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Healthcare Resource Utilization and Time to Long Term Care Admission among Patients with Parkinson's Disease Psychosis with Co-Existing Dementia initiated on Pimavanserin vs Quetiapine: Analysis of US Medicare Beneficiaries

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INTRODUCTION

- Parkinson's disease (PD) psychosis (PDP) can lead to a range of neuropsychiatric symptoms (NPS), mental health issues, including dementia and reduced cognitive abilities.[1]
- The co-occurrence of psychosis and dementia significantly impacts PDP patients' and caregivers' quality of life, leading to increased morbidity, mortality, caregiver burden, and nursing home placement.[2,3]
- Pimavanserin (PIM) is the only atypical antipsychotic (AAP) approved by the FDA in 2016 for treating PDP, with or without the presence of co-existing dementia (PDP+D).
- Even though PIM is the only current FDA approved therapy for the treatment of PDP with or without dementia, other AAPs such as quetiapine (QUE) are often prescribed off-label in the real-world setting.
- Real-world studies examining patients who are treated with PIM vs other-AAPs, especially with QUE for PDP+D are lacking.

OBJECTIVES

- The objectives of this study were to compare all-cause and psychiatric related healthcare resource utilization (HCRU) rates and evaluate the time to long term care admission (LTCA) among PIM vs QUE treated patients with co-existing dementia in real-world settings.

METHODS

Study Design and Data Source

- A retrospective analysis of Parts A, B, and D claims from 100% Medicare sample of PDP+D patients from April 2015 to December 2021 was conducted (the study period).

Study Population

- PDP+D patients initiating (i.e., index date) continuous monotherapy of PIM or QUE for ≥12-months during April 2016 to December 2020 without any prior-AAP use during the 12-month pre-index period were selected.
  - ***Exclusion Criteria:*** Patients with a pre-index diagnosis of secondary parkinsonism, delirium, psychosis/other psychotic disorders, alcohol/drug-induced psychosis, schizophrenia, paranoia, or personality disorders

Study Measures & Outcomes

- Demographics: age, sex, race, geographic region and comorbidities
- HCRU Measures during 12-month follow-up:
  - Rates of all-cause and psychiatric (psych)-related inpatient hospitalizations [IP] (including type of stay: short-term stay, long-term stay, or skilled nursing facility (SNF) stay)
  - Rates of all-cause and psychiatric-related emergency room (ER) visits
  - Rates of all cause and psychiatric-related office visits (OV) and outpatient visits (OP)
- Time to LTCA: LTCA was defined as a composite of SNF and LTC stays

Statistical Methods

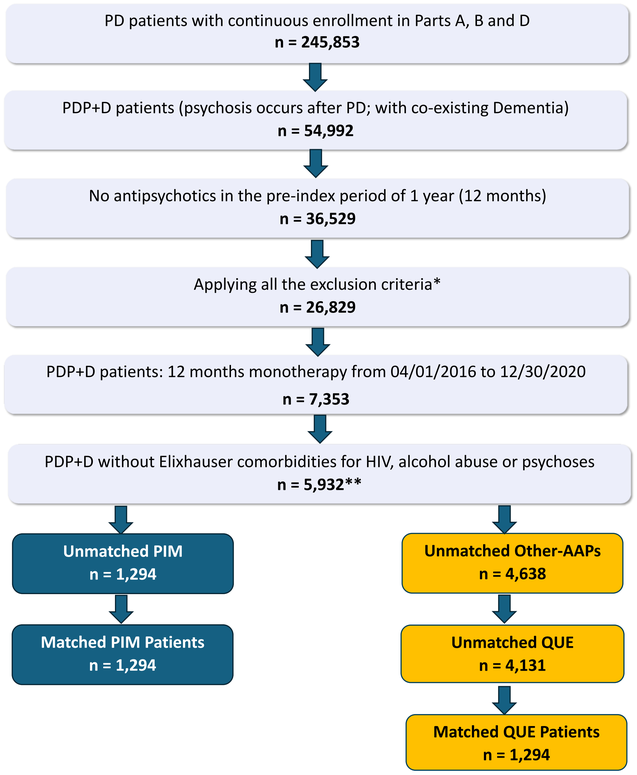
- Patients on PIM vs QUE were 1:1 propensity score-matched (PSM) on 31 variables (age, sex, race, region, and 27 Elixhauser comorbidity characteristics).
- Descriptive statistics were reported as frequencies and percentages for categorical variables; mean, median, and range for continuous variables. Chi-square tests (categorical measures), t-tests, and Wilcoxon-Rank Sum tests (continuous measures) were used to describe differences in outcomes associated with PIM vs QUE.
- HCRU differences between PIM vs QUE patients were evaluated using Log binomial regressions controlled for demographic characteristics, comorbidities and reported as relative risks (RR) and 95% confidence intervals (95% CI).
- Time (in days) to LTCA were examined for PIM and QUE using Kaplan-Meier plots. Log-rank tests was performed to compare differences between cohorts. Hazard ratios (HR) and 95% confidence intervals (CIs) was estimated via cox proportional hazard model to assess the risk among patients with PIM vs QUE.
- Analyses were performed using SAS® Enterprise Server via the CMS Virtual Research Data Center.

RESULTS

Demographic and Clinical Characteristics

- A total of 5,932 patients met our study inclusion and exclusion criteria.
- There were 1,294 PDP+D patients on PIM continuous monotherapy; 4,131 PDP+D patients on QUE continuous monotherapy (Figure 1). PDP+D patients were matched 1:1 to PIM patients, and 1,294 PDP+D patients on PIM and QUE were included in the analyses (Figure 1).

Figure 1: Patient Attrition Population Selection



*Diagnosis of secondary parkinsonism, delirium, other psychotic disorder, alcohol/drug-induced psychosis, schizophrenia, paranoia, or personality disorders. **Patients treated with other-AAPs were limited to risperidone (n = 242), olanzapine (n = 147), aripiprazole (n = 118), and quetiapine (n = 4131); excluded clozapine, paliperidone, brexpiprazole due to small numbers.

Abbreviations: AAPs, Atypical anti-psychotics; PD, Parkinson's disease; PDP, Parkinson's disease psychosis, PDP+D, Parkinson's disease psychosis with Dementia; PIM, Pimavanserin, QUE, Quetiapine; HIV, Human immunodeficiency virus

Table 1: Baseline Demographic and Clinical Characteristics

Characteristics	PIM (n = 1,294)	QUE (n = 1,294)	SMD
Age (in years)			
Mean (SD)	77.34 (6.75)	77.71 (6.54)	0.055
Median (IQR)	77 (73, 82)	78 (73, 82)	
Male, n(%)	726 (56.11%)	714 (55.18%)	0.019
Race, n (%)			
White	1,179 (91.11%)	1,197 (92.50%)	0.050
Black	36 (2.78%)	35 (2.70%)	0.005
Asian	25 (1.93%)	15 (1.16%)	0.063
Hispanic	10 (0.77%)	7 (0.54%)	0.029
North American native	7 (0.54%)	3 (0.23%)	0.050
others	18 (1.39%)	22 (1.70%)	0.025
Unknown	19 (1.47%)	15 (1.16%)	0.027
Region, n (%)			
South	522 (40.34%)	531 (41.04%)	0.014
Midwest	280 (21.64%)	276 (21.33%)	0.008
Northeast	246 (19.10%)	254 (19.63%)	0.016
West	246 (19.10%)	233 (18.10%)	0.026
Comorbidities, n (%)			
Insomnia	592 (45.75%)	566 (43.74%)	0.040

PIM, pimavanserin; QUE, quetiapine; SD, standard deviation; IQR, interquartile range; SMD, standardized mean difference

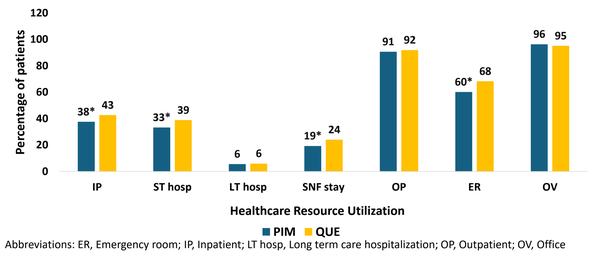
- A SMD value <0.1 means that there is no difference between the groups; The groups were well balanced in Table 1 after PSM.

Table 2: Baseline Clinical Comorbidities

Comorbidities, n (%)	PIM (n = 1,294)	QUE (n = 1,294)	SMD
Congestive Heart Failure	134 (10.36%)	145 (11.21%)	0.027
Cardiac Arrhythmia	271 (20.94%)	271 (20.94%)	0.000
Valvular Disease	126 (9.74)	126 (9.74)	0.000
Pulmonary Circulation Disorder	32 (2.47%)	46 (3.55%)	0.063
Peripheral Vascular Disease	261 (20.17%)	250 (19.32%)	0.021
Hypertension Uncomplicated	843 (65.15%)	837 (64.68%)	0.010
Hypertension Complicated	186 (14.37%)	160 (12.36%)	0.059
Paralysis	17 (1.31%)	8 (0.62%)	0.071
Other Neurological Disorders	1,282 (99.07%)	1,278 (98.76%)	0.030
Chronic Pulmonary Disease	152 (11.75%)	172 (13.29%)	0.047
Diabetes Uncomplicated	225 (17.39%)	219 (16.92%)	0.012
Diabetes Complicated	155 (11.98%)	140 (10.82%)	0.036
Hypothyroidism	273 (21.10%)	273 (21.10%)	0.000
Renal Failure	161 (12.44%)	151 (11.67%)	0.024
Liver Disease	13 (1.00%)	19 (1.47%)	0.042
Peptic ulcer excluding bleeding	8 (0.62%)	15 (1.16%)	0.058
Solid Tumors without Metastasis	103 (7.96%)	117 (9.04%)	0.039
Lymphoma	13(1.00%)	19 (1.47%)	0.042
Metastatic Cancer	10 (0.77%)	13 (1.00%)	0.025
Rheumatoid Arthritis	44 (3.40%)	32 (2.47%)	0.055
Coagulopathy	57 (4.40%)	56 (4.33%)	0.004
Obesity	79 (6.11%)	64 (4.95%)	0.051
Weight Loss	117 (9.04%)	150 (11.59%)	0.084
Fluid and Electrolyte Disorders	238 (18.39%)	230 (17.77%)	0.016
Blood Loss Anemia	13 (1.00%)	15 (1.16%)	0.015
Deficiency Anemia	104 (8.04%)	100 (7.73%)	0.011
Depression	467 (36.09%)	467 (36.09%)	0.000

- Clinical characteristics and descriptive statistics for the 1:1 matched groups are described in Tables 1 and 2.
- Both PIM and QUE cohorts appeared to have similar mean age, gender and comorbidity profile after matching.

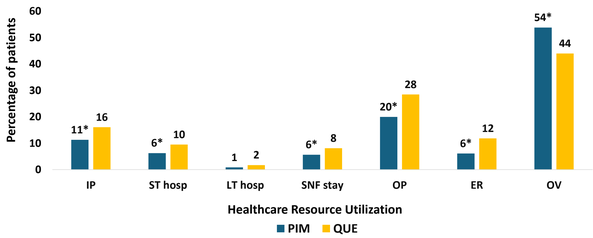
Figure 2: Rates of All-Cause Health Care Resource Utilization



Abbreviations: ER, Emergency room; IP, Inpatient; LT hosp, Long term care hospitalization; OP, Outpatient; OV, Office Visits; PIM, Pimavanserin; QUE, Quetiapine; SNF, Skilled nursing facility; ST hosp, Short term hospitalization; * P-value <0.05.

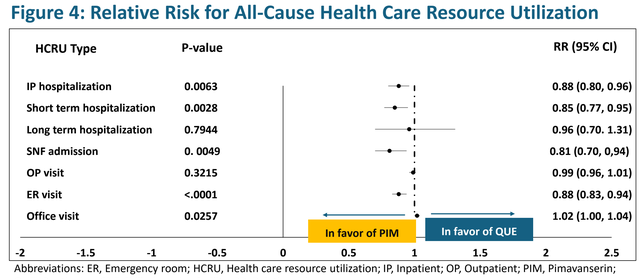
- Patients on PIM-monotherapy reported lower all-cause HCRU compared to QUE-monotherapy for IP hospitalizations (37.6% vs. 42.7%, p<0.05), ER visits (60.1% vs. 68.2%, p<0.05), and OP visits (90.6% vs. 91.8%, p=0.32), Figure 2.
- Rates of pscyh-related visits were lower for PIM-monotherapy vs QUE patients, IP hospitalizations (11.3% vs. 16.1%, p<0.05), ER visits (6.1% vs. 11.8%, p<0.05), and OP visits (19.9% vs. 28.4%, p<0.05), Figure 3.
- Patients on PIM-monotherapy also reported lower relative risk for all-cause HCRU across all settings except office visits and outpatient visits was close to no difference, Figure 4; patients on PIM-monotherapy reported lower relative risk for psych-related HCRU across all settings except office visit, Figure 5.

Figure 3: Rates of Psych-Related Health Care Resource Utilization



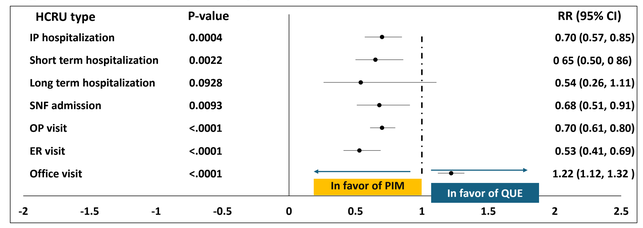
Abbreviations: ER, Emergency room; IP, Inpatient; LT hosp, Long term care hospitalization; OP, Outpatient; OV, Office Visits; PIM, Pimavanserin; QUE, Quetiapine; SNF, Skilled nursing facility; ST hosp, Short term hospitalization; * P-value <0.05.

Figure 4: Relative Risk for All-Cause Health Care Resource Utilization



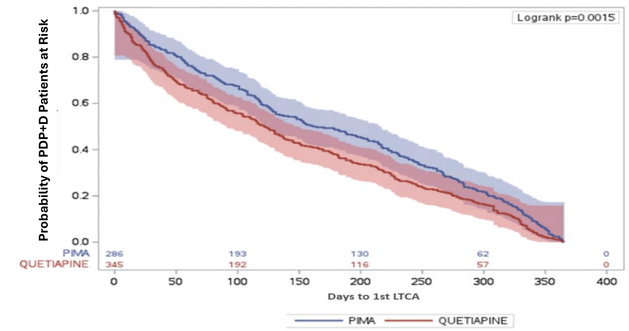
Abbreviations: ER, Emergency room; HCRU, Health care resource utilization; IP, Inpatient; OP, Outpatient; PIM, Pimavanserin; QUE, Quetiapine; SNF, Skilled nursing facility; RR, Relative risk.

Figure 5: Relative Risk for Psych-Related Health Care Resource Utilization



Abbreviations: ER, Emergency room; HCRU, Health care resource utilization; IP, Inpatient; OP, Outpatient; PIM, Pimavanserin; QUE, Quetiapine; SNF, Skilled nursing facility; RR, Relative risk.

Figure 6: Time to Long Term Care Admissions



- PIM vs QUE had lower LTCA (22.1% vs.26.7%, p<0.05) and greater median days to LTCA [163 (65, 284) vs. 122 (39, 245), p<0.05)].
- The corresponding adjusted Hazard Ratio (95% Confidence Interval) was 0.77 (0.66, 0.90) (p<0.05); translating this result to 23% lower risk of LTC admissions for patients on PIM compared to QUE; the results are statistically significant (P=0.0015).

CONCLUSIONS

- Patients with PDP+D who are treated with PIM-monotherapy vs QUE-monotherapy showed significantly lower rates and lower relative risk for all-cause and psych-related IP hospitalizations and ER visits.
- Patients with PDP+D PIM-monotherapy group had a 23% lower risk of LTCA vs QUE-monotherapy and longer delay in being admitted to LTCA vs QUE-monotherapy by 41 median days.
- These results are consistent with prior research of PDP PIM-monotherapy vs QUE-monotherapy suggesting that with or without dementia, patients with PDP+D on PIM-monotherapy show significant better HCRU outcomes in the real-world setting.

REFERENCES: 1.Fénelon G, Alves G. Epidemiology of psychosis in Parkinson's disease. J Neurol Sci. 2010;289(1-2):12-17; 2.Aarsland D, Larsen JP, Tandberg E, Laake K. Predictors of nursing home placement in Parkinson's disease: a population-based, prospective study. J Am Geriatr Soc. 2000;48(8):938-942; 3.Segal GS, Xie SJ, Paracha SU, Grossberg GT. Psychosis in Parkinson's Disease: Current Treatment Options and Impact on Patients and Caregivers. J Geriatr Psychiatry Neurol. 2021;34(4):274-279.

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