

# Fall Risk with Trazodone versus Zolpidem for the Treatment of Insomnia in the Elderly

Christine E. Vaudo, PharmD; Maileah Nguyen, PharmD; Amy Boutet, PharmD; Jason Lancaster, PharmD  
Lahey Hospital & Medical Center, Burlington, MA

## Background

- The prevalence of insomnia has been found to increase with age to more than 50% in the elderly population<sup>1,2</sup>
- Zolpidem and trazodone are the two most commonly prescribed medications for insomnia<sup>2</sup>
- There is limited data demonstrating the efficacy of zolpidem and trazodone for the treatment of insomnia in the elderly population<sup>1,2</sup>
- Zolpidem or trazodone use in the elderly has been associated with an increase in adverse effects that put patients at risk for falls and subsequent injury<sup>3-6</sup>

## Objectives

- Primary Objective:** To determine if there is a difference in fall risk with trazodone compared to zolpidem for the treatment of insomnia in patients 65 years or older in the ambulatory setting
- Secondary Objective:** To determine if there is a difference in efficacy with trazodone compared to zolpidem for the treatment of insomnia in patients 65 years or older in the ambulatory setting

## Endpoints

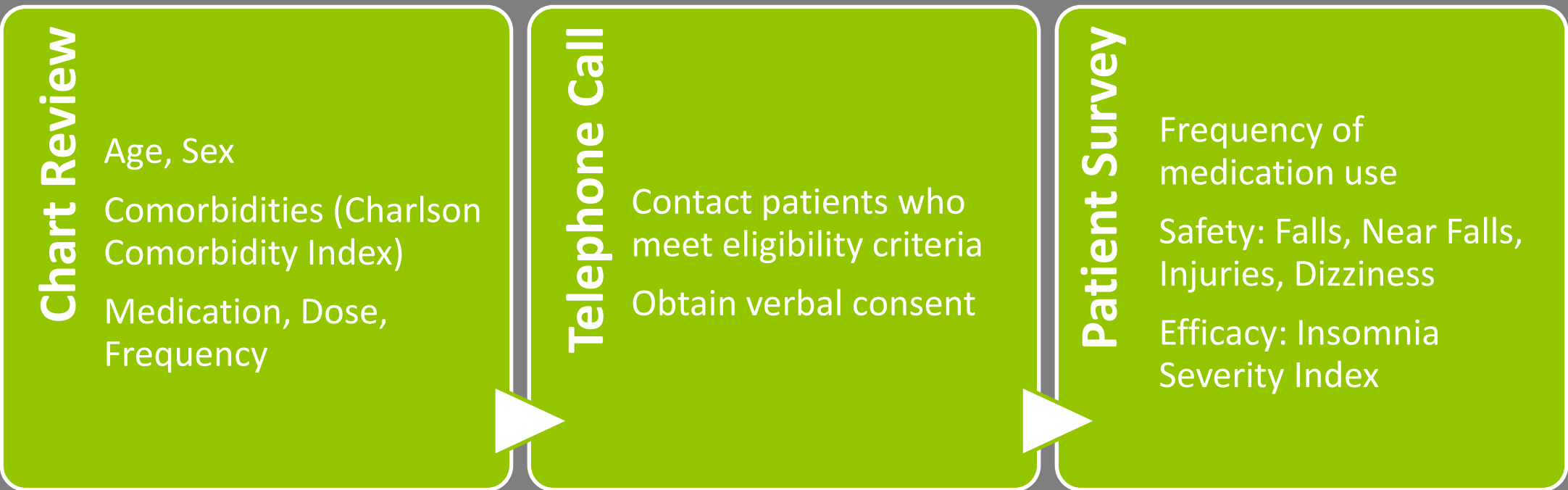
- Primary Endpoint:** Difference in the composite of patient reported falls or near falls in patients treated with zolpidem versus trazodone over the preceding 12 months
- Secondary Endpoints:**
  - Difference in patient reported falls over the preceding 12 months
  - Difference in patient reported near falls over the preceding 12 months
  - Difference in Insomnia Severity Index score

## Methods

- IRB approved survey study of ambulatory patients meeting pre-specified eligibility criteria
- Patients with prescriptions for trazodone or zolpidem from Sept 2014 – Mar 2015 identified retrospectively by chart review

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"><li>Age ≥ 65 years old</li><li>Insomnia</li><li>Active prescription for trazodone or zolpidem</li></ul>	<ul style="list-style-type: none"><li>Depression</li><li>Parkinson’s disease</li><li>Dementia</li><li>Concomitant prescriptions for:<ul style="list-style-type: none"><li>Antidepressants</li><li>Benzodiazepines (BZDs)</li><li>Non-BZD hypnotics</li></ul></li><li>&lt; 3 month insomnia treatment duration</li></ul>

## Data Collection

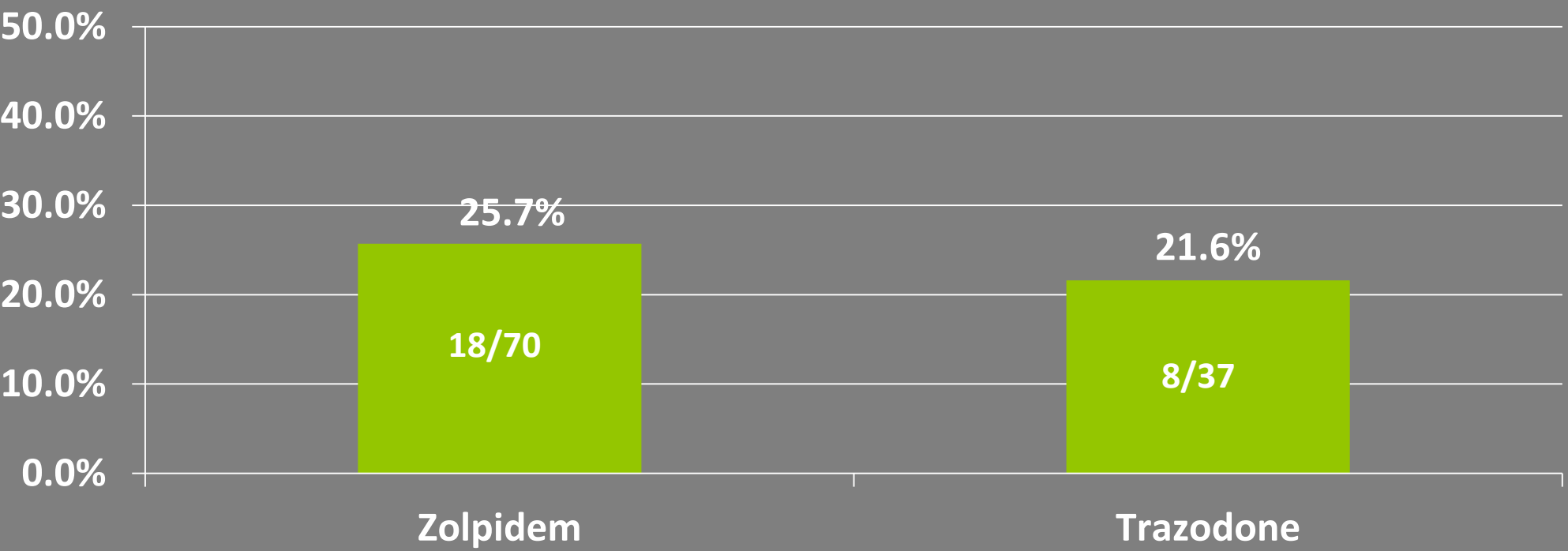


## Baseline Characteristics

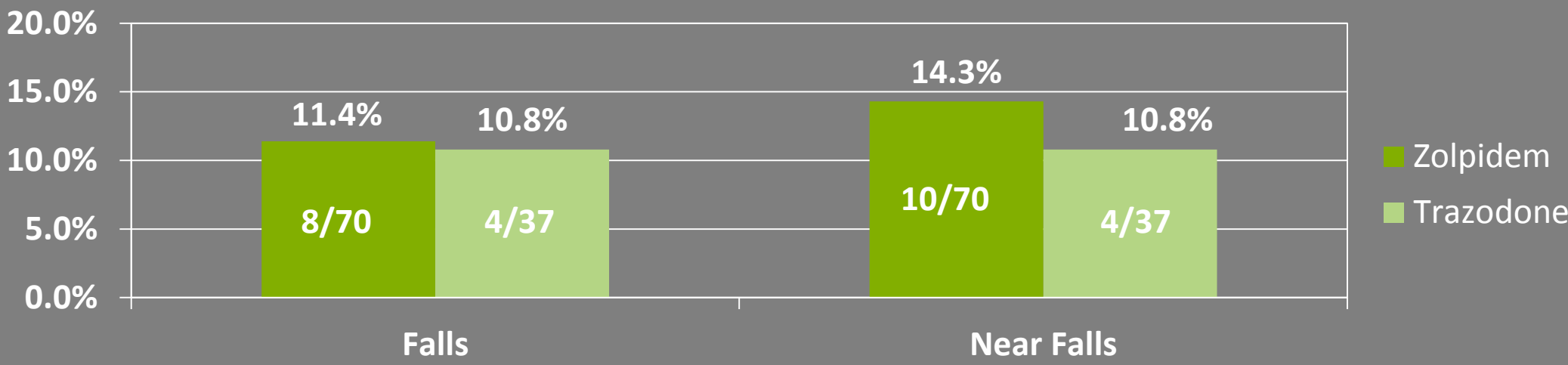
	Zolpidem (n=70)	Trazodone (n=37)
<b>Age:</b> 65 to 74	30 (42.9%)	17 (46.0%)
75 to 84	34 (48.6%)	14 (37.8%)
≥85	6 (8.6%)	6 (16.2%)
<b>Sex:</b> Female	41 (58.6%)	20 (54.1%)
<b>BMI (mean)</b>	28.3	28.4
<b>1<sup>st</sup> Generation Antihistamines</b>	1 (1.4%)	0 (0%)
<b>Vasodilators</b>	38 (54.3%)	24 (64.9%)
<b>Opioids</b>	6 (8.6%)	5 (13.5%)
<b>Charlson Comorbidity, range (mean)</b>	2–8 (3.8)	2–11 (4.6)

## Interim Results

### Composite of Percentage of Patients with a Fall or Near Fall



### % of Patients with a Fall & % of Patients with a Near Fall



	Zolpidem (n=70)	Trazodone (n=37)
<b>Insomnia Severity Index*, range (mean)</b>	<b>0–18 (7.2)</b>	<b>0–25 (7.4)</b>

\*6.5% of patient’s unable to complete the ISI

Insomnia Severity Index Key:

0–7: No clinically significant insomnia  
8–14: Sub threshold insomnia  
15–21: Clinical insomnia (moderate)  
22–28: Clinical Insomnia (severe)

## Limitations



## Interim Results Conclusions

- Zolpidem may be associated with more falls and near falls than trazodone
- Efficacy for the treatment of insomnia appears similar for zolpidem and trazodone
- Based on these results, clinicians may consider preferential use of trazodone in older patients with multiple comorbidities for insomnia treatment

## References

- Schutte-Rodin S, Broch L, Buysse D, et al. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med* 2008;4(5):487–504.
- Kamel N, Gammack J. Insomnia in the elderly: cause, approach, and treatment. *J Am Med* 2006 119:463–469.
- American Geriatrics Society 2015 Updated Beers Criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc* 2015;63:2227–2246.
- Mahoney D, Sullivan D, Byrne S, et al. STOPP/START criteria for potentially inappropriate prescribing in older people: version 2. *Age Ageing* 2015;44:213–218.
- McCall, W. Sleep in the elderly: burden, diagnosis, and treatment. *J Clin Psychiatry* 2004;6:9–20.
- Mendelson W. A review of the evidence for the efficacy and safety of trazodone in insomnia. *J Clin Psychiatry* 2005;66:469–476.

## Disclosures

The authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.