The Insomnia Severity Index

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Outline of Presentation

- Insomnia – what is it and how do we measure it?
- Description of Insomnia Severity Index (ISI), background, scoring guidelines
- Psychometric data – reliability, validity, sensitivity
- Scope and clinical utility
- Questions and answers
Introduction/Context

- Insomnia is a common health complaint that can occur independently or comorbidly with another medical (pain) or psychiatric (depression) condition.
- Insomnia affects 10% of the adult population on a chronic basis, plus an additional 15% to 20% occasionally.
- Persistent insomnia carries significant economic burden.
- Despite its high prevalence and negative consequences, insomnia often remains undetected and untreated.
- It is essential to have brief and psychometrically-sound assessment instruments to detect insomnia and evaluate treatment outcome.
Insomnia Diagnostic Criteria

- Dissatisfaction with sleep quality or duration associated with:
  - Difficulty falling sleep
  - Difficulty maintaining sleep
  - Early-morning awakening

- Significant distress or impairment in daytime functioning (fatigue, mood disturbances)

- The sleep difficulty occurs at least 3 nights per week and is present for at least 3 months

- The sleep difficulty occurs despite adequate opportunity for sleep
Methods to Evaluate Insomnia

- Clinical Interview/sleep history
- Daily sleep diaries
  - Completed for several days upon arising in morning
- Polysomnography
  - Gold standard for measuring sleep and diagnosing sleep disorders other than insomnia
- Patient-reported outcome questionnaires

Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, Morin CM. Sleep 2006; 29:1155-1173
Insomnia Screening Assessment Instruments

- Self-report questionnaires designed to evaluate/quantify subjective dimensions of nighttime sleep and daytime functioning
- Typically conducted as point estimates, with repeated assessment as needed
- Time frame “last night”, “past week”, “past month”
- Number of items varies from 1 to 50+ and response format usually involves Likert-type ratings or VAS
Key Considerations in Selecting Assessment Instruments

- **Conceptual basis**: Is the instrument conceptually sound and relevant?
- **Psychometrics**:  
  - Reliability (internal consistency, temporal stability)  
  - Validity (construct, convergent, predictive, etc)  
  - Sensitivity to detect cases  
  - Sensitivity to detect changes  
  - Normative data
- **Practical considerations**: availability, ease of use/administration, burden on patient and clinician
Background on Insomnia Severity Index (ISI)

- The ISI was developed to provide a brief/practical PRO assessment tool to screen for insomnia and evaluate treatment outcome.
- Development of initial pool of items was based on typical complaints reported by patients with insomnia and on standard diagnostic criteria.
- The goal was to sample critical domains reflecting on both nighttime sleep disturbances and daytime impairments associated with insomnia.
Insomnia Severity Index

- 7-item questionnaire that quantifies insomnia severity (0-4 format) according to several indicators:
  - sleep difficulties (initial, middle, late insomnia), dissatisfaction with sleep, daytime impairments, noticeability of impairments, distress
- Covers critical DSM-5 and ICD-10 insomnia diagnostic criteria
- Usual time frame is “last month” (2-wk version available)
- Yields a total score that varies between 0 and 28:
  - 0 - 7 : no insomnia
  - 8 -14 : subclinical insomnia
  - 15 -21 : moderate severity
  - 22 -28 : severe insomnia
For the first 3 questions, please rate the SEVERITY of your sleep difficulties.

1. Difficulty falling asleep
   - 0: None
   - 1: Mild
   - 2: Moderate
   - 3: Severe
   - 4: Very Severe

2. Difficulty staying asleep
   - 0: None
   - 1: Mild
   - 2: Moderate
   - 3: Severe
   - 4: Very Severe

3. Problem waking up too early
   - 0: None
   - 1: Mild
   - 2: Moderate
   - 3: Severe
   - 4: Very Severe

4. How SATISFIED/DISSATISFIED are you with your current sleep pattern?
   - 0: Very satisfied
   - 1: Satisfied
   - 2: Neutral
   - 3: Dissatisfied
   - 4: Very dissatisfied
Insomnia Severity Index

5. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g., fatigue, concentration, memory, mood, etc.)?

   0  1  2  3  4
   Not interfering at all  A little  Somewhat  Much  Very much interfering

6. How NOTICEABLE to others do you think your sleeping problem is in terms of impairing the quality of your life?

   0  1  2  3  4
   Not at all noticeable  Barely  Somewhat  Much  Very much noticeable

7. How WORRIED/distressed are you about your current sleep problem?

   0  1  2  3  4
   Not at all  A little  Somewhat  Much  Very much
## ISI Psychometrics

<table>
<thead>
<tr>
<th>Item</th>
<th>Clinical (N = 183)</th>
<th>Community (N = 959)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliability (cronbach’s alpha)</td>
<td>0.91</td>
<td>0.90</td>
</tr>
<tr>
<td>Item – total correlations</td>
<td>mean: 0.73</td>
<td>mean: 0.71</td>
</tr>
<tr>
<td></td>
<td>range: .50 to .85</td>
<td>range: .55 to .81</td>
</tr>
<tr>
<td>Difficulty falling asleep</td>
<td>0.50</td>
<td>0.66</td>
</tr>
<tr>
<td>Difficulty staying asleep</td>
<td>0.80</td>
<td>0.68</td>
</tr>
<tr>
<td>Waking up too early</td>
<td>0.66</td>
<td>0.55</td>
</tr>
<tr>
<td>Satisfaction w/ sleep pattern</td>
<td>0.83</td>
<td>0.81</td>
</tr>
<tr>
<td>Interference w/ daytime functioning</td>
<td>0.79</td>
<td>0.78</td>
</tr>
<tr>
<td>Noticeability of sleep problem</td>
<td>0.69</td>
<td>0.72</td>
</tr>
<tr>
<td>Worries/Distress caused by sleep</td>
<td>0.85</td>
<td>0.79</td>
</tr>
</tbody>
</table>
## Convergent and discriminant validit y

<table>
<thead>
<tr>
<th></th>
<th>Clinical</th>
<th>Community</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression (BDI)</td>
<td>.48*</td>
<td>.50*</td>
</tr>
<tr>
<td>Anxiety (BAI)</td>
<td>.48*</td>
<td></td>
</tr>
<tr>
<td>Anxiety (STAI-Trait)</td>
<td></td>
<td>.50*</td>
</tr>
<tr>
<td>General fatigue (MFI)</td>
<td>.41*</td>
<td>.55*</td>
</tr>
<tr>
<td>Physical fatigue (MFI)</td>
<td>.27*</td>
<td>.45*</td>
</tr>
<tr>
<td>Reduced activities (MFI)</td>
<td>.23*</td>
<td>.31*</td>
</tr>
<tr>
<td>Reduced motivation (MFI)</td>
<td>.20*</td>
<td>.38*</td>
</tr>
<tr>
<td>Mental fatigue (MFI)</td>
<td>.24*</td>
<td>.37*</td>
</tr>
<tr>
<td>General health (SF-12)</td>
<td></td>
<td>-.30*</td>
</tr>
<tr>
<td>Mental health (SF-12)</td>
<td></td>
<td>-.51*</td>
</tr>
<tr>
<td>Sleep quality (PSQI)</td>
<td></td>
<td>.80*</td>
</tr>
</tbody>
</table>

*p < .05
Distribution of ISI Scores
Community Sample (N= 959)

- No insomnia (0-7) : 576 (59.9%)
- Subclinical (8-14) : 260 (27.1%)
- Moderate (15-21) : 116 (12.1%)
- Severe (22-28) : 9 (0.9%)
### ISI Discriminative Properties

(Community Sample)

#### Cutoff ISI Score for Insomnia

<table>
<thead>
<tr>
<th>ISI Score</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>False Positive Rate</th>
<th>False Negative Rate</th>
<th>Correct Classification Rate</th>
<th>Positive Predictive Power</th>
<th>Negative Predictive Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISI ≥ 8</td>
<td>227/237 (95.8%)</td>
<td>565/722 (78.3%)</td>
<td>157/722 (21.7%)</td>
<td>10/237 (4.2%)</td>
<td>792/959 (82.6%)</td>
<td>227/384 (59.1%)</td>
<td>565/575 (98.3%)</td>
</tr>
<tr>
<td>ISI ≥ 10</td>
<td>204/237 (86.1%)</td>
<td>633/722 (87.7%)</td>
<td>89/722 (12.3%)</td>
<td>33/237 (13.9%)</td>
<td>657/959 (87.3%)</td>
<td>204/293 (69.6%)</td>
<td>633/666 (95.0%)</td>
</tr>
<tr>
<td>ISI ≥ 15</td>
<td>113/237 (47.7%)</td>
<td>710/722 (98.3%)</td>
<td>12/722 (1.7%)</td>
<td>124/237 (52.3%)</td>
<td>823/959 (85.8%)</td>
<td>113/125 (90.4%)</td>
<td>710/834 (85.1%)</td>
</tr>
</tbody>
</table>
## ISI Sensitivity to Treatment

**ISI Change Scores**  
**(Baseline to Post-Treatment)**

<table>
<thead>
<tr>
<th>Clinical Global Improve. (external evaluator)</th>
<th>$n$</th>
<th>Mean ISI Change Scores</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight improvement</td>
<td>20</td>
<td>-4.7</td>
<td>-2.6 to -6.7</td>
</tr>
<tr>
<td>Moderate improvement (partial remission)</td>
<td>63</td>
<td>-8.3</td>
<td>-7.2 to -9.5</td>
</tr>
<tr>
<td>Marked improvement (complete remission)</td>
<td>63</td>
<td>-10.1</td>
<td>- 8.7 to -11.1</td>
</tr>
</tbody>
</table>
Changes in ISI scores with treatment

ISI Long-Term Follow Ups

- CBT-CBT
- CBT-no tx
- COMB-taper
- COMB-prn

Baseline (N=160) Post Tx I (N=146) Post Tx II (N=146) 6-mo FU (N=127) 12-mo FU (N=124) 24-mo FU (N=110)
Changes in ISI scores over time

Ancoli-Israel et al. Sleep 2010; 33:225-34
Shift in distribution of ISI scores with treatment

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CBT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>10.1</td>
<td>6.7</td>
</tr>
<tr>
<td>Moderate</td>
<td>63.3</td>
<td>54.1</td>
</tr>
<tr>
<td>Subthreshold</td>
<td>26.6</td>
<td>39.2</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>44.4</td>
</tr>
<tr>
<td><strong>CBT+MED</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>6.3</td>
<td>15.3</td>
</tr>
<tr>
<td>Moderate</td>
<td>77.2</td>
<td>40.3</td>
</tr>
<tr>
<td>Subthreshold</td>
<td>16.5</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Morin et al. JAMA 2009; 301; 2005-15
Critical ISI Cut-off Scores

- Detection of a case in a community sample: ISI of 10 or greater
- Best cut point to diagnose insomnia in a clinical (primary care) sample: ISI of 14 or more
- Treatment response: a change score of 7 or more
- Treatment remission: a total score of 7 or lower
- Minimally important difference (MID): a difference score of 6 or more

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Key Points and Conclusion

- The ISI is a brief and practical instrument to assess insomnia severity in observational and randomized clinical trials.
- The ISI has excellent psychometric properties – reliability, validity, sensitivity, and clinical utility.
- Widely recognized by the professional and research community as a key end point in clinical trials (> 1500 citations; Google Scholar).
- Available in more than 60 languages, paper-and-pencil and electronic formats.
- Additional work is in progress to define optimal cut-off scores for different utilizations:
  - to optimize case detection (primary care, epidemiology).
  - to document therapeutic response (MID) and remission in clinical trials.
How to obtain the ISI?

- Available free of charge to individual clinicians and researchers, but organizations require a license to use it.
- Use of the ISI in commercial studies is subject to royalty fees.
- For licensing process and translations, contact Mapi Research Trust.
- E-mail: PROinformation@mapi-trust.org – Internet: www.proqolid.org
Key references