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## A review of the evidence for the efficacy and safety of trazodone in insomnia.

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### Abstract

**OBJECTIVE:** Trazodone, a triazolopyridine antidepressant, is currently the second most commonly prescribed agent for the treatment of insomnia due to its sedating qualities. Given trazodone's widespread use, a careful review of the literature was conducted to assess its efficacy and side effects when given for treatment of insomnia.

**DATA SOURCES:** In April 2003, a MEDLINE search was conducted using the search terms trazodone and insomnia and trazodone and sleep and restricted to 1980-2003, human subjects, and English language. As trazodone has been implicated in cardiac disorders, a further search was conducted using the term cardiac and trazodone.

**STUDY SELECTION:** All clinical trials that measured any endpoint for insomnia efficacy were included in the assessment. A total of 18 studies were identified from the literature search. In addition, commonly used texts were consulted for information regarding adverse effects related to trazodone.

**DATA EXTRACTION:** Because so few studies were identified by the literature search, all were evaluated and described.

**DATA SYNTHESIS:** Evidence for the efficacy of trazodone in treating insomnia is very limited; most studies are small, conducted in populations of depressed patients, raise issues of design, and often lack objective efficacy measures. Side effects associated with trazodone are not inconsequential, with a high incidence of discontinuation due to side effects, such as sedation, dizziness, and psychomotor impairment, which raise particular concern regarding its use in the elderly. There is also some evidence of tolerance related to use of trazodone.

**CONCLUSION:** Given the relative absence of efficacy data in patients with insomnia and the adverse events associated with trazodone's use in general, it is uncertain whether the risk/benefit ratio warrants trazodone's use in nondepressed patients with insomnia.

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