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Falls and fractures among long–term care residents with Parkinson's disease psychosis treated with pimavanserin versus other atypical antipsychotics: a plain language summary

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Plain Language Summary of Publication

Falls and fractures among long–term care residents with Parkinson's disease psychosis treated with pimavanserin versus other atypical antipsychotics: a plain language summary

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Where can I find the original article on which this summary is based?

The original article, titled 'Falls and Fractures Among Nursing Home Residents Treated With Pimavanserin versus Other Atypical Antipsychotics: Analysis of Medicare Beneficiaries With Parkinson's Disease Psychosis,' was published in the journal *Drugs – Real World Outcomes* in 2024. The article is open access and freely available at: https://link.springer.com/article/10.1007/s40801-024-00433-2

Summary

What is this summary about?

Diseases such as Parkinson's disease can increase the risk for falls and fractures. Additionally, among patients with Parkinson's disease, approximately 25%-40% develop **psychosis**. Both Parkinson's disease psychosis and treatment with **off-label atypical antipsychotics** may further increase the risk for falls and fractures, which are one of the major causes of injury and death among elderly residents of long-term care facilities, like nursing homes.

How to say (download PDF and double click sound icon to play sound)…

- **Antipsychotic:** an-tee-sahy-kot-ik
- **Parkinson's disease:** paar-kihn-suhnz duh-zeez
- **Pimavanserin:** pim-a-van-ser-in
- **Psychosis:** sai-koh-suhs
- **Quetiapine:** kwuh-tai-uh-peen

What were the results?

Pimavanserin is a type of drug called an atypical antipsychotic, and it is the only on-label drug approved by the United States Food and Drug Administration (FDA) to treat hallucinations and delusions related to Parkinsons's disease psychosis. However, other atypical antipsychotics are often prescribed off-label to patients with Parkinson's disease psychosis. This article summarizes a study that evaluated whether pimavanserin or other atypical antipsychotics were associated with more falls and fractures in residents living in long-term care facilities with Parkinson's disease psychosis.

What do the results mean?

The results of this study indicate that residents in long-term care facilities with Parkinson's disease psychosis had a lower risk of experiencing falls only and a lower combined risk of falls or fractures if they were taking pimavanserin instead of other atypical antipsychotics.

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Psychosis: A condition where someone experiences things that are not real, like seeing or hearing things that others don't (ie, hallucinations), or has strong beliefs that are not supported by evidence (ie, delusions). This condition can make it hard to determine what is real and what is not.

Off-label: A term used when a medication is prescribed for a purpose not specifically approved by the FDA. A medication is prescribed 'on-label' when it is prescribed for a purposed approved by the FDA.

Atypical antipsychotic: A medication used to treat mental health conditions like schizophrenia or bipolar disorder. It helps reduce symptoms like hearing voices or having beliefs that are different from reality.

What is the purpose of this plain language summary?

The results of this study may differ from those of other prior studies. Healthcare professionals should make treatment decisions based on all of the available evidence, not on the results of just 1 study.

Pimavanserin is used to treat Parkinson's disease psychosis, the condition discussed in this summary. Currently, pimavanserin is only available in the United States.

Who should read this article?

This plain language summary was written for long-term care residents with Parkinson's disease psychosis, their caregivers, and their healthcare providers. While healthcare professionals and long-term care facility staff are the ones who prescribe medications, all parties involved can benefit from informed discussion about the best possible care plan and which medications are the best fit.

The findings of this study may also be of interest to patients with Parkinson's disease who are not long-term care residents or who do not have symptoms of Parkinson's disease psychosis.

Who sponsored the study?

This study was **sponsored** by Acadia Pharmaceuticals Inc. (San Diego, California, United States), the makers of pimavanserin.

Sponsor: A company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information from the study.

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What is Parkinson's disease psychosis?

Parkinson's disease psychosis

Patients with Parkinson's disease psychosis have symptoms **of Parkinson's disease** as well as symptoms of **psychosis**

25%-40% of patients with Parkinson's disease may experience psychosis

Parkinson's disease

Includes motor and nonmotor symptoms

Motor symptoms

- Tremors
- Uncontrolled shaking
- Slowed/limited body movements
- Body stiffness (usually arms, shoulders or neck)
- Little to no facial expressions

Nonmotor symptoms

- Reduced sense of smell
- Sleep problems
- **Dementia**
- Depression
- Psychosis

Psychosis

Symptoms include hallucinations and/or delusions

Hallucinations

Involve sensing things that are not real:

- Smelling
- Feeling
- Tasting
- Seeing
- Hearing

Delusions

Include having beliefs that are not real

Unlike other forms of psychosis, Parkinson's disease psychosis usually involves just visual or auditory hallucinations

Dementia: A condition where a person progressively loses the ability to think and remember, negatively impacting day-to-day life.

What are the current treatment options for Parkinson's disease psychosis?

Pimavanserin

Pimavanserin is an atypical antipsychotic and the only drug approved by the United States FDA to treat Parkinson's disease psychosis.

Although pimavanserin is approved to treat hallucinations and delusions related to Parkinson's disease, it is not approved for patients with dementia who have these symptoms if they are unrelated to Parkinson's disease. Many patients have both Parkinson's disease psychosis and dementia.

Other atypical antipsychotics

Atypical antipsychotics vary in several ways, including how they work, what symptoms they treat, and what side effects they can have.

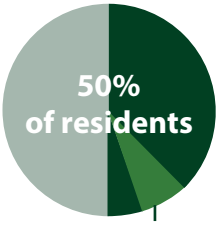
Atypical antipsychotics, with the possible exception of pimavanserin, may have side effects such as sedation (feeling sleepy), problems thinking, and changes in movement (walking or standing).

The potential risk of death is a concern among older patients who have dementia-related psychosis and are treated with atypical antipsychotics, including pimavanserin.

What does this study examine?

1.6 million
residents are living in long-term care facilities in the US

6% of all Medicare spending
is attributed to falls and fractures



will experience a fall in any given year

10%-25%
of residents who experience a fall also experience a serious injury like a fracture

Falls and fractures may drastically reduce an individual's quality of life and may lead to increased physical and mental disabilities.

Medicare: A health insurance program administered by the United States government for people aged 65 years or older and younger people with disabilities.

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Falls and fractures can lead to premature death in some cases.

28,000 deaths were attributed to falls among the elderly in 2017

40% increase in mortality risk in nursing home residents who experience a hip fracture

Motor symptoms associated with Parkinson's disease may increase the risk of falls and fractures, while hallucinations and delusions associated with Parkinson's disease psychosis may lead to an even higher risk.

Several studies have shown that some drugs used to treat Parkinson's disease psychosis, like off-label atypical antipsychotics, may increase the risk of falls and fractures. Certain side effects of atypical antipsychotics, such as sedation, slowed reflexes, and loss of balance, may increase the risk of falls and fractures. However, few studies show the differences in risk of falls or fractures between different atypical antipsychotics.

This study compared the risk of falls and fractures in residents living in long-term care facilities who have Parkinsons's disease psychosis and were treated with either pimavanserin or another atypical antipsychotic.

What was the purpose of this study?

The overall goal of this study was to provide information that may guide the decision-making processes when choosing a medication to treat residents with Parkinson's disease psychosis. This information is relevant to all patients with Parkinson's disease psychosis, their caregivers, and healthcare professionals working in long-term care facilities. This study will inform them of the risks of falls and fractures associated with several atypical antipsychotics.

In this summary:

Patients

Refers to all patients, regardless of where they live

Community setting

Long-term care facility

Residents

Refers only to people living in long-term care facilities, including those analyzed in this study

How was the study carried out?

This was an observational database study, which means it involved reviewing existing healthcare records from databases rather than evaluating patients.

Researchers gathered information from existing Medicare healthcare insurance claims data. This includes information like diagnoses, drug prescriptions, and hospital services.

To be included in this study, long-term care residents with Parkinson's disease psychosis had to:

- Be residing in a long-term care facility for at least 6 months.
- Have started taking pimavanserin or a different atypical antipsychotic between January 1, 2014, and December 31, 2018. Only residents continuously taking pimavanserin or another antipsychotic for at least 6 months were eligible. Residents could not have taken pimavanserin or another atypical antipsychotic for at least 12 months before the study.
- Not have a psychosis diagnosis before the beginning of the study.
- Not have psychosis caused by anything other than Parkinsons's disease. Other causes of psychosis could include delirium, other psychotic disorders, alcohol-drug induced psychosis, schizophrenia, paranoia, or personality disorders; thus, residents with these conditions were not included.

Group matching

Group matching is a statistical technique that was used to identify residents with similar characteristics between the two different treatment groups: residents taking pimavanserin and residents taking off-label atypical antipsychotics. Residents were matched based on characteristics such as sex, age, race/ethnicity, location, and other medical conditions like dementia or insomnia.

Group matching ensures the treatment groups being compared are as similar as possible, making it easier to observe differences in treatment effects.

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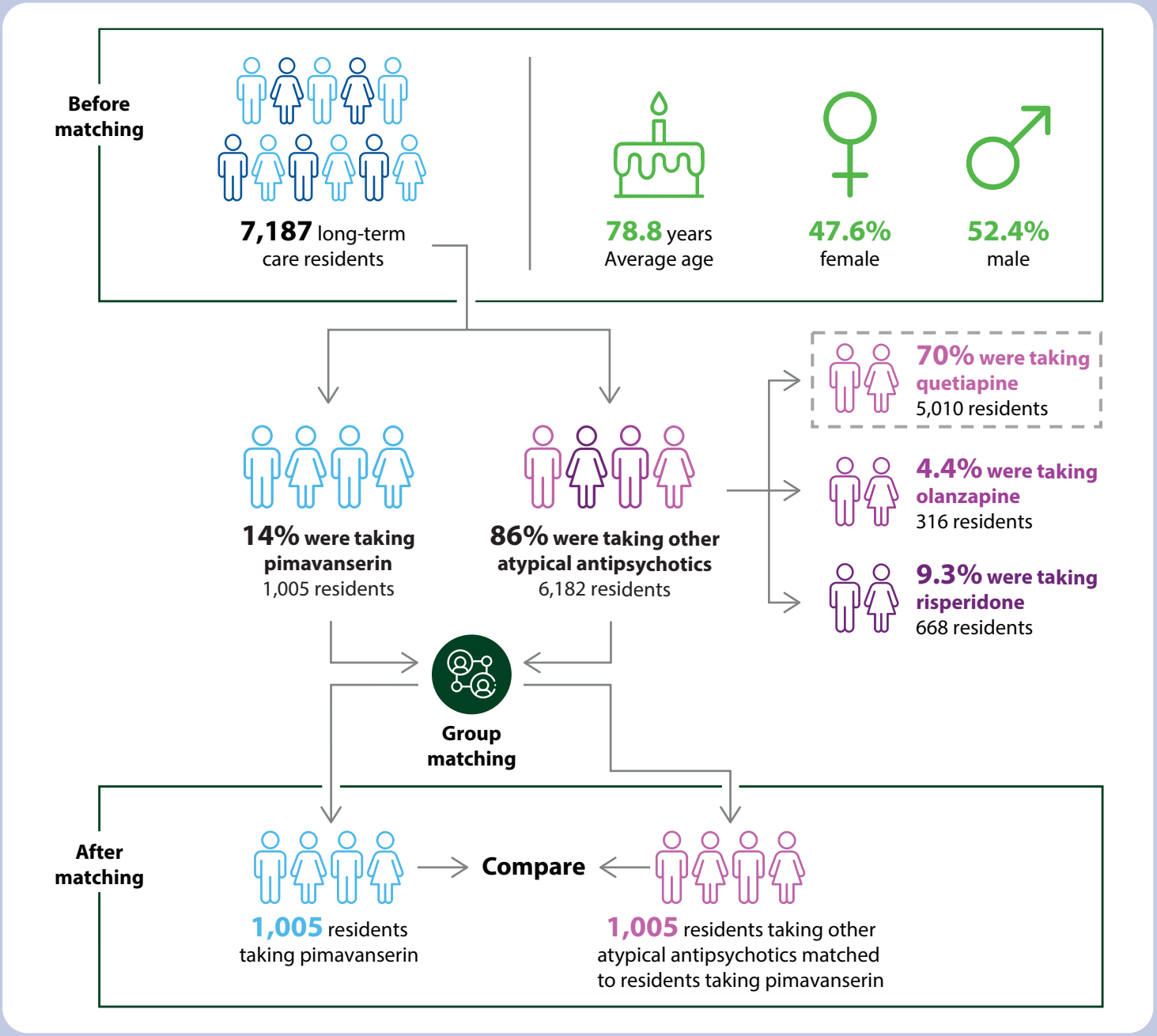
About the study population



After matching, 1,005 residents out of 6,182 who were taking another atypical antipsychotic were compared to the 1,005 residents taking pimavanserin.

The average age before matching was 78.8 years; 47.6% were female and 52.4% were male.

Quetiapine: An atypical antipsychotic used to treat conditions like schizophrenia and bipolar disorder. It is not approved by the FDA to treat Parkinson's disease psychosis.

After matching, resident characteristics were generally similar between the two groups.

How were the results reported?

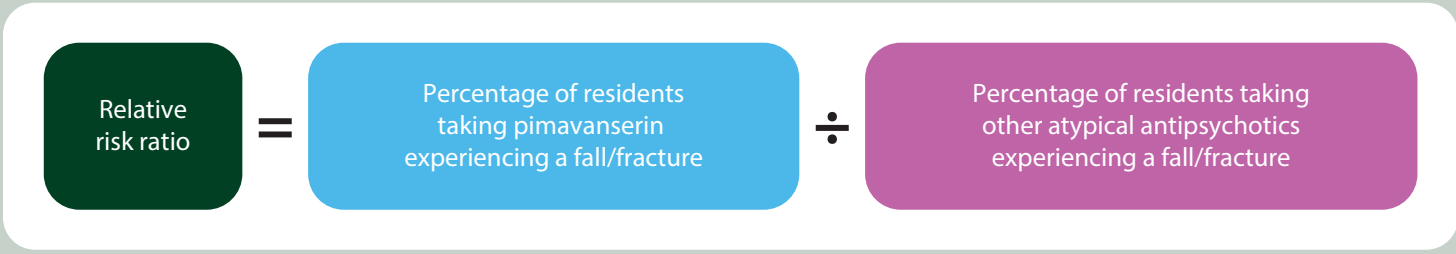
Resident characteristics

Results from this study include resident characteristics like age, sex, race/ethnicity, and other medical conditions reported as averages (in the case of age) or percentages (for all others).

Rates and risk of falls and fractures

Rates were reported as the percentage of residents who experienced a fall only, a fracture only, or a fall or fracture during the 6-month period that they were taking pimavanserin or another atypical antipsychotic. Risk of falls only, fractures only, or falls and fractures were reported as the relative risk ratio.

The relative risk ratio is a number that compares the risk between 2 groups. For example, 1 group is residents taking pimavanserin and the other group is residents taking other atypical antipsychotics.



A relative risk ratio greater than 1 would mean the pimavanserin group experienced more falls and/or fractures than the other atypical antipsychotics group. A relative risk ratio less than 1 would mean the pimavanserin group experienced fewer falls and/or fractures than the other atypical antipsychotics group.

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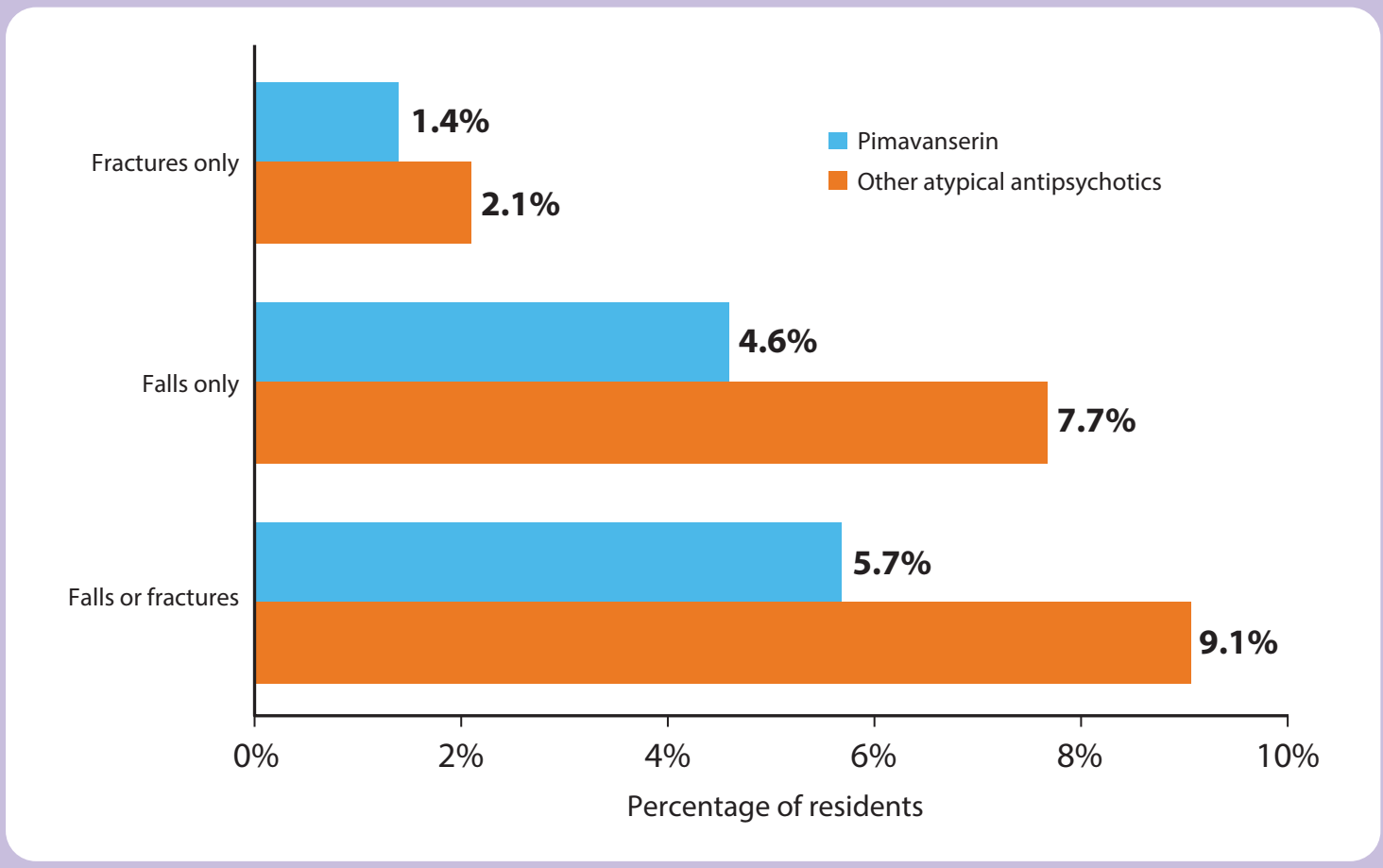
What were the results of this study?

Pimavanserin vs other atypical antipsychotics



Residents taking pimavanserin had lower rates of falls (4.6%) compared with residents taking other atypical antipsychotics (7.7%). This result was **statistically significant**.

Statistical significance: A result is most likely due to an experimental factor like a drug treatment, rather than occurring by random chance.

Residents taking pimavanserin had lower rates of fractures (1.4%) compared with residents taking other atypical antipsychotics (2.1%). This result was not statistically significant.

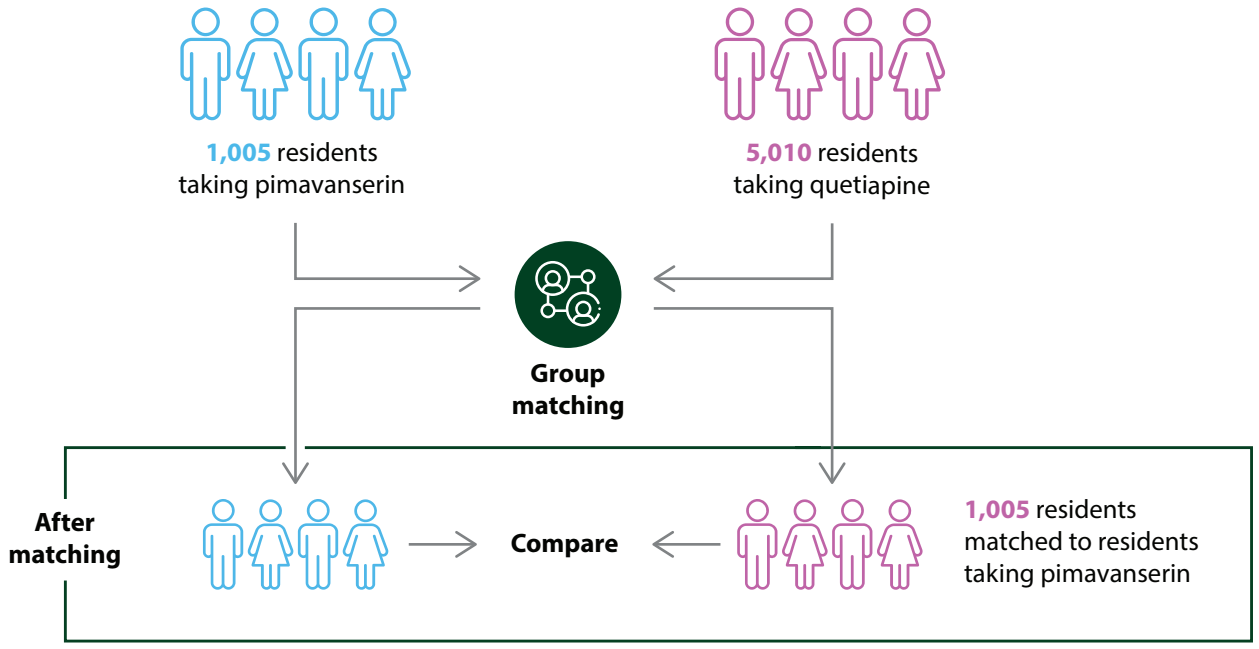
Residents taking pimavanserin had lower rates of falls or fractures (5.7%) compared with residents taking other atypical antipsychotics (9.1%). This result was statistically significant.

Relative risk ratios – pimavanserin vs other atypical antipsychotics		
Falls only 0.60	Fractures only 0.67	Falls or fractures 0.63

Residents taking pimavanserin had an approximately **40% lower risk** of falls only and falls or fractures compared to residents taking other atypical antipsychotics.

Pimavanserin vs quetiapine

A secondary analysis was performed to specifically compare pimavanserin and quetiapine. 1,005 residents taking quetiapine were compared with the 1,005 residents taking pimavanserin using the same group matching technique described above.



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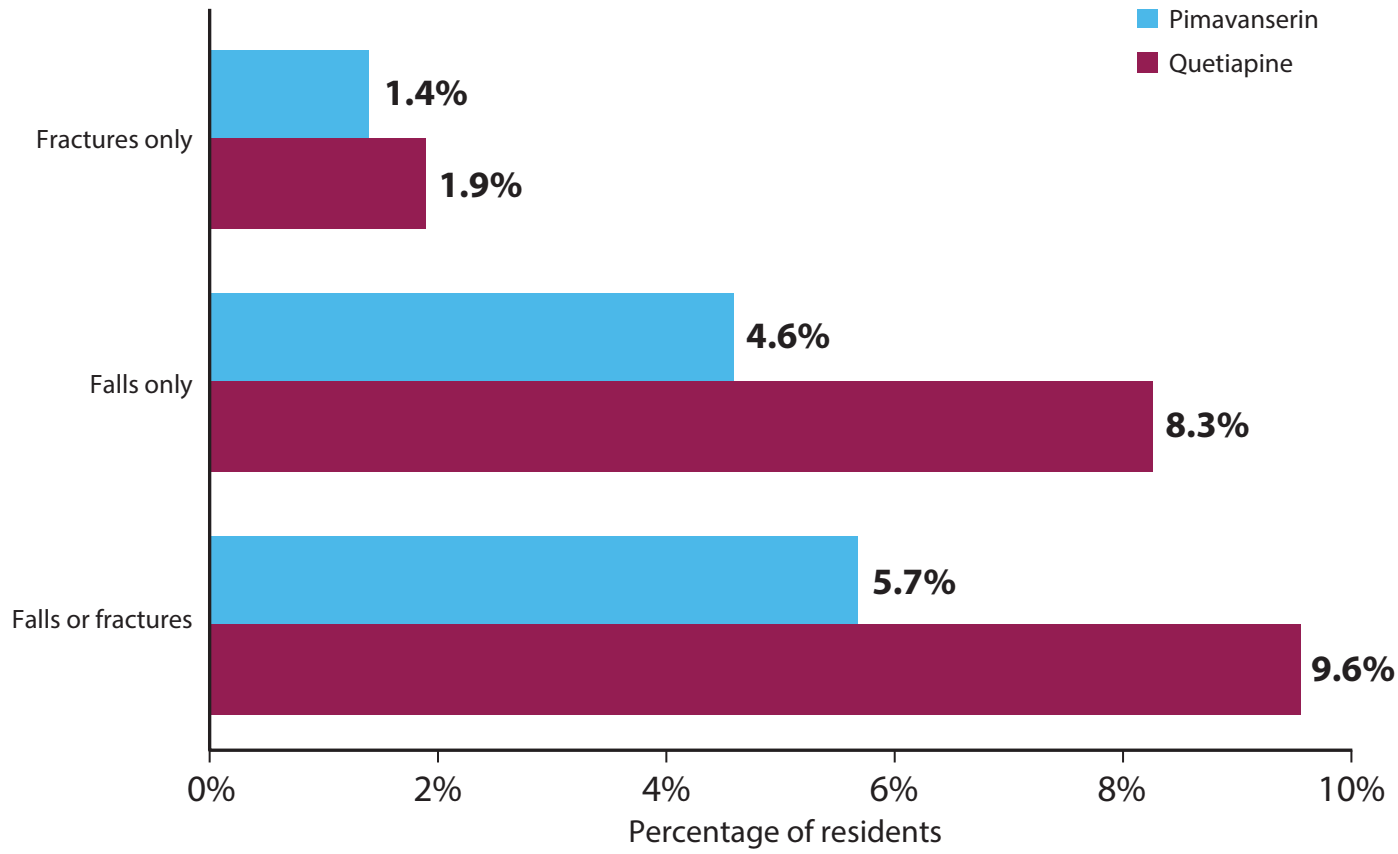

Residents taking pimavanserin had lower rates of falls (4.6%) compared with residents taking quetiapine (8.3%). This result was statistically significant.

Residents taking pimavanserin had lower rates of fractures (1.4%) compared with residents taking quetiapine (1.9%). This result was not statistically significant.

Residents taking pimavanserin had lower rates of falls or fractures (5.7%) compared with residents taking quetiapine (9.6%). This result was statistically significant.

Relative risk ratios – pimavanserin vs quetiapine

Falls only	Fractures only	Falls or fractures
0.55	0.74	0.59

Residents taking pimavanserin had an approximately **40% lower risk** of falls only and falls or fractures compared to residents taking quetiapine.

What do the results of the study show?

These results show that residents who lived in long-term care facilities with Parkinson's disease psychosis had lower rates of falls only and falls or fractures if they were taking pimavanserin instead of quetiapine or other atypical antipsychotics. This study also shows that these residents have an approximately 40% lower risk of falls only and falls or fractures if they are taking pimavanserin instead of quetiapine or other atypical antipsychotics.

Future studies may yield more information on the association of different characteristics and the rates and risk of falls and fractures.

What were the limitations of this study?

Any analysis of claims data may contain mistakes in coding or under-coding of claims, such as not coding every hospitalization. This could have led to some uncertainty in the results of this study.

The kind of data covered in Medicare claims has limitations. Claims do not cover characteristics that cannot be observed in a doctor's office or hospital, like social and financial conditions, social support, or history of smoking. Individual claims also do not include prior fall history or the underlying severity of Parkinson's disease or Parkinson's disease psychosis. These factors may also influence study results.

Residents may have been taking other medications, like blood pressure medication, that may cause dizziness and lead to falls, meaning not every fall or fracture would be caused by Parkinson's disease psychosis or an atypical antipsychotic.

This analysis only studied major fractures including, but not limited to, hips, femurs, and pelvic regions. Other fall-related injuries like bruises and sprains or minor fractures in the wrist or fingers may not have been captured. This may have led to the overall number of fractures being underestimated.

The results of this study may not be internationally generalizable; pimavanserin is only available in the United States. Outside the United States, another atypical antipsychotic called clozapine is commonly prescribed for Parkinson's disease psychosis.

Finally, because this was an observational study of existing Medicare claims data, direct connections cannot be made between the risk of falls and fractures and different medications. Direct connections would only be possible in an interventional (not observational) clinical trial comparing the outcomes of patients taking different medications.

Where can i find further information on Parkinson's disease psychosis?

Parkinson's Foundation
https://www.parkinson.org/understanding-parkinsons/non-movement-symptoms/hallucinations-delusions

American Parkinson Disease Association
https://www.apdaparkinson.org/what-is-parkinsons/symptoms/psychosis/

The Michael J. Fox Foundation for Parkinson's Research
https://www.michaeljfox.org/news/ask-md-parkinsons-disease-psychosis

Where can readers find more information?

This study began in January 2014 and ended in December 2018. The original article, titled 'Falls and Fractures Among Nursing Home Residents Treated With Pimavanserin Versus Other Atypical Antipsychotics: Analysis of Medicare Beneficiaries With Parkinson's Disease Psychosis,' was published in the journal *Drugs – Real World Outcomes* in 2024: Rajagopalan K, Rashid N, Gopal D, & Doshi D. *Drugs – Real World Outcomes*. 2024;11(3):441-449. You can access the article using the link below. The article is open access and available for free at: https://link.springer.com/article/10.1007/s40801-024-00433-2.

A similar study into healthcare resource utilization among patients with Parkinson's disease psychosis who were treated with pimavanserin or other atypical antipsychotics was previously published in a plain language summary and is available for free at: https://www.tandfonline.com/doi/abs/10.1080/14796708.2024.2430813.

Another free of charge plain language summary describes a study of the overall mortality of patients with Parkinson's disease psychosis treated with pimavanserin or other atypical antipsychotics is available at: https://www.tandfonline.com/doi/abs/10.1080/14796708.2025.2463315.

Disclosure statement

Krithika Rajagopalan and Daksha Gopal are current employees of Anlitiks Inc, a company that received funding from Acadia Pharmaceuticals to conduct this study. Nazia Rashid and Dilesh Doshi are current employees of Acadia Pharmaceuticals and may own stock. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. No AI-based tools were used in the composition of this plain language summary.

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