Efficacy and safety of doxepin 6 mg in a four-week outpatient trial of elderly adults with chronic primary insomnia
Lankford et al., Sleep Medicine, 2012

I Background
- Insomnia affects 5-15% of older adults
- Treatment options include cognitive-behavioral therapy for insomnia, or pharmacotherapy. The latter may be associated with daytime sedation and drug dependence

II Hypothesis of the study: Low dose doxepin will lead to subjective improvements in sleep for older adults with primary insomnia.

III Methods review
• Population chosen: Adults >65 years of age with primary insomnia for at least 3 months. Recruited from 32 clinical sites. 130 were randomized to doxepin 6mg and 124 were randomized to placebo
• Intervention: 4 weeks of treatment with doxepin 6 mg before bedtime vs placebo
• Outcome chosen: self-report measures of sleep (sleep diary, Insomnia Severity Index, Patient Global Impression Scale
• Statistics: Intent-to-treat; stratified by center. 120 subjects per arm will provide 90% power to detect a 30 min improvement in total sleep time to a p-value of <0.05.

IV Results
-Doxepin was associated with statistically significant improvements in total sleep time, reductions in wakefulness after sleep onset and improvements in sleep quality compared to placebo
-The clinical significance of these improvements, though, was small compared to placebo: total sleep time increased by 63 minutes compared to pre-treatment, but the difference with placebo was only 10 minutes.
-There was no improvement in sleep onset latency

V Authors conclusions: Low dose doxepin can reduce wakefulness after sleep onset with no increase in serious adverse events

VI Reviewers Critique
- Distinction between statistically significant and clinically significant differences
- Approximately 45% of patients treated with Doxepin will continue to have sleep complaints

VII Summary for practice implications
- Doxepin may have a role in the treatment of insomnia due to its relatively benign side effect profile
- The 6mg dose cost about $5 per tablet, but the 10mg dose (generic) is about 50 cents and may be a reasonable alternative.