

Atypical antipsychotics may aid symptoms for some off-label uses, but not others

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Medical evidence suggests that psychiatric drugs known as atypical antipsychotics are effective in reducing symptoms for some off-label conditions, but not others, according to a new RAND Corporation study.

Evidence supports the effectiveness of some [atypical antipsychotics](#) in reducing symptoms of [generalized anxiety disorder](#), [obsessive-compulsive disorder](#), [post-traumatic stress disorder](#) and behavioral symptoms in elderly patients with dementia, although significant [side effects](#) were noted.

Researchers found insufficient evidence to support efficacy of the medications for treating eating disorders, substance abuse and insomnia. The findings are published in the Sept. 28 edition of the [Journal of the American Medical Association](#).

"The use of atypical antipsychotic medications has spread rapidly beyond the illnesses they originally were developed to treat," said lead author Dr. Alicia Ruelaz Maher, a psychiatrist and researcher at RAND, a nonprofit research organization. "While evidence suggests the drugs help reduce symptoms for some off-label illnesses, we found a lack evidence for others."

Atypical antipsychotic medications are approved for marketing and labeling by the U.S. [Food and Drug Administration](#) to treat schizophrenia, bipolar disorders and depression under drug-specific circumstances.

Use of atypical antipsychotic medications has grown rapidly, with one study estimating that treatment visits for the drugs increased from 6.2 million in 1995 to 14.3 million in 2008. Use of these drugs for off-label indications -- uses not approved by the U.S. Food and Drug Administration -- doubled during the same period.

While [prescription medications](#) frequently are prescribed for illnesses prior to approval by the FDA, concerns have been raised about the practice with atypical antipsychotics because they have substantial side effects.

Researchers from the RAND-based Southern California Evidence-Based Practice Center conducted an extensive review of the [medical](#) literature to find studies that examined the safety and effectiveness of atypical antipsychotics for off-label uses.

They identified 162 clinical trials that involved one or more of the nine atypical antipsychotic medications approved by the FDA, as well as 231 large observational studies that followed patients being prescribed one of the medications.

The review found that aripiprazole, olanzapine and risperidone are associated with small, but significant benefits with the treatment of behavioral symptoms in dementia. Drug dosage generally was about half of that needed in treating adults with schizophrenia or bipolar disorder.

Three large trials of quetiapine reported a modest benefit for treatment of generalized anxiety disorder. The review found risperidone is associated with improvement in symptoms of obsessive compulsive disorder among those who have not responded sufficiently to standard therapy. Risperidone also can improve symptoms of post-traumatic stress disorder among those who have not responded to standard drugs.

Atypical antipsychotics were associated with side effects, including a small but significant increased risk of death among elderly patients with dementia. Other risks in the elderly included cardiovascular problems, movement disorders and urinary tract infections. Side effects in younger patients included weight gain, fatigue and sedation.

"Because these medications pose the risk of serious side effects, I would hope they would be prescribed for these off-label illnesses only in the most-serious cases and for those patients who have not responded to other drugs," Maher said. "But use of atypical antipsychotic medications has grown so fast that we can't be sure that is the case."

The RAND analysis did not find evidence to support the efficacy of atypical antipsychotic medications for substance abuse, eating disorders or insomnia.

"This type of review is designed to help clinicians, patients and families better understand whether there is evidence regarding medications for off-label uses," said Margaret Maglione, a study co-author and a RAND policy analyst. "These findings will help physicians and families better weigh benefits and possible harms of using atypical antipsychotic medications off-label."

Provided by RAND Corporation

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