Falls/Fractures Among LTC Residents Receiving Antipsychotics for Parkinson's Disease Psychosis

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PLAIN-LANGUAGE SUMMARY

Background

Chronic diseases such as Parkinson's disease can increase the risk for falls and fractures. Additionally, approximately 25%-40% of patients with Parkinson's disease 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 a major cause of injury and death among elderly residents of long-term care (LTC) facilities, like nursing homes.

What was the purpose of this study?

The overall goal of this study was to provide healthcare professionals working in long-term care facilities with information that may guide their decision-making processes when treating residents with Parkinson's disease psychosis. This study will inform them of the risks of falls and fractures associated with different atypical antipsychotics.

What are the key takeaways and main conclusions?

This is a plain-language summary of 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. The results of this study indicate that long-term care residents 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.

WHAT IS 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.

Parkinsons's disease symptoms		Psychosis symptoms	
Motor symptoms	Nonmotor symptoms	Hallucinations	Delusions
• Tremors/uncontrolled shaking • Body stiffness (usually in arms, shoulders, or neck) • Little to no facial expressions	• Reduced sense of smell • Sleep problems • Depression • Dementia • Psychosis	• Hearing, tasting, seeing, smelling, or feeling things that are not real • Hallucinations (usually visual or auditory)	• Having beliefs that are not real

WHAT DOES THIS STUDY EXAMINE?

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

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

50% of residents **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.
- Falls and fractures may even 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 long-term care residents who experience a hip fracture

- Although motor symptoms associated with Parkinson's disease may increase the risk of falls and fractures, the risk is even higher with hallucinations and delusions associated with Parkinson's disease psychosis.
- 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.
  - Some side effects of atypical antipsychotics that may increase the risk of falls and fractures are sedation, slowed reflexes, and loss of balance.
  - 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 Parkinson's disease psychosis and were treated with either pimavanserin or another atypical antipsychotic.

CURRENT TREATMENT OPTIONS FOR PARKINSON'S DISEASE PSYCHOSIS

Pimavanserin

- Pimavanserin is an atypical antipsychotic and the only drug approved by the US Food and Drug Administration 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 differ in several ways, including how they work, what symptoms they treat, and what side effects they have.
- Other atypical antipsychotics 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.

HOW WAS THE STUDY CARRIED OUT?

- This was an observational database study, which means it involved reviewing existing records from databases.
- Researchers gathered information from existing Medicare health care 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 been taking pimavanserin or another atypical antipsychotic for at least 12 months before the study.

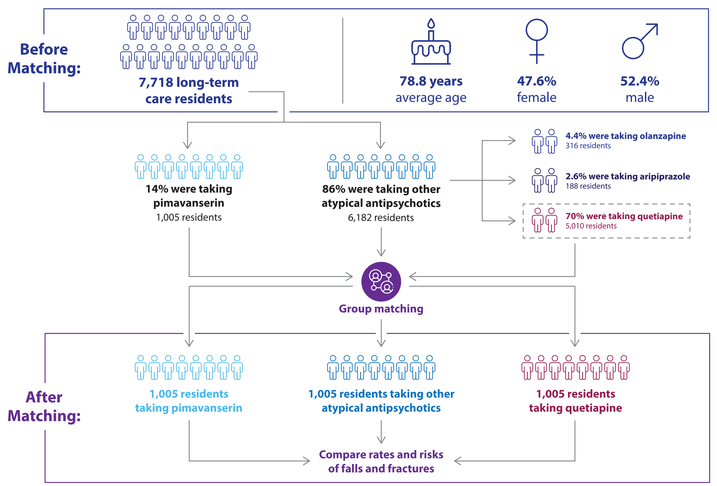
✓ Not have psychosis diagnosed before the beginning of the study.

✓ Not have psychosis caused by anything other than Parkinsons's disease.
  - Other causes of psychosis could include delirium, other psychotic disorders, alcohol- or drug-induced psychosis, schizophrenia, paranoia, or personality disorders; thus, these were not included.

Group matching

- Group matching is a statistical method that was used to identify residents with similar characteristics between the 2 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 that the treatment groups being compared are as similar as possible, making it easier to observe differences in treatment effects.

About the study population



- After matching, resident characteristics were generally similar between the 2 groups.
- A secondary analysis was performed to compare rates and risk of falls and fractures between residents taking pimavanserin and those taking quetiapine.

HOW WERE THE RESULTS REPORTED?

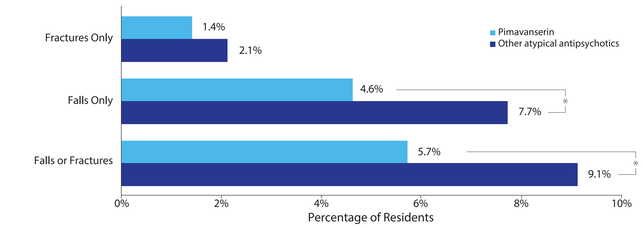
Resident characteristics

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

Rates 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.

Pimavanserin vs other atypical antipsychotics



*These results were statistically significant.

Risk of falls and fractures

- Risk of falls only, fractures only, or falls and fractures were reported as a relative risk ratio.
  - The relative risk ratio is a number that compares the risk of an event happening between 2 groups.
  - In this study, the relative risk ratio was calculated as the percentage of residents experiencing a fall and/or fracture in the pimavanserin group divided by the percentage of residents experiencing a fall and/or fracture in the other atypical antipsychotics group.

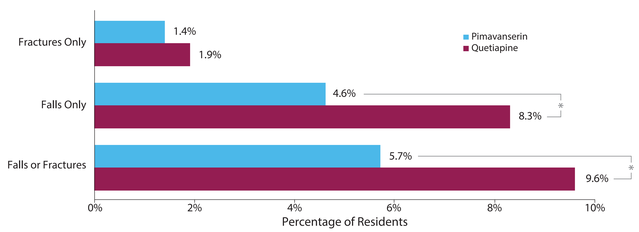
Relative risk ratio = **Percentage of residents taking pimavanserin experiencing a fall/fracture** ÷ **Percentage of residents taking other atypical antipsychotics experiencing a fall/fracture**

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

- In the secondary analysis, 1,005 residents taking quetiapine were compared with the 1,005 residents taking pimavanserin using the same group-matching technique



*These results were 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 MEAN?

- These results show that residents with Parkinson's disease psychosis who lived in long-term care facilities 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 long-term care 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 reveal more information on how different characteristics may affect the rates and risk of falls and fractures.

LIMITATIONS

Inaccuracies in study data may have resulted from

- Mistakes in coding or undercoding of claims.
- Claims covering characteristics that cannot be observed in a doctor's office or hospital (social/financial conditions, social support, history of smoking).
- Claims do not include severity of Parkinson's disease or Parkinson's disease psychosis.
- Other medications leading to falls; not every fall or fracture would be caused by Parkinson's disease psychosis or an atypical antipsychotic.
- Including only major fractures like hips, femurs, and pelvic regions. Other fractures resulting from falls (eg, in the wrist or fingers) may not have been captured. This may have led to underestimation of the overall number of fractures.
- 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.

Where can readers 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.

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DISCLOSURES

JA, NR, and DD are employees of Acadia Pharmaceuticals and may own stock. KR and DG are employees of Anlitiks, which received funding from Acadia Pharmaceuticals to conduct this research.

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