It is illegal to post this copyrighted PDF on any website. Use of Sleep Aids in Insomnia:

The Role of Time Monitoring Behavior

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ABSTRACT

Objective: Over-the-counter (OTC) and prescription sleep medications are frequently used as treatments for chronic insomnia, despite risks and limited long-term efficacy. Investigating mechanisms underlying this predilection for pharmacotherapy may uncover strategies to decrease reliance on sleep aids. The objective of this study was to determine how time monitoring behavior (TMB; clock-watching) and associated frustration may interact with insomnia symptoms to drive the use of sleep aids.

Methods: Patients (N = 4,886) presenting for care at a communitybased, private sleep medical center between May 2003 and October 2013 completed the Insomnia Severity Index (ISI) and Time Monitoring Behavior-10 (TMB-10) and reported their frequency of sleep medication use (OTC and prescription, separately). Mediation analyses examined how clock-watching and related frustration could be associated with insomnia symptoms and medication use.

Results: The relationship between TMB and sleep medication use was significantly explained by ISI (P < .05), in that TMB (especially related frustration) appears to aggravate insomnia, which in turn leads to sleep aid use. Similarly, but to a lesser extent, the relationship between ISI and sleep medication use was explained by TMB, in that ISI may lead to increased TMB, which may in turn lead to sleep aid use.

Conclusions: TMB and the associated frustration it engenders may perpetuate a negative cycle of insomnia and sleep aid use. Future longitudinal and interventional research is necessary to examine the developmental course of these clinical symptoms and behaviors and to test whether decreasing frustration by limiting TMB reduces the proclivity for pharmacotherapy.

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*Corresponding author: Barry Krakow, MD, 211 Early St, Savannah, GA 31405 (bkrakow@sleeptreatment.com). I nsomnia is a common disorder affecting 3.9%–22.1% of adults.¹ Beyond nighttime symptoms and daytime impairment, insomnia is associated with long-term health problems, including cardiovascular disease,^{2,3} diabetes,² depression,^{4,5} acute myocardial infarction,⁶ and increased mortality risks.⁷ Treatment guidelines recommend cognitive-behavioral therapy for insomnia (CBT-I) for adult chronic insomnia.^{8,9} However, barriers persist in accessing CBT-I,^{10,11} especially compared to sleep aids.

Recent evidence demonstrates serious risks with the use of prescription and over-the-counter (OTC) sleep aids.¹²⁻¹⁹ OTC antihistamine risks include cognitive decline¹² and possibly dementia.¹³ Further concerns associated with prescription sleep aids include cognitive impairment,²⁰ dementia,¹⁴ Alzheimer's disease,¹⁵ cancer,¹⁶ psychiatric disorders,¹⁷ and mortality.^{18,21} Despite these troubling observations, use of sleep aids remains high.¹⁹

While tolerance to sedative effects of diphenhydramine (most common OTC sleep aid) emerges after 3 days,²² prescription sleep aids have demonstrated efficacy in reducing nighttime insomnia symptoms for 12 months or longer.²³ Thus, it is no surprise that prescribing rates of benzodiazepines for insomnia remained stable from 2003 to 2015, with 1 in 4 medical visits for insomnia resulting in a prescription.¹⁹ Notwithstanding, approximately half of patients with insomnia taking prescription sleep aids do not attain remission.²⁴ Accordingly, many patients using prescription or OTC medications may be eager and willing to discontinue these drugs, and so research examining modifiable behavioral risk factors to reduce sleep aid use may prove useful. Time monitoring behavior (TMB) is one such factor.

TMB, clock-watching during periods of sleeplessness, is common among individuals with insomnia.^{25–27} TMB appears as an effort to predict or control sleep duration, arising from the unpredictability and fear of sleep loss. Clock-watching may offer a temporary sense of control through mental calculations about lost sleep or sleep still to be achieved. Though no prospective research exists on the developmental origins of TMB, both theory and clinical experience suggest ways in which clock-watching may arise during insomnia episodes. For example, the 3P (predisposing, precipitating, perpetuating) model of insomnia posits specific responses to sleep loss perpetuate chronic insomnia,²⁸ while the attention-intention-effort model suggests attempts to control sleep cause or exacerbate insomnia.²⁹

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Clinical Points

- Time monitoring behavior (TMB) is linked to insomnia severity.
- Because of its influence on insomnia severity, TMB, and especially the frustration it causes, may amplify demand for sleeping pills.
- TMB may negatively influence efforts to discontinue sleeping pills.
- Simple behavioral steps (remove bedroom timepieces) or targeted psychotherapy (address frustration response) may potentially alleviate adverse TMB effects on insomnia symptoms and on sedative/hypnotic use.

TMB is probably an adaptive short-term response, allowing one to compensate for sleep loss by hoping for more sleep through planning, usually to extend time in bed, based on knowing the time of night. This can be a precise analysis, for example, "If I can fall back asleep within 15 minutes, reset my alarm by 30 minutes, I can still gain 60 more minutes of sleep, but if ..." and so on.²⁶ This clock-watching and mental arithmetic directly aggravate sleeplessness by spending time engaged in stressful waking activities instead of sleeping.

The behavior results in additional negative consequences-reinforcing the belief that self-initiation of sleep is impossible and promoting psychophysiologic conditioning³⁰ by creating frustration about sleep loss. Frustration may then aggravate sleeplessness,³¹ perpetuating more TMB and frustration, a cycle known as "losing sleep over losing sleep."²⁶ This emotional response may explain more about how TMB adversely influences insomnia and use of sleep aids than the actual act of clock-watching or arithmetic calculations in bed.

As frustration fuels greater sleep loss, sleep aids may be used to gain control over sleep and break this cycle. Taking a hypnotic allows a patient to relax and thereby promote sleep^{32,33}; however, continued TMB and efforts to force sleep could counteract hypnotic effects or natural sleepiness.²⁹ Worse, despite the variable range of benefits that sleeping pills provide, discontinuing hypnotics can result in rebound insomnia.³⁴ While this exacerbation of insomnia may last just 1 or 2 nights,³⁵ it may aggravate TMB and the cycle of losing sleep over losing sleep. With no alternative means to initiate or return to sleep, resumption of sleep medications may be immediate.

Vochem et al³⁶ examined a sample of treatment-seeking insomnia patients compared to a cohort of good sleepers and demonstrated a significant correlation between greater scores on the Time Monitoring Behavior-10 (TMB-10) scale and worse insomnia severity, without examining sleep aid use. Another work evaluated TMB in a large group of patients with mixed sleep disorders presenting to a sleep medical center.²⁵ Among those reporting clinically meaningful posttraumatic stress symptoms, more severe TMB, associated frustration, and insomnia were noted compared to those with minimal or no posttraumatic stress symptoms,²⁵ a salient finding as sleep disturbance is a core

diagnoses.38

Sleep disturbance in psychiatric disorders requires special attention, as (1) insomnia is a very common residual symptom following pharmacologic and psychological treatments for major depressive disorder,³⁹ (2) insomnia is a risk factor for relapse in alcohol use disorder,⁴⁰ and (3) nocturnal wakefulness is associated with risk of suicide.⁴¹ Further underscoring the importance of TMB to insomnia comorbid with psychiatric disorders, such patients receive more prescriptions for benzodiazepines,¹⁹ and their insomnia is less likely to remit with medications compared to patients without psychiatric comorbidities.24

In the current study, we used a large sample of patients with mixed sleep disorders to examine the relationship between TMB, insomnia symptoms, and use of sleep aids. In addition to examining whether TMB was associated with sleep aid use, we investigated how TMB and insomnia symptoms may together influence use. We hypothesized TMB would aggravate insomnia severity, leading to increased use of sleep aids.

METHODS

Participants

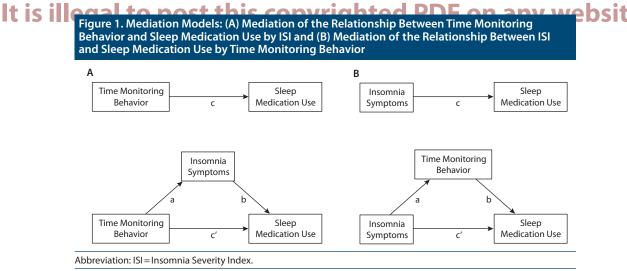
This retrospective chart review was conducted for patients presenting at Maimonides Sleep Arts & Sciences, Ltd (MSAS), a community-based, private sleep medical center in Albuquerque, New Mexico, between May 2003 and October 2013. The University of Arizona Institutional Review Board determined this research exempt from further human subject review. As per standard MSAS protocol, all patients provided written consent for their medical information to be used anonymously for research purposes. All patients completed online questionnaires regarding sleep and medical history. The sample comprised 4,886 patients at least 18 years of age who completed the questionnaires.

Measurements

All data were extracted from questionnaires. Prevalence of an insomnia complaint was based on a single question asking whether patients reported this sleep problem and for how long. Patients were also asked whether they had psychiatric disorders. Medication use frequency was reported on a scale from 0 (rarely/never) to 5 (nightly) in response to "How often do you use prescription medication to help you sleep?" The same scale assessed frequency of non-prescription or natural remedies to help with sleep. To compare frequency, weekly or greater use of sleep medication was classified as regular use. For the mediation analyses, the full scale was used as a continuous variable.

The Insomnia Severity Index (ISI), a validated measure of insomnia symptoms,⁴² quantified insomnia symptom severity. The ISI is a 7-item scale with higher scores indicating greater symptom severity (score range, 0-28).

The TMB-10²⁵ is a 10-item measure of TMB and related frustrations. The 10 items evaluate both TMB engaged



in before sleep onset (sleep onset insomnia) and during nocturnal awakenings (sleep maintenance insomnia). For each period, (sleep initiation and sleep maintenance), 2 questions assess behavior, and 3 questions assess associated frustration. The TMB-10 has a range of 0–30, with higher scores indicating greater TMB and associated frustration. Prior research⁴³ found that the TMB-10 can be split into 3 factors: behavior (TMB-BX: actual clock-watching and mental calculations), sleep onset frustration (TMB-SOF), and sleep maintenance frustration (TMB-SMF).

For additional analysis, chronic insomnia disorder was defined by insomnia symptoms of at least moderate severity (ISI > 14), with insomnia-related daytime impairment (ISI item $5 \ge 1$) and a minimum of 3 months duration, which is consistent with current nosologies.^{44,45}

Data Analysis

To characterize how TMB (and aspects thereof) and insomnia symptom severity may influence one another with regard to medication use, a series of mediation analyses were conducted, depicted graphically in Figure 1. Each analysis compared a direct path between independent and dependent variables (IV and DV, respectively) to an indirect path that included a mediator. The indirect path was tested for statistical significance using bootstrapping.⁴⁶ Full mediation occurred if the direct path was not statistically significant after controlling for the indirect path; otherwise, partial mediation was judged to have occurred.47 Full mediation suggests that the mediator may be able to fully explain the relationship between IV and DV. Partial mediation suggests that the relationship between IV and DV cannot be fully explained by the mediator; a direct relationship remains between the IV and DV. The proportion of mediation (PM) is an estimate of the percent of the total path that could be accounted for by the indirect path; it may exceed 1.0 depending on the relationship between the direct path between IV and DV and the total relationship between IV and DV.48 Accordingly, greater values of PM may be interpreted as indications of a more robust mediation and a weaker direct relationship between the IV and DV.

Mediation models differed in 3 aspects: (1) whether prescription or OTC medication use was being tested as the sleep medication use outcome, (2) the directionality of the mediation model (ie, insomnia mediating the relationship between TMB and medication use versus TMB mediating the relationship between insomnia symptoms and medication use), and (3) whether the full TMB-10 scale or one of its 3 subscales was being examined. Follow-up analyses were conducted in 3 separate groupings: (1) the full sample, (2) those patients reporting psychiatric diagnosis, and (3) those patients who met study criteria for chronic insomnia disorder.

RESULTS

Sample Descriptive Statistics

The sample was 45.5% female, with an average age of 50.1 (SD = 13.8) years. Insomnia complaint was reported by 2,086 participants, and 1,558 met study criteria for chronic insomnia disorder. Psychiatric disorders were reported by 2,295 participants. For the entire sample, the mean ISI score was 14.77 (SD = 6.22), and the mean score on the TMB-10 was 11.73 (SD = 8.76). Also, 37.8% of the sample used any sleeping medications at least weekly, and 26.2% used prescription sleep medication at least weekly.

Consistent with the hypothesis that TMB would be related to medication use, scores on the TMB-10 were higher among patients reporting regular use of any sleep medication (mean = 13.91, SD = 8.93) than those who did not (mean = 10.41, SD = 8.39, $t_{3702.7}$ = 13.57, *P* < .0001, Δ =0.42). Similarly, those patients who reported regular use of prescription sleep medication had higher scores on the TMB-10 (mean = 14.07, SD = 9.10) than those who did not (mean = 10.90, SD = 8.49, $t_{2118.5}$ = 10.88, *P* < .0001, Δ =0.37).

TMB and Medication Use in Patients With Reported Insomnia or Psychiatric Diagnoses

Regular use of sleep medication was more common in patients reporting insomnia than not (58.10% vs 22.61%, χ^2_1 =640.82, *P*<.0001). Among those reporting insomnia,

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Table 1. Mediation Models of Sleep Medication Use in the Full Sample^a

| | TMB Mediated by ISI | | | | | ISI Mediated by TMB | | | | |
|-----------------------|----------------------------------|----------------------------------|---------------------------------|---|------|----------------------------------|----------------------------------|--------------------------------|--|------|
| Effect ^b | Estimate | SE | Р | 95% CI | PM | Estimate | SE | Р | 95% CI | PM |
| Full TMB | -10 scale an | d OTC m | edication | | | | | | | |
| a b c' | 0.287 0.052 0.015 | 0.010 0.004 0.003 | <.001 <.001 <.001 | 0.268-0.306 0.043-0.060 0.009-0.021 | | 0.570 0.015 0.052 | 0.018 0.003 0.004 | <.001 <.001 <.001 | 0.535-0.604 0.009-0.022 0.043-0.060 | |
| a x b c | 0.015 0.030 | 0.001 0.003 | <.001 <.001 | 0.012-0.018 0.009-0.022 | 0.50 | 0.009 0.060 | 0.002 0.004 | <.001 <.001 | 0.005–0.012 0.053–0.069 | 0.15 |
| FullTMB | -10 scale an | d prescri | ption me | | | | | | | |
| a b c' a x b | 0.287 0.115 0.005 0.033 | 0.009 0.005 0.003 0.002 | <.001 <.001 .116 <.001 | 0.269-0.305 0.105-0.124 -0.002-0.012 0.030-0.036 | | 0.570 0.005 0.115 0.003 | 0.018 0.004 0.005 0.002 | <.001 .114 <.001 .116 | 0.536-0.608 -0.002-0.012 0.106-0.124 -0.001-0.007 | |
| с | 0.038 | 0.003 | <.001 | 0.032-0.045 | 0.87 | 0.118 | 0.004 | <.001 | 0.109-0.126 | NS |

^aThis table reports mediation analyses that examine the relationship between ISI and TMB regarding medication use in the full sample. The left half of the table reports analyses in which TMB is the IV, and ISI is the mediator. In the right half, ISI is the IV, and TMB is the mediator. Regular use of OTC sleep medication is the DV in the top half of the table. Prescription sleep medication use is the DV in the bottom half.

^bPaths are represented as follows: a = path from IV to M, b = path from M to DV, c' = direct path from IV to DV, a x

b = indirect path from IV to DV through M, c = direct path from IV to DV after controlling for indirect effect (a x b). Abbreviations: DV = dependent variable, ISI = Insomnia Severity Index, IV = independent variable, NS = not significant, OTC = over the counter, PM = proportion mediated (ratio of indirect path a x b to direct path c), SE = standard error, TMB = time monitoring behavior.

Table 2. Mediation Models of Sleep Medication Use Among Participants Reporting Psychiatric Diagnoses^a

| | TMB Mediated by ISI | | | | | ISI Mediated by TMB | | | | |
|--|--|---|--|---|------|---|---|---|---|------|
| Effect ^b | Estimate | SE | Р | 95% CI | PM | Estimate | SE | Р | 95% CI | PM |
| Full TMB-10 scale and OTC medication | | | | | | | | | | |
| a b c' a x b c Full TMB | 0.234 0.054 0.012 0.013 0.025 -10 scale and | 0.012 0.007 0.005 0.002 0.005 d prescrip | <.001 <.001 .013 <.001 <.001 | 0.209-0.257 0.039-0.068 0.003-0.023 0.009-0.016 0.016-0.034 lication | 0.52 | 0.568 0.012 0.054 0.007 0.061 | 0.028 0.005 0.007 0.003 0.007 | <.001 .008 <.001 .009 <.001 | 0.513-0.622 0.003-0.021 0.039-0.067 0.002-0.012 0.047-0.073 | 0.11 |
| a b c' a x b c | 0.234 0.134 -0.003 0.031 0.028 | 0.013 0.008 0.005 0.003 0.005 | <.001 <.001 .54 <.001 <.001 | 0.208-0.259 0.118-0.149 -0.014-0.007 0.027-0.036 0.018-0.038 | 1.11 | 0.568 -0.003 0.134 -0.002 0.132 | 0.029 0.005 0.008 0.003 0.007 | <.001 .538 <.001 .538 <.001 | 0.509-0.622 -0.013-0.008 0.118-0.149 -0.008-0.005 0.118-0.147 | NS |

^aThis table reports mediation analyses that examine the relationship between ISI and TMB regarding medication use in the subset of the sample reporting psychiatric diagnoses. The left half of the table reports analyses in which TMB is the IV and ISI is the mediator. In the right half, ISI is the IV and TMB is the mediator. Regular use of OTC sleep medication is the DV in the top half of the table. Prescription sleep medication use is the DV in the bottom half. ^bPaths are represented as follows: a = path from IV to mediator, b = path from mediator to DV, c'= direct path from IV to DV, a x b = indirect path from IV to DV through mediator, c = direct path from IV to DV after controlling for indirect effect (a x b).

Abbreviations: DV = dependent variable, ISI = Insomnia Severity Index, IV = independent variable, NS = not significant, OTC = over the counter, PM = proportion mediated (ratio of indirect path a x b to direct path c), SE = standard error, TMB = time monitoring behavior.

regular use of sleep medication was more common in those reporting psychiatric diagnosis than not (67.01% vs 44.48%, $\chi^2_1 = 103.95$, *P* < .0001). Similarly, regular use of prescription sleep medication was more common in patients who reported insomnia complaints than not (44.15% vs 12.82%, $\chi^2_1 = 606.89$, *P* < .0001). And again, among those with insomnia, regular use of prescription sleep medication was more common in those who had comorbid psychiatric diagnoses than not (53.45% vs 29.94%, $\chi^2_1 = 111.79$, *P* < .0001).

In a 2 x 2 analysis of variance, both insomnia complaint and psychiatric diagnoses were associated with higher scores on the TMB-10 ($F_{3,4882}$ = 144.79, P < .0001, η^2 = 0.08). There were statistically significant main effects for both insomnia (mean = 14.44, SD = 8.98 vs mean = 9.71, SD = 8.03, F₁, 4882 = 295.64, P < .0001, $\eta^2_{partial} = 0.0571$) and psychiatric diagnosis (mean = 13.23, SD = 9.00 vs mean = 10.40, SD = 8.33, F_{1,4882} = 52.34, P < .0001, $\eta^2_{partial} = 0.0106$), but the interaction between the 2 variables was not significant (F₁, 4882 = 0.79, P = .3742, $\eta^2_{partial} = 0.0002$).

Mediation Analysis

The mediation models for the TMB-10, the ISI, and both OTC sleep and prescription sleep medications are shown in Table 1. Taken together, the models show greater effect sizes for a TMB to ISI to medication use path than ISI to TMB to

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Table 3. Mediation Models of TMB Subscales, ISI, and Sleep Medication Use in the Full Sample^a

| Jamp | | | | | | | | | | |
|---|--|---|---|--|------|---|---|---|---|------|
| | TMB Mediated by ISI | | | | | ISI Mediated by TMB | | | | |
| Effect ^b | Estimate | SE | Р | 95% CI | PM | Estimate | SE | Р | 95% Cl | PM |
| TMB behavior and OTC medication | | | | | | | | | | |
| a b c' a x b C | 0.443 0.057 0.016 0.025 0.041 | 0.022 0.004 0.006 0.002 0.006 | <.001 <.001 .013 <.001 <.001 | 0.398-0.485 0.049-0.065 0.003-0.028 0.021-0.030 0.029-0.053 | 0.61 | 0.186 0.016 0.057 0.003 0.060 | 0.008 0.006 0.004 0.001 0.004 | <.001 .016 <.001 .017 <.001 | 0.171-0.202 0.003-0.028 0.049-0.066 0.001-0.005 0.053-0.068 | 0.05 |
| TMB sle | ep onset fru | ustration | and OTC | medication | | | | | | |
| a b c' a x b C | 0.971 0.049 0.058 0.048 0.106 | 0.029 0.004 0.010 0.004 0.010 | <.001 <.001 <.001 <.001 <.001 | 0.914–1.027 0.041–0.058 0.038–0.078 0.040–0.057 0.088–0.127 | 0.45 | 0.188 0.058 0.049 0.011 0.060 | 0.006 0.010 0.004 0.002 0.004 | <.001 <.001 <.001 <.001 <.001 | 0.177-0.199 0.036-0.077 0.042-0.058 0.007-0.015 0.053-0.068 | 0.18 |
| TMB sle | | | | nd OTC medication | า | | | | | |
| a b c' a x b c | 0.965 0.049 0.058 0.047 0.106 | 0.029 0.004 0.010 0.004 0.009 | <.001 <.001 <.001 <.001 <.001 | 0.907-1.021 0.040-0.057 0.040-0.080 0.039-0.056 0.087-0.124 | 0.44 | 0.197 0.058 0.049 0.011 0.060 | 0.005 0.010 0.004 0.002 0.004 | <.001 <.001 <.001 <.001 <.001 | 0.187-0.208 0.038-0.080 0.041-0.058 0.008-0.016 0.052-0.067 | 0.18 |
| TMB bel | havior and p | orescript | ion medio | ation | | | | | | |
| a b c' a x b c | 0.443 0.120 -0.012 0.053 0.041 | 0.022 0.004 0.007 0.003 0.007 | <.001 <.001 .082 <.001 <.001 | 0.398-0.487 0.112-0.130 -0.027-0.002 0.047-0.060 0.028-0.057 | 1.29 | 0.186 -0.012 0.120 -0.002 0.118 | 0.009 0.007 0.004 0.001 0.004 | <.001 .100 <.001 .103 <.001 | 0.112-0.129 -0.025-0.003 0.112-0.129 -0.005-0.000 0.110-0.126 | NS |
| TMB sle | ep onset fru | stration | and prese | ription medicatio | n | | | | | |
| a b c' a x b C | 0.971 0.109 0.047 0.106 0.154 | 0.029 0.005 0.012 0.005 0.011 | <.001 <.001 <.001 <.001 <.001 | 0.909-1.027 0.100-0.118 0.023-0.070 0.096-0.116 0.131-0.176 | 0.69 | 0.188 0.047 0.109 0.009 0.109 | 0.005 0.012 0.005 0.002 0.005 | <.001 <.001 <.001 <.001 <.001 | 0.177-0.198 0.024-0.070 0.100-0.119 0.005-0.013 0.099-0.119 | 0.08 |
| TMB sleep maintenance frustration and prescription medication | | | | | | | | | | |
| a b c' a x b | 0.965 0.111 0.037 0.107 0.144 | 0.028 0.005 0.011 0.005 0.010 | <.001 <.001 .001 <.001 <.001 | 0.904–1.017 0.100–0.119 0.013–0.061 0.097–0.118 0.123–0.165 | 0.74 | 0.197 0.037 0.111 0.007 0.118 | 0.005 0.011 0.005 0.002 0.004 | <.001 .001 <.001 .001 <.001 | 0.186-0.207 0.014-0.059 0.102-0.121 0.003-0.012 0.110-0.126 | 0.06 |
| C | 0.144 | 0.010 | <.001 | 0.125-0.105 | 0.74 | 0.110 | 0.004 | <.001 | 0.110-0.120 | 0.00 |

^aThis table reports mediation analyses that examine the relationship between ISI and TMB regarding medication use in the full sample. The left half of the table reports analyses in which TMB is the IV, and ISI is the mediator. In the right half, ISI is the IV, and TMB is the mediator. Regular use of OTC sleep medication is the DV in the top half of the table. Prescription sleep medication use is the DV in the bottom half. Both the top and bottom half of the table are further divided according to what aspect of TMB is being examined: behavior, sleep onset frustration, or sleep maintenance frustration.

^bPaths are represented as follows: a = path from IV to mediator, b = path from mediator to DV, c'=direct path from IV to DV, a x b = indirect path from IV to DV through mediator, c = direct path from IV to DV after controlling for indirect effect (a x b).

Abbreviations: DV = dependent variable, ISI = Insomnia Severity Index, IV = independent variable, NS = not significant, OTC = over the counter, PM = proportion mediated (ratio of indirect path a x b to direct path c), SE = standard error, TMB = time monitoring behavior.

medication use, with the greatest effect size demonstrated for prescription medication.

The mediation models for the TMB-10, the ISI, and both OTC sleep and prescription sleep medications among patients with self-reported psychiatric diagnoses are shown in Table 2. The effect sizes followed the same pattern as for the whole sample.

The mediation models for the TMB subscales, the ISI, and both OTC sleep and prescription sleep medications are shown in Table 3. A similar pattern was shown in that mediation effect sizes were greater for a TMB to ISI to medication use path and for prescription medication use. In addition, greater mediation was found for TMB-BX than for the frustration-related factors: TMB-SOF and TMB-SMF. The mediation models for the TMB subscales, the ISI, and both OTC sleep and prescription sleep medications among patients with self-reported psychiatric diagnoses are shown in Table 4. Once again, mediation effect sizes were greater for TMB to ISI to medication use path and for prescription medication use. Also, greater mediation was again found for TMB-BX than for the frustration-related factors: TMB-SOF and TMB-SMF.

See the Supplementary Material for more detailed description of the above mediation models and for results of mediation analyses focused on patients who met study criteria for chronic insomnia disorder. In brief, the majority of analyses focused on chronic insomnia disorder did not show statistically significant mediation.

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Table 4. Mediation Models of Sleep Medication Use Among Participants Reporting Psychiatric Diagnoses^a

| | TMB Mediated by ISI | | | | | ISI Mediated by TMB | | | | |
|----------------------------|--|---|--|---|---------|---|---|--|--|------|
| Effect ^b | Estimate | SE | Р | 95% CI | PM | Estimate | SE | Р | 95% Cl | PM |
| TMB beł | navior and (| DTC med | ication | | | | | | | |
| a b c' a x b c | 0.348 0.059 0.009 0.021 0.030 | 0.029 0.007 0.010 0.003 0.010 | <.001 <.001 .356 <.001 .003 | 0.292-0.404 0.046-0.072 -0.011-0.029 0.016-0.027 0.008-0.048 | 0.70 | 0.173 0.009 0.059 0.002 0.061 | 0.014 0.011 0.007 0.002 0.007 | <.001 .329 <.001 .329 <.001 | 0.145-0.199 -0.010-0.028 0.046-0.073 -0.002-0.005 0.047-0.074 | NS |
| TMB slee | ep onset fru | | and OTC r | nedication | | | | | | |
| a b c' a x b c | 0.814 0.050 0.053 0.041 0.094 | 0.040 0.007 0.015 0.006 0.014 | <.001 <.001 .001 <.001 <.001 | 0.731-0.888 0.036-0.064 0.019-0.081 0.029-0.053 0.063-0.120 | 0.44 | 0.198 0.053 0.050 0.011 0.061 | 0.009 0.015 0.007 0.003 0.007 | <.001 <.001 <.001 .001 <.001 | 0.182-0.216 0.022-0.084 0.036-0.064 0.005-0.017 0.048-0.073 | 0.18 |
| TMB slee | • | | | d OTC medication | | | | | | |
| a b c' a x b C | 0.791 0.051 0.050 0.040 0.090 | 0.038 0.008 0.016 0.006 0.014 | <.001 <.001 .001 <.001 <.001 | 0.717-0.866 0.037-0.065 0.019-0.079 0.029-0.053 0.061-0.117 | 0.44 | 0.197 0.050 0.051 0.010 0.061 | 0.009 0.015 0.007 0.003 0.006 | <.001 .001 <.001 .001 <.001 | 0.179-0.214 0.021-0.078 0.036-0.064 0.004-0.016 0.047-0.072 | 0.16 |
| TMB beł | navior and p | orescripti | on medic | ation | | | | | | |
| a b c' a x b c | 0.348 0.138 -0.030 0.048 0.018 | 0.029 0.008 0.011 0.005 0.012 | <.001 <.001 .008 <.001 .132 | 0.293 to 0.405 0.121 to 0.151 -0.052 to -0.006 0.039 to 0.057 -0.006 to 0.040 | NS | 0.173 -0.030 0.138 -0.005 0.132 | 0.014 0.011 0.007 0.002 0.007 | <.001 .006 <.001 .009 <.001 | 0.146 to 0.202 -0.052 to -0.008 0.122 to 0.151 -0.009 to -0.001 0.117 to 0.145 | NS |
| TMB slee | ep onset fru | stration | and presc | ription medication | | | | | | |
| a b c' a x b c | 0.814 0.128 0.024 0.104 0.128 | 0.041 0.008 0.017 0.008 0.017 | <.001 <.001 .165 <.001 <.001 | 0.733-0.893 0.110-0.143 -0.009-0.061 0.088-0.121 0.093-0.161 | 0.81 | 0.198 0.024 0.128 0.005 0.132 | 0.009 0.018 0.008 0.004 0.007 | <.001 .181 <.001 .185 <.001 | 0.178-0.214 -0.015-0.059 0.110-0.142 -0.003-0.012 0.116-0.145 | NS |
| TMB slee | ep mainten | ance frus | tration an | d prescription med | ication | | | | | |
| a b c' a x b c | 0.791 0.130 0.011 0.103 0.114 | 0.038 0.008 0.017 0.008 0.016 | <.001 <.001 .529 <.001 <.001 | 0.717-0.868 0.115-0.146 -0.019-0.046 0.089-0.120 0.085-0.148 | 0.90 | 0.197 0.011 0.130 0.002 0.132 | 0.009 0.017 0.008 0.003 0.007 | <.001 .523 <.001 .524 <.001 | 0.180-0.216 -0.022-0.044 0.114-0.147 -0.004-0.009 0.118-0.146 | NS |

^aThis table reports mediation analyses that examine the relationship between ISI and TMB regarding medication use in the subset of the sample reporting psychiatric diagnoses. The left half of the table reports analyses in which TMB is the IV and ISI is the mediator. In the right half, ISI is the IV and TMB is the mediator. Regular use of OTC sleep medication is the DV in the top half of the table. Prescription sleep medication use is the DV in the bottom half. Both the top and bottom half of the table are further divided according to what aspect of TMB is being examined: behavior, sleep onset frustration, or sleep maintenance frustration.

^bPaths are represented as follows: a = path from IV to mediator, b = path from mediator to DV, c'=direct path from IV to DV, $a \times b = indirect path$ from IV to DV through mediator, c = direct path from IV to DV after controlling for indirect effect (a x b).

Abbreviations: DV = dependent variable, ISI = Insomnia Severity Index, IV = independent variable, NS = not significant, OTC = over the counter, PM = proportion mediated (ratio of indirect path a x b to direct path c), SE = standard error, TMB = time monitoring behavior.

DISCUSSION

The current study demonstrated TMB is of particular importance to patients with insomnia who use sleep medications. First, sleep medication was more common among patients reporting both insomnia and psychiatric conditions. Second, TMB was higher in those same patients. Finally, our findings suggest a bidirectional relationship between TMB and insomnia symptom severity in the context of sleep medication use. Primarily, TMB appears to be related to sleep medication use due to its relationship with insomnia symptom severity. That is, TMB may provoke worsening of insomnia, which leads to greater use of sleep aids. To a lesser extent, as insomnia symptoms worsen, so too may TMB, potentially resulting in greater sleep aid use. In sum, while insomnia symptoms and TMB may feed off one another, TMB may be upstream of insomnia with regard to association with sleep medication use.

Whereas many factors influence patients' decisions to use sedating drugs, frustration due to TMB seems noteworthy. Evidence pointing to this emotional response was consistently observed across all mediation models for sleep aid use when using TMB frustration instead of TMB alone. Furthermore, the relationship between frustration and sleep medication use was more likely to be partially, rather than fully, mediated by insomnia symptom severity. This finding suggests TMB frustration retains a significant relationship with sleep medication use, outside of its

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It is illegal to post this copy relationship with insomnia symptom severity. Overall, the observed relationships tended to be stronger and more consistent when examining the OTC use, rather than prescription sleep medications, as well as among the entire sample, rather than only those with psychiatric diagnoses or chronic insomnia. These differences are likely due to greater availability of OTC medications, greater complexity of psychiatric patients, and reduced range of ISI scores among chronic insomnia patients, as a cutoff of ISI > 14 was used to define this group.

The importance of sleep-related frustration aligns with research where clock-watching by people with insomnia increased both worry and subjective sleep latency,³¹ either of which may exacerbate TMB, creating a vicious cycle of clock-watching and sleep loss. These findings are relevant to clinicians treating insomnia and those providing CBT-I, because long-term CBT-I benefits are optimized after sleep medication discontinuance,⁴⁹ albeit CBT-I can be effectively combined with medication tapering.⁵⁰

A standard recommendation is to turn around the clock or remove it from the bedroom to reduce TMB. Notwithstanding, the present results suggest the behavior itself is not the sole driver of medication use; rather, frustration is at least as important, if not more so. Clinically, 2 potential approaches could effectively address frustration. Cognitive restructuring may alleviate frustration related to probability overestimation or catastrophizing,⁵¹ or an emotion-focused approach may be helpful to address maladaptive emotional processing.²⁶ For patients with psychiatric disorders, for whom CBT-I has been found effective,^{52,53} reducing frustration may prove particularly helpful.

In the past decade, numerous studies and review articles raised questions about the efficacy of specific sleep aids and adverse effects associated with OTC and prescription sleep medications.^{12–18,54,55} Regardless of agreement or disagreement with these critiques, the vexing nature of insomnia clearly leads a substantial proportion of patients or medical professionals to seek or to prescribe sleep medications.^{56,57} Given the potential role of TMB-related frustration in the exacerbation of insomnia, we speculate interventions to diminish TMB may be helpful for patients who wish to improve insomnia symptoms and discontinue use of sleep aids. If the frustration arising from TMB contributes to the patient's insomnia and drive to take a

steeping pill, then defusing this frustration may improve insomnia and reduce sedative use.

Frustration associated with TMB is likely an important area of research and clinical attention for insomnia patients. It remains a question whether reducing TMB-induced frustration would decrease insomnia symptoms or sleep aid use; nonetheless, the current findings suggest this hypothesis should be tested. Such research must involve longitudinal studies of TMB, insomnia symptoms, and medication use as well as the effects of different therapeutic pathways. Since previous experimental research demonstrated deleterious effects of TMB on sleep in just one night,³¹ benefits of reducing TMB may emerge in a similar time frame. Moreover, randomized controlled trials of TMB interventions could test whether such treatments reduce insomnia and facilitate tapering off sleep aids.

Limitations

Measures were limited to self-report and did not include other constructs likely to influence medication use, such as beliefs about sleep, attitudes toward medication use in general, availability of medications, which medication(s) patients used, and dosage instructions, frequency, and duration of use for prescription medications. In addition, psychiatric diagnoses were self-reported rather than based on symptom scales or structured interviews. As a crosssectional study, our findings are correlational and cannot address causality.

CONCLUSIONS

The US public health burden of insomnia and associated sleep aid use is substantial and appears to be worsening. The identification of specific, modifiable behaviors that confer risk for insomnia has potential to reduce this burden. Results from this study demonstrated TMB may be such a factor, because TMB and insomnia symptom severity were reciprocally associated with sleep medication use. Mediation models provided best support for a pathway by which TMB and the associated frustration may contribute to insomnia symptom severity. Finally, data from this largescale sleep clinic sample provide solid proof-of-concept for future longitudinal studies to assess the role of TMB in the prevention or treatment of insomnia as well as its possible impact on decreasing sleep medication use.

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