Treatment of Insomnia and Anxiety

Christopher Schneck, M.D.
Associate Professor of Psychiatry
Medical Director, Helen & Arthur E Johnson Depression Center
Behavioral Health Director, UCH ID/HIV Clinic

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Course Objectives

• Increase understanding, appropriateness of evidence based pharmacologic treatment of insomnia;
• Increase understanding and appropriateness of evidenced-based pharmacologic treatment for anxiety;
• Learn how to best treat anxiety/insomnia in the elderly.
Insomnia
A 35 year old man complains of insomnia lasting several months. He has no trouble falling asleep but wakes up in the middle of the night and can’t fall back asleep. He has no other medical problems, but states that a few years ago he thought alcohol was becoming a concern. He requests a medication to help him sleep. You would:

1. Start quetiapine 100 mg at bedtime.
   - 3%

2. Start zaleplon (Sonata) 5 mg at bedtime
   - 0%

3. Start clonazepam (Klonopin) 1 mg upon awakening in the middle of the night.
   - 3%

4. Refer him to cognitive behavioral therapy for insomnia (CBT-I)
   - 84%

5. Start eszopiclone (Lunesta) 2 mg at bedtime.
   - 11%
Sleep System (Process S) vs. Circadian System (Process C)

• Sleep is a balance of 2 fundamental processes:
  – Process S: homeostatic process—The longer one is awake, the stronger the drive for sleep.
  – Process C: Circadian arousal process, dictates onset of sleep & the timing of arousal.
    • An entrained, synchronized cycle of physiologic systems
    • Reinforced by light input into the retina.
Two Process Model of Sleep Regulation

Stable mood regulation requires good temporal alignment between sleep wake cycle and circadian system.
Sleep Physiology

• **Sleep-Wake cycle**: architecture of phases
  – **Stage I**: Transition from sleep to wakefulness
  – **Stage II**: Further slowing of EEG, most common sleep stage.
  – **Stage III and IV**: Deep sleep, ~20-25% of sleep time in adults.
  – **REM sleep**: 20% of total sleep time in adults
Stages of Sleep

- Awake
- Stage 1
- REM
- Stage 2
- Stages 3 & 4

Hours:

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
Zeitgebers (Time-Givers or Synchronizing Agents)

More Powerful

Light (suppresses melatonin)
Food
Exercise

Less Powerful

Social interactions (work, other activities)
Sleepiness over the day

Assessment

• Sleep **onset vs maintenance**
• Nighttime routine
  – **Setting:** dark room, clock, temp
  – **Habit:** time in bed, time to sleep, awakenings during the night, early morning awakening
• Patients: over-estimate **sleep latency**, **wakefulness after sleep onset**, underestimate **sleep duration**
• Sleep diaries

<table>
<thead>
<tr>
<th>Sample</th>
<th>2/12/16</th>
<th>ID/Name: ____________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4/5/11</td>
<td></td>
</tr>
<tr>
<td>1. What time did you get into bed?</td>
<td>10:15 p.m</td>
<td>9:30 pm</td>
</tr>
<tr>
<td>2. What time did you try to go to sleep?</td>
<td>11:30 p.m</td>
<td>10:00 pm</td>
</tr>
<tr>
<td>3. How long did it take you to fall asleep?</td>
<td>55 min.</td>
<td>2 hours</td>
</tr>
<tr>
<td>4. How many times did you wake up, not counting your final awakening?</td>
<td>3 times</td>
<td>4 times</td>
</tr>
<tr>
<td>5. In total, how long did these awakenings last?</td>
<td>1 hour 10 min.</td>
<td>1.5 hours</td>
</tr>
<tr>
<td>6. What time was your final awakening?</td>
<td>6:35 a.m.</td>
<td>8:30 am</td>
</tr>
<tr>
<td>7. What time did you get out of bed for the day?</td>
<td>7:20 a.m</td>
<td>8:45 am</td>
</tr>
<tr>
<td>8. How would you rate the quality of your sleep?</td>
<td>□ Very poor □ Poor □ Fair □ Good □ Very good</td>
<td>□ Very poor □ Poor □ Fair □ Good □ Very good</td>
</tr>
<tr>
<td>9. Comments (if applicable)</td>
<td>I have a cold</td>
<td></td>
</tr>
</tbody>
</table>
Pluses and Minuses of Prescribing Sleeping Medications

+ • They often work!
  • Initial relief of insomnia, improved therapeutic alliance,
  • “Mood stabilizing”

- • Issues of physical and psychological dependence
  • Insidious effects of long-term alteration of sleep architecture
  • Tolerance, rebound
  • Abuse, falls, memory, MVAs
  • Sleep eating/walking
# FDA-Approved Medications for Insomnia

## Antihistamine
- Diphenhydramine
- Doxylamine

## Benzodiazepines
- Estazolam (ProSom)
- Flurazepam (Dalmane)
- Quazepam (Doral)
- Temazepam (Restoril)
- Triazolam (Halcion)

## Benzodiazepine Receptor Agonists
- Zolpidem (Ambien)
- Zaleplon (Sonata)
- Eszopiclone (Lunesta)

## Barbituate
- Pentobarbital
- Secobarbital
- Butalbital

## Melatonin Receptor Agonist
- Ramelteon (Rozerem)

## Orexin Antagonist
- Suvorexant (Belsomra)

## Unknown Mechanism
- Chloral Hydrate

## Tricyclic Antidepressant
- Doxepin
Non-FDA Approved Medications for Insomnia, commonly used

Anxiolytic Benzodiazepines
- Clonazepam
- Alprazolam
- Diazepam

Antidepressants
- Trazodone
- Mirtazapine (Remeron)
- Amitriptyline

Atypical Antipsychotics
- Quetiapine (Seroquel)
- Olanzapine (Zyprexa)

Melatonin Receptor Agonists
- Melatonin

Alternative/Herbal
- Valerian Root extract
Selecting Treatment

- Difficulty *initiating* sleep (38%)
  - Short-acting, rapid-onset agent (e.g. zolpidem, zaleplon)
- Difficulty *maintaining* sleep (61%)
  - Longer-acting agent (e.g. eszopiclone) or
  - Shorter-acting for nocturnal awakening (e.g. zaleplon)
- Early morning *awakening* (52%):
  - Longer-acting
## Benzodiazepines

<table>
<thead>
<tr>
<th>Medication</th>
<th>Duration of Action</th>
<th>Half-life</th>
<th>Dose</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triazolam (Halcion)</td>
<td>Short</td>
<td>2-5</td>
<td>0.125-0.25 mg</td>
<td>Onset</td>
</tr>
<tr>
<td>Estazolam (Prosom)</td>
<td>Intermediate</td>
<td>10-24</td>
<td>0.5-2 mg</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Temazepam (Restoril)</td>
<td>Intermediate</td>
<td>8-15</td>
<td>7.5-30 mg</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Lorazepam* (Ativan)</td>
<td>Intermediate</td>
<td>8-12</td>
<td>1-2 mg</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Quazepam (Doral)</td>
<td>Long</td>
<td>50-200 (active metabs)</td>
<td>7.5-15 mg</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Flurazepam (Dalmane)</td>
<td>Long</td>
<td>35</td>
<td>15-30 mg</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Clonazepam* (Klonopin)</td>
<td>Long</td>
<td>35</td>
<td>0.5-1 mg</td>
<td>??????</td>
</tr>
</tbody>
</table>

*Not FDA approved for insomnia
## Benzodiazepine-Receptor Agonists

<table>
<thead>
<tr>
<th>Medication</th>
<th>Duration of Action</th>
<th>Half-life (hr)</th>
<th>Dose</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zaleplon (Sonata)</td>
<td>Ultra-short</td>
<td>1</td>
<td>5-20 mg</td>
<td>Onset/Maintenance*</td>
</tr>
<tr>
<td>Zolpidem (Ambien)</td>
<td>Short</td>
<td>3</td>
<td>5-10 mg</td>
<td>Onset</td>
</tr>
<tr>
<td>Zolpidem CR (Ambien CR)</td>
<td>Short</td>
<td>(80% initial release, 20% delayed)</td>
<td>6.25-12.5 mg</td>
<td>Maintenance</td>
</tr>
<tr>
<td>Eszopiclone (Lunesta)</td>
<td>Intermediate</td>
<td>5-7</td>
<td>1-3 mg</td>
<td>Maintenance</td>
</tr>
</tbody>
</table>

*For maintenance, given on waking during the night*
## Melatonin Receptor Agonists

<table>
<thead>
<tr>
<th>Medication</th>
<th>Duration of Action</th>
<th>Half-life (hr)</th>
<th>Dose</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melatonin</td>
<td>Ultra-short</td>
<td>30-50 Mins</td>
<td>0.3-5 mg (&gt;1 mg supra-physiologic)</td>
<td>Sleep onset, circadian rhythm shifting</td>
</tr>
<tr>
<td>Remelteon (Rozerem)</td>
<td>Short</td>
<td>2-5</td>
<td>8 mg</td>
<td>Onset</td>
</tr>
</tbody>
</table>
Suvorexant (Belsomra)

• Orexin receptor antagonist
  – Orexin implicated in stimulation of wake-promoting systems and stabilization of sleep-wake cycle
• Schedule IV drug
• Tabs: 5 mg, 10 mg, 15 mg, 20 mg
• TDD NTE 20 mg. Start at 10 mg.
• Most common SE: Drowsiness (!)
• Price?????
# Sleep Effects of Specific Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Clinical Issues</th>
<th>Stg2</th>
<th>EDS</th>
<th>SE</th>
<th>SL</th>
<th>WASO</th>
<th>SWS%</th>
<th>REM%</th>
<th>TST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trazodone</td>
<td>Tolerance can develop to hypnotic effects by week 2</td>
<td></td>
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<tr>
<td>Quetiapine</td>
<td>May induce insomnia &amp; “dramatically” ↑s PLMS</td>
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<tr>
<td>BNZOs</td>
<td>Drug T1/2 determines sleep maintenance. Anterograde amnesia.</td>
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<tr>
<td>Non-BNZO agonists</td>
<td>Have been associated w/ sleep-eating. Little effect on sleep architecture.</td>
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Stg2= Stage 2; EDS=excessive daytime sleepiness; SE=sleep efficiency; SL=sleep latency; WASO=wake time after sleep onset; SWS=slow wave sleep; REM=REM sleep latency; TST=total sleep Time

Behavioral Interventions for Insomnia

- Sleep hygiene education
- Stimulus control
- Sleep restriction therapy
- Relaxation training
- Cognitive-behavioral therapy for insomnia

Online interventions appear efficacious

CBT-i Coach

By US Department of Veterans Affairs (VA)

Open iTunes to buy and download apps.

Description

CBT-i Coach is for people who are engaged in Cognitive Behavioral Therapy for Insomnia with a health provider, or who have experienced symptoms of insomnia and would like to improve their sleep habits. The app will guide users through the process of learning about sleep, developing positive sleep routines, and improving their sleep.

US Department of Veterans Affairs (VA) Web Site ➤ CBT-i Coach Support ➤ Application License ➤ ...More Agreement ➤

What's New in Version 2.0

Graphs for healthcare providers and patients to review together for data clarity and dynamic algorithm adjustment.
Long-term Treatment?

- No well-controlled, prospective objective data on long-term benefit or consequence
- Long-term effects of chronic, untreated insomnia
- Some data regarding long-term treatment with zolpidem, zaleplon.
- Behavioral interventions may create more durable gains.

Insomnia in the Elderly
Sleep Assessment & Treatment in the Elderly

• Unclear how much sleep is “normal” for elderly.
• Elderly spend more time in stage 1, less time in stages 3, 4.
• Problems in sleep maintenance is most commonly reported among elderly, vs sleep initiation.
• Sleep problems often secondary to existing chronic disease
• DDx: Medical vs medicine vs psychiatric
Number of Awakenings in Men and Women as a Function of Age

McCall VW. Prim Care Companion J Clin Psych 2004
Common Medical Causes of Insomnia in the Elderly

• Non-prescription drugs
  – Caffeine, diet pills, nicotine

• Prescription drugs
  – B-blockers
  – Albuterol
  – Quinidine
  – Decongestants
  – Thyroid preparations
  – Corticosteroids
  – Chemotherapy

• Neurologic disease
  – Parkinson’s
  – Alzheimer’s
  – Multiple sclerosis

• Medical conditions
  – Primary sleep disorders (e.g. Apnea, periodic limb movement, restless leg, etc)
  – Dyspnea
  – Pain
  – Thyrotoxicosis

• Acute & chronic medical dz
  – Arthritis
  – CV disease
  – Asthma/COPD

McCall VW. Prim Care Companion J Clin Psych 2004
Issues of Prescribing in the Elderly

• Next day sedation
• Impaired immediate and delayed recall
• Cognitive impairment (short term, ? long term)
• Risk for abuse/dependence
• Increased risk of falls/femur fractures
• Rebound insomnia
• Paucity of data

McCall VW. Prim Care Companion J Clin Psych 2004
• Temazepam
  – Tolerance
  – Use exceeding 4-5 weeks not recommended
  – Dose recommended: 15 mg qhs vs 30 mg
  – Higher incidence of daytime drowsiness and fatigue vs PCB in elderly
  – Major, independent risk factor for falls leading to hip fx.

McCall VW. Prim Care Companion J Clin Psych 2004
Trazodone

- Hypnotic dosing: 50-100 mg
- **Pharmacokinetics dependent on age:**
  - T1/2 6.4 h adults (~age 24) vs 11.6 h elderly
  - Decreased clearance rates
- **Side effects:**
  - Dizziness, constipation, nausea/vomiting, headache, blurry vision, dry mouth, hypotension
- “The observation that trazodone is used more often than any other prescription medication [for insomnia] is startling given the dearth of hypnotic efficacy data.”

McCall VW. Prim Care Companion J Clin Psych 2004
Zolpidem

- $T_1/2$ 2.4 h adults vs 2.9 h elderly
- No active metabolite
- Recommended dosing: 5 mg vs 10 mg men
- However, higher doses needed to improve sleep latency, total sleep time
- Adverse events:
  - Confusion, cognitive impairment, falls, hip fx
No Guidelines, but if used...

- Lowest effective dose
- Shorter half-life drugs
- Short-term (3-4 weeks) use
- Gradual discontinuation
- Monitoring for rebound insomnia
- Strong consideration of cognitive-behavioral strategies.
Anxiety, 1894 by Edvard Munch
All of the following statements about anxiety disorders are true except:

1. They are the most common psychiatric illness in the US
   - 3%

2. They respond more often to lower doses of antidepressant compared to depression
   - 45%

3. When comorbid with other medical or psychiatric illnesses, they worsen prognosis
   - 21%

4. They often herald a more chronic illness course.
   - 31%
Sequential Relationships

Anxiety — 59% — Depression

Depression — 15% — Anxiety

Depression — 48% — Anxiety

References:
- Alloy et al. Comorbidity of Mood & Anxiety Dis. 1990
Prevalence of Anxiety Disorders

- Social Phobia: 13.30%
- Specific Phobia: 10%
- PTSD: 8%
- GAD: 5%
- Panic: 4%
- OCD: 2.50%

Consequences of Comorbidity

- Increased severity of symptoms
- Increased frequency of episodes
- Poorer response to treatment
- Poorer prognosis
- Higher suicide rates
- More chronic course
- Limited data in treatment

Mineka S. Annu Rev Psychol. 1998 49:377-412  
Treatment
General Principles

• Very effective psychotherapies for both GAD and Panic:
  – Cognitive Behavioral Therapy
• Look for medications with overlapping indications
• Paucity of controlled data in the comorbid population
• When mood disorder clearly present, treatment of mood symptoms is the priority
Initiation of Treatment

- “Low and Slow” when anxiety present: typically half the usual starting dose
- Follow more frequently upon initiation
- Lengthen time between appts as pt’s condition improves
- Monitor for worsening suicidality, irritability, impulsivity
- Push dose until remission or side effects
Treatment of Anxiety & Depression

• May need higher doses than in depression alone
  – Panic, e.g.
    • Paroxetine 40-60 mg*
    • Sertraline 75-150 mg†
  – OCD, e.g.
    • Fluoxetine 60-80 mg

Generalized Anxiety Disorder: Effect Sizes

Mean Effect Sizes

Effect sizes
Small ≤ 0.2
Medium 0.5
Large ≥ 0.8

Generalized Anxiety Disorder: Treatment

1. SSRIs or SNRIs: NNT=5
   – Class effect

2. Tricyclic antidepressants or benzodiazepines or mirtazapine
   – TCAs: side effect burden, toxicity
   – BZDs: abuse/dependency, withdrawal, memory issues; rapid + effect

3. Buspirone/hydroxyzine/pregabalin
   – BUSP: if pt hasn’t been on BZDs
   – Hydroxyzine: sedation, lack of efficacy in other psychiatric illness

Generalized Anxiety Disorder: Treatment

4. Buspirone/hydroxyzine/pregabalin (cont)
   – Pregabalin: other indications include neuralgias, partial szs, fibromyalgia

5. (Propranolol)
   – Little evidence to support use: block physiology of anxiety, but not emotion
Panic Disorder: Treatment

Therapy + Medications best treatment

1. SSRIs & SNRIs
   - Evidence of class effect

2. Benzodiazepines
   - Rapid relief vs. dependency/abuse/addiction

3. Tricyclic antidepressants
   - Side effects, toxicity

Panic Disorder: Treatment

- **Benzodiazepines**
  - All equally effective
  - Longer half-life drugs preferred (e.g. clonazepam, alprazolam XR, diazepam)
  - Higher potency generally preferred over lower potency
  - Longer T ½ avoids inter-dose rebound
# FDA Indications of Antidepressants

<table>
<thead>
<tr>
<th></th>
<th>MDD</th>
<th>OCD</th>
<th>Panic</th>
<th>PTSD</th>
<th>GAD</th>
<th>SocAnx</th>
<th>PMDD</th>
<th>Bulimia</th>
<th>Pain</th>
<th>Smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Citalopram</strong></td>
<td>✓</td>
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<tr>
<td><strong>Escitalopram</strong></td>
<td>✓</td>
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<tr>
<td><strong>Fluoxetine</strong></td>
<td>✓†</td>
<td>✓†</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Fluvoxamine</strong></td>
<td>✓†</td>
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<tr>
<td><strong>Paroxetine</strong></td>
<td>✓</td>
<td>✓†</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Sertraline</strong></td>
<td>✓</td>
<td>✓†</td>
<td>✓</td>
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<td>✓</td>
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<tr>
<td><strong>Desvenlafaxine</strong></td>
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<tr>
<td><strong>Duloxetine</strong></td>
<td>✓</td>
<td></td>
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<td>✓</td>
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<tr>
<td><strong>Venlafaxine</strong></td>
<td>✓</td>
<td>✓</td>
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<tr>
<td><strong>Bupropion</strong></td>
<td>✓</td>
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<td>✓</td>
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<tr>
<td><strong>Mirtazapine</strong></td>
<td>✓</td>
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<tr>
<td><strong>Vilazodone</strong></td>
<td>✓</td>
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</tbody>
</table>

† = Pediatric indication
Prevalence of Anxiety in the Elderly

Blay SL & Marinho V. Current Op Psych 2012
General Treatment Guidelines

• 75% of healthy older adults would prefer psychotherapy if diagnosed with an anxiety disorder.
• Limited data
• Efficacy shown for both psychopharmacological and psychotherapeutic strategies

Forest Plot for Pharmacological Trials of Generalized Anxiety Disorder

**Benzodiazepine**
- Bresolin et al., 1988: OR = 0.20 (0.07, 0.60), % Weight = 10.04
- Frattola et al., 1992: OR = 0.18 (0.04, 0.80), % Weight = 7.33
- Subtotal (I-squared = 0.0%, p = 0.897): OR = 0.19 (0.08, 0.46), % Weight = 17.37

**Antidepressant**
- Davidson et al., 2008: OR = 0.50 (0.18, 1.37), % Weight = 10.74
- Katz et al., 2005: OR = 0.53 (0.27, 1.05), % Weight = 13.56
- Kimuna et al., 2003: OR = 0.12 (0.02, 0.69), % Weight = 6.17
- Lenze et al., 2005: OR = 0.17 (0.04, 0.75), % Weight = 7.39
- Lenze et al., 2009: OR = 0.62 (0.34, 1.12), % Weight = 14.24
- Subtotal (I-squared = 21.4%, p = 0.278): OR = 0.46 (0.29, 0.73), % Weight = 52.10

**Other**
- Eriksson et al., 2008: OR = 0.14 (0.09, 0.22), % Weight = 15.61
- Montgomery et al., 2008: OR = 0.62 (0.37, 1.03), % Weight = 14.92
- Subtotal (I-squared = 94.8%, p = 0.000): OR = 0.30 (0.07, 1.25), % Weight = 30.53

**Overall** (I-squared=74.8%, p=0.000) OR = 0.32 (0.18, 0.54), % Weight = 100.00

NOTE: Weights are from random effects analysis

Forest Plot for Psychotherapy Trials of Generalized Anxiety Disorder

Goncalves & Byrne. "J Anx Disorders. 2012"
Conclusions for GAD Treatment in the Elderly

• Older adults might benefit more from non-specific, non-pharmacologic interventions
  – General psychoeducation in a primary care setting
  – Supportive treatment (active listening)
  – Psychotherapy if willing and interested

• Pharmacologic treatment likely to work
  – No good long term data
  – Same rules apply as with treatment of insomnia re dosing, use of benzodiazepines

Panic Disorder in Older Patients

• Rarely begins in older patients
  – Consider depression, physical illness or drugs with late onset

• Paucity of data
  – Data extrapolated from treatment of younger patients
  – One prospective, PCB-controlled trial of citalopram in the elderly with anxiety*

Panic in Older Patients

Toxicity from Other Medications
- Albuterol
- Thyroid medication
- Caffeine
- Stimulants

Withdrawal/rebound from other medications
- Benzos
- Alcohol

Undiagnosed medical illness
- Paroxysmal SVT
- Temporal lobe seizures
Treatment of Panic

• Antidepressants
  – SSRIs: citalopram, sertraline have fewest CYP effect
  – TCAs: anticholinergic side effects

• Benzodiazepines
  – Alprazolam, clonazepam, lorazepam
    • Lorazepam: no active metabolites, does not undergo oxidative metabolism (clearance not affected by age)

• Cognitive Behavioral Therapy (CBT)
  – May need greater explanation for older adults, depending on cognitive abilities

Flint AJ & Gagnon N. Drugs & Aging. 2003
The Anxiety & Phobia Workbook

FIFTH EDITION

Practical, step-by-step directions for the mastery of:
- Relaxation
- Exercise
- Coping with panic
- Exposure
- Overcoming negative self-talk
- Changing mistaken beliefs
- Specific phobias
- Self-esteem
- Nutrition
- Medication
- Meditation techniques
- Anxiety-evoking health conditions

EDMUND J. BOURNE, PH.D.
Final Conclusions

• **Insomnia:** Meds work short-term, therapy is better for the long-term.

• **Anxiety:** Anxiety makes everything worse. Medications plus therapy is the best treatment.

• **The elderly:** lower and slower is better. Be very cautious with benzodiazepines. Look for comorbid depression.

• **Life:** Wear sunscreen.
Key Articles: Insomnia

• Buysse DJ. Insomnia. *JAMA*. 2013; vol 309(7): 706-716
• McCall WV. Sleep in the elderly: Burden, diagnosis & treatment. *Prim Care Companion J Clin Psychiatry* 2004;6(1)
Key Articles: Anxiety


Questions?

Thank you!