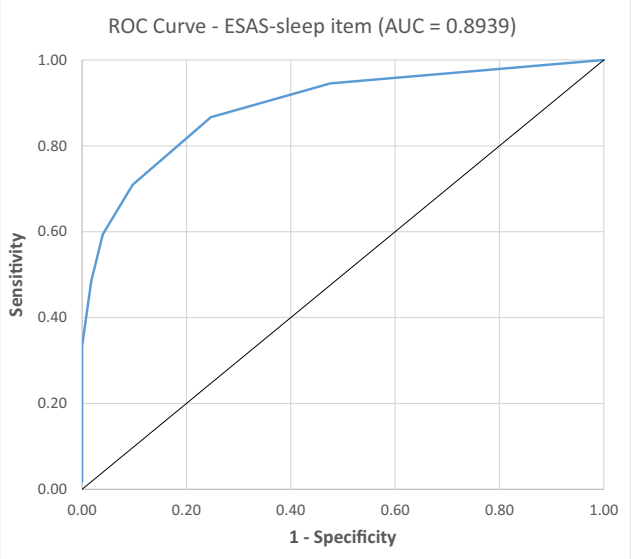
Descriptive statistics

Participants reported an average score of 2.36 (SD = 2.59; range 0–10) on the ESAS-r-sleep item, 3.63 (SD = 2.55; range 0–10) on the ESAS-r-tiredness item, and 7.31 on the ISI (SD = 5.95, range 0–25). Overall, 42.1% (n = 165) of the participants had an ISI score exceeding the clinical cutoff score (≥ 8).

Screening capacity of ESAS items

ESAS-r-sleep item The ROC curve analysis revealed an AUC of 0.894, 95% confidence interval (CI) = 0.862–0.926 (see Fig. 1a). Table 2 shows the sensitivity, specificity, PPV, and NPV values obtained for each possible score on the ESAS-r-sleep item. A score of 2 or greater appears to be ideal for screening purposes with its high sensitivity (86.7%) and very good specificity (75.3%).

ESAS-r-tiredness item An AUC of 0.718, 95% CI = 0.668–0.768, was obtained. When looking at Fig. 1b, it is obvious that the ROC curve has a far from ideal shape. Indeed, the curve is rather flat and remains close to the diagonal which corresponds to a screening capacity no better than random. To obtain a sensitivity that is comparable to the one associated with a score of 2 or greater on the ESAS-r-sleep item, a score of 2 or greater on the ESAS-r-tiredness appears the best (see Table 2). It was associated with a sensitivity of 90.3%, but with a very low specificity of 33.9%.



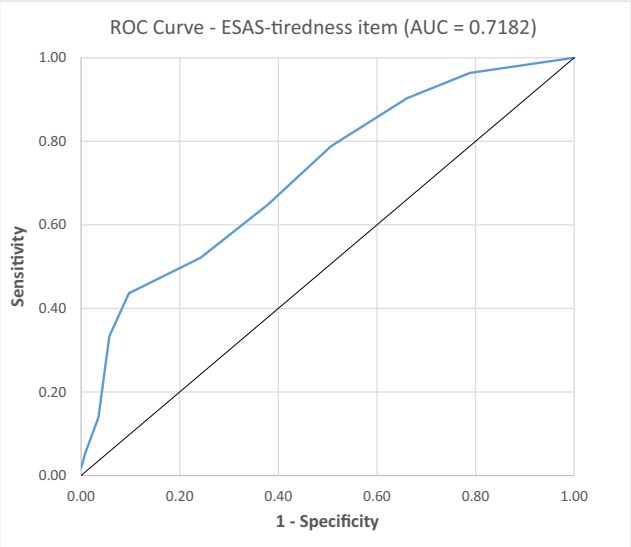


Fig. 1 **a** ROC curve obtained for the ESAS-sleep item. **b** ROC curve obtained for the ESAS-tiredness item

Conclusions

The goals of this study were to evaluate the capacity of the ESAS-r-sleep item to screen for clinical insomnia in patients with early-stage cancer and to compare it to the screening capacity of the ESAS-r-tiredness item. As hypothesized, the ESAS-r-sleep item proved to be superior to the ESAS-r-tiredness item, thus indicating that the former constitutes a more specific and effective screening tool for insomnia.

The AUC that we found for the ESAS-r-sleep item of 0.89 is excellent and much greater than the one we obtained previously for the ESAS-r-drowsiness item (0.69) and the CPC sleep item (0.75) [33]. It is also much better than the AUC of 0.72 obtained for the ESAS-r-tiredness item in the current study. Together, this suggests that not only is the ESAS-r-sleep item an excellent tool to detect clinical insomnia in patients with early-stage cancer, but it also provides a specific screening.

In terms of the best cutoff score to use, the answer to this question is always somewhat subjective. It depends on the purpose of the assessment. When a tool is used to perform a first screening of a given problem, which will be followed by a more in-depth assessment to confirm its presence, sensitivity should be prioritized over specificity. The goal is then to identify as many patients as possible who are likely to have the problem and to avoid as much as possible missing real cases. For that reason, we suggest using a score of 2 or greater on the ESAS-r-sleep item to perform a first screening, which yielded a high sensitivity of 86.7% and a very good specificity (75.3%). This differs from the recommendation by Delgago-Guay et al. [22] to use a score of 3 or greater on that item

Table 2 Screening capacity of ESAS-sleep and ESAS-tiredness items

Score	Rate[a] (%)	Sensitivity	Specificity	PPV	NPV	Mean[b]
ESAS-sleep item						
≥0	100.0%	100.0%	0.0%	42.1%	–	35.5%
≥1	67.3%	94.5%	52.4%	59.1%	93.0%	74.8%
≥2	50.8%	86.7%	75.3%	71.9%	88.6%	80.6%
≥3	35.5%	70.9%	90.3%	84.2%	81.0%	81.6%
≥4	27.3%	59.4%	96.0%	91.6%	76.5%	80.9%
≥5	21.4%	48.5%	98.2%	95.2%	72.4%	78.6%
≥6	14.0%	33.3%	100.0%	100.0%	67.4%	75.2%
≥7	9.7%	23.0%	100.0%	100.0%	64.1%	71.8%
≥8	6.9%	16.4%	100.0%	100.0%	62.2%	69.6%
≥9	2.8%	6.7%	100.0%	100.0%	59.6%	66.6%
≥10	0.8%	1.8%	100.0%	100.0%	58.4%	65.0%
ESAS-tiredness item						
≥0	100.0%	100.0%	0.0%	42.1%	–	35.5%
≥1	86.2%	96.4%	21.1%	47.0%	88.9%	63.4%
≥2	76.3%	90.3%	33.9%	49.8%	82.8%	64.2%
≥3	62.5%	78.8%	49.3%	53.1%	76.2%	64.3%
≥4	49.2%	64.8%	62.1%	55.4%	70.9%	63.3%
≥5	36.0%	52.1%	75.8%	61.0%	68.5%	64.4%
≥6	24.0%	43.6%	90.3%	76.6%	68.8%	69.8%
≥7	17.3%	33.3%	94.3%	80.9%	66.0%	68.6%
≥8	7.9%	13.9%	96.5%	74.2%	60.7%	61.3%
≥9	2.8%	5.5%	99.1%	81.8%	59.1%	61.4%
≥10	0.8%	1.8%	100.0%	100.0%	58.4%	65.0%

[a] The percentage of patients meeting each criterion

[b] The overall discriminative index is computed as the arithmetic mean of sensitivity, specificity, PPV, and NPV values

(sensitivity of 74% and specificity of 73%). Interestingly, in their study, a score of 2 or greater on the ESAS-r-sleep item was associated with a similar sensitivity to that of the current study (86%) but with a much lower specificity (53%). This difference may be due to the population they investigated, i.e., patients with advanced cancer, but may also be attributable to their use of PSQI scores as their standard criterion. Compared to the ISI that evaluates insomnia specifically, the PSQI provides a more general measure of sleep disturbances. Alternatively, a score of 3 or greater on the ESAS-r-sleep item could also be used if one wishes to attain a higher degree of certainty that insomnia is really present (sensitivity of 70.9% and specificity of 90.3%). But it is important to keep in mind that, in that case, nearly 30% of possible cases would be missed.

The poor performance of the ESAS-r-tiredness item also deserves some comments. Fatigue is a well-known consequence of sleep difficulties, and it is often the main complaint of patients with insomnia and the reason why they seek treatments [34, 35]. However, there is some evidence showing that, while there is a high correlation between insomnia and fatigue in cancer patients, fatigue predicts increased insomnia more frequently than insomnia predicts augmentations in fatigue [33]. Cancer-related fatigue is a complex condition that has a multifactorial etiology involving both biological and psychosocial/behavioral factors [36–38]. Hence, while fatigue is an important correlate of insomnia, it is a poor, too unspecific indicator when it comes to screening for insomnia.

Strengths and limitations

The conduct of the study directly in the clinic, rather than with research volunteers, increases its external validity. The fairly large number of participants is another strength. The most important limitation of this investigation is that the screening tool was compared to the ISI, a self-report scale of insomnia severity. Although the ISI was found to be reliable, valid, and able to detect clinical insomnia in the context of cancer [32], the gold standard measure to which a screening tool should be compared is a clinical interview assessing specific diagnostic criteria (e.g., DSM-5 [39]).

Clinical implications

In light of the results of this report and those of our previous study [33], we strongly recommend that cancer centers using the ESAS-r as a screening tool for psychological distress now add a sleep item to it. Making this change will allow clinicians to better detect insomnia in their patients, a problem that unfortunately remains overlooked in clinical care. An effective screening for insomnia is the necessary initial step towards a better management of this disorder. The addition of a sleep item to the ESAS can also be extremely useful for research purposes, for instance, to identify potential participants for clinical trials on cancer-related insomnia. In order to avoid any confusion, we also suggest giving a different name to the ESAS-r when adding a sleep item, that is, the Edmonton Symptom Assessment System-Revised-Sleep (ESAS-r-S).[2]

[2] We are indebted to Dr. Cheryl Nekolaichuk for suggesting this.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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