

Clinical follow-up of Parkinson disease with newly prescribed quetiapine

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Psychosis is a significant psychiatric disorder in Parkinson disease (PD), with a long-term cumulative prevalence of 60%(1). Approximately 50% of patients with PD psychosis (PDP) are treated with an antipsychotic (AP), most commonly quetiapine(2). Large-scale pharmacoepidemiological research in PD demonstrated that AP treatment is associated with increased mortality(3) and morbidity(4), but little is known about mortality and morbidity at the individual patient level. Using administrative and clinical record data from six specialty PD centers, we assessed correlates of negative outcomes in patients initiating quetiapine.

The study included 261 patients receiving care at a US Veterans Affairs PD center (PADRECC), with idiopathic PD, stable physical health, and a new quetiapine prescription(3, 4). Two raters abstracted data from medical notes in the year preceding quetiapine treatment. Administrative data included a diagnosis of depression, use of non-psychiatric medications, and medical comorbidity.

We utilized a combined physical morbidity-mortality outcome of a VA ER visit, VA hospitalization, or death as a “negative” outcome. Comparisons between those with and without a negative outcome during the 180-days of follow-up were made using the χ^2 test or two-sample t-test. A Cox regression model was used to model time to first occurrence of a negative outcome, adding clinical measures individually after adjusting for administrative data-based

measures. Adjusted hazard ratios (AHR) are reported for clinical measures, and analyses were repeated after multiply imputing the missing measures.

The study cohort of 261 newly-treated quetiapine patients was elderly (mean age =75 years), nearly all male (99.2%), diverse in terms of PD severity based on H&Y stage, and with high rates of cognitive (80%) and gait (90%) impairment, indicating a vulnerable population. Prevalence of a negative outcome was high, with 104 (39.8%) individuals having at least one over the 180-day follow-up period. This included (groups not mutually exclusive) 18 (17.3%) individuals who died, 88 (33.7%) with an ER visit, and 57 (21.8%) who were hospitalized.

In bivariate analyses a comorbid depression diagnosis and greater medical co-morbidity were correlates of a negative outcome. Of the chart abstraction-based measures, PD severity, decreased mobility, and orthostasis were predictive of a negative outcome (**Table 1**). In the Cox models greater PD severity (AHR=3.37; 95% CI=2.14, 5.30), impaired balance (AHR=2.14; 95%CI=1.18, 3.86) and gait impairment (AHR=2.02; 95% CI=1.19, 3.42) predicted a negative outcome (**Supplementary Table 1**). When the analyses were repeated using 25 multiply imputed datasets, positive association for gait and balance impairment remained significant.

The clinical correlates of a negative outcome with quetiapine treatment fit into three categories: severe disease, autonomic dysfunction and co-morbidity. APs can worsen parkinsonism, and the

association between more severe disease and a negative outcome might be mediated by injuries. Orthostasis is common in PD and a side-effect of low-potency APs. Co-morbid medical conditions and depression might be associated with a risk of negative outcomes through interactions with neurobiological and psychological factors or concomitant medications.

Study limitations include no matched comparison of non-treated patients to determine if predictors of a negative outcome are different for quetiapine-treated versus non-treated patients; examination of quetiapine only; examination of male veterans only; retrospective study design with some missing chart-abstracted variables; and lack of data on the cause of negative outcomes, PD or psychosis duration, and dose or duration of quetiapine treatment, or use of other APs, during the observation period. These data would allow further understanding of the potential role of these variables in negative outcomes.

Initiation of AP for PDP needs to be informed by the risks and benefits. Future prospective controlled research should compare rates and predictors of negative outcomes in patients treated with quetiapine and other APs, and a matched comparison group.

Author Contributions:

Daniel Weintraub, MD contributed to the conception and design of the work described as well as interpretation of the data and drafting the manuscript.

Claire Chiang, PhD contributed to the conception and design of the work described as well as analysis and interpretation of the data and drafting the manuscript.

Hyungjin Myra Kim, ScD contributed to the conception and design of the work described as well as analysis and interpretation of the data and drafting the manuscript.

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Helen C. Kales, MD contributed to the conception and design of the work described as well as interpretation of the data and drafting the manuscript.

Additionally, **all** the authors approved the submitted version of the manuscript and agree both to be personally accountable for their own contributions and to ensure that questions related to the

accuracy and integrity of any part of this manuscript, even ones in which the author was not personally involved, are appropriately resolved.

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Table 1: Demographic and clinical predictors of negative outcome in PD patients treated with quetiapine

	Total (N=261)		Negative Outcome				p value ²
			Yes (N=104)		No (N=157)		
			N	%	N	%	
Administrative data-based variables							
Age (mean±S.D. years)	75.0±8.0		75.4±8.2		74.8±8.0		0.56
Female	2	0.8%	1	1.0%	1	0.6%	0.77
Race							
White	206	78.9%	85	81.7%	121	77.1%	0.29
Black	19	7.3%	6	5.8%	13	8.3%	
Other	4	1.5%	3	2.9%	1	0.6%	
Unknown	32	12.3%	10	9.6%	22	14.0%	
Married	195	74.7%	74	71.2%	121	77.1%	0.28
New non-psych meds in past 14 days	14	5.4%	5	4.8%	9	5.7%	0.75
Within one year prior to index							
Depression	74	28.4%	38	36.5%	36	22.9%	0.02
Charlson=0	161	61.7%	49	47.1%	112	71.3%	<0.001
Charlson=1	39	14.9%	24	23.1%	15	9.6%	
Charlson>1	61	23.4%	31	29.8%	30	19.1%	
Inpatient days=0	227	87.0%	85	81.7%	142	90.4%	0.09
Inpatient days=1-5	14	5.4%	9	8.7%	5	3.2%	
Inpatient days>5	20	7.7%	10	9.6%	10	6.4%	
Nursing homes days=0	258	98.9%	102	98.1%	156	99.4%	0.75
Nursing home days>0	3	1.2%	2	2.0%	1	0.6%	
Chart-based variables							
Hoehn & Yahr stage (3-5 vs. 0-2.5)	70	61.4%	35	81.4%	35	49.3%	0.001
Missing ¹	147	56.3%	61	58.7%	86	54.8%	
Gait impairment	231	89.9%	96	94.1%	135	87.1%	0.09
Missing ¹	4	1.5%	2	1.9%	2	1.3%	
Cognitive impairment	189	79.1%	76	79.2%	113	79.0%	1.00
Missing ¹	22	8.4%	8	7.7%	14	8.9%	
Swallowing difficulty	87	46.8%	34	47.2%	53	46.5%	1.00
Missing ¹	75	28.7%	32	30.8%	43	27.4%	
Falls by history	165	72.1%	69	76.7%	96	69.1%	0.23
Missing ¹	32	12.3%	14	13.5%	18	11.5%	
Mobility level							0.03
Without assistance: 0	61	27.4%	17	18.7%	44	33.3%	
Walker or Cane: 1	118	52.9%	51	56.0%	67	50.8%	

Wheelchair: 2	43	19.3%	22	24.2%	21	15.9%	0.06
Bedridden: 3	1	0.4%	1	1.1%	0	0.0%	
Missing ¹	38	14.6%	13	12.5%	25	15.9%	
Balance impairment	214	87.0%	93	92.1%	121	83.4%	0.03
Missing ¹	15	5.7%	3	2.9%	12	7.6%	
Orthostasis present	84	45.4%	39	55.7%	45	39.1%	
Missing ¹	76	29.1%	34	32.7%	42	26.8%	

Note: Some patients had more than 1 negative outcome. Among 104 quetiapine users with negative outcomes, 84.6% had ER, 54.8% had IP, 17.3% died in follow-up.

¹ Percentages are calculated out of total N=261, N=104 with negative outcome and N=157 without negative outcome.

² From comparing means for age using two group t-test and comparing percentages with the characteristics for other variables using chi-square test between those with vs. without negative outcome. For chart-based variables, comparisons excluded those with missing information on the characteristics.

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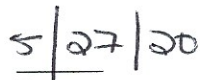
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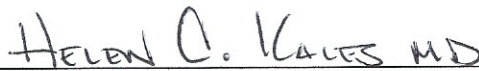
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Manuscript number: MDS-20-0642.R1

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Table 1: Demographic and clinical predictors of negative outcome in PD patients treated with quetiapine

	Total (N=261)		Negative Outcome				p value ²
			Yes (N=104)		No (N=157)		
			N	%	N	%	
Administrative data-based variables							
Age (mean±S.D. years)	75.0±8.0		75.4±8.2		74.8±8.0		0.56
Female	2	0.8%	1	1.0%	1	0.6%	0.77
Race							
White	206	78.9%	85	81.7%	121	77.1%	0.29
Black	19	7.3%	6	5.8%	13	8.3%	
Other	4	1.5%	3	2.9%	1	0.6%	
Unknown	32	12.3%	10	9.6%	22	14.0%	
Married	195	74.7%	74	71.2%	121	77.1%	0.28
New non-psych meds in past 14 days	14	5.4%	5	4.8%	9	5.7%	0.75
Within one year prior to index							
Depression	74	28.4%	38	36.5%	36	22.9%	0.02
Charlson=0	161	61.7%	49	47.1%	112	71.3%	<0.001
Charlson=1	39	14.9%	24	23.1%	15	9.6%	
Charlson>1	61	23.4%	31	29.8%	30	19.1%	
Inpatient days=0	227	87.0%	85	81.7%	142	90.4%	0.09
Inpatient days=1-5	14	5.4%	9	8.7%	5	3.2%	
Inpatient days>5	20	7.7%	10	9.6%	10	6.4%	
Nursing homes days=0	258	98.9%	102	98.1%	156	99.4%	0.75
Nursing home days>0	3	1.2%	2	2.0%	1	0.6%	
Chart-based variables							
Hoehn & Yahr stage (3-5 vs. 0-2.5)	70	61.4%	35	81.4%	35	49.3%	0.001
Missing ¹	147	56.3%	61	58.7%	86	54.8%	
Gait impairment	231	89.9%	96	94.1%	135	87.1%	0.09
Missing ¹	4	1.5%	2	1.9%	2	1.3%	
Cognitive impairment	189	79.1%	76	79.2%	113	79.0%	1.00
Missing ¹	22	8.4%	8	7.7%	14	8.9%	
Swallowing difficulty	87	46.8%	34	47.2%	53	46.5%	1.00
Missing ¹	75	28.7%	32	30.8%	43	27.4%	
Falls by history	165	72.1%	69	76.7%	96	69.1%	0.23
Missing ¹	32	12.3%	14	13.5%	18	11.5%	
Mobility level							0.03
Without assistance: 0	61	27.4%	17	18.7%	44	33.3%	
Walker or Cane: 1	118	52.9%	51	56.0%	67	50.8%	
Wheelchair: 2	43	19.3%	22	24.2%	21	15.9%	
Bedridden: 3	1	0.4%	1	1.1%	0	0.0%	
Missing ¹	38	14.6%	13	12.5%	25	15.9%	
Balance impairment	214	87.0%	93	92.1%	121	83.4%	0.06
Missing ¹	15	5.7%	3	2.9%	12	7.6%	
Orthostasis present	84	45.4%	39	55.7%	45	39.1%	0.03

Missing ¹	76	29.1%		34	32.7%		42	26.8%
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Note: Some patients had more than 1 negative outcome. Among 104 quetiapine users with negative outcomes, 84.6% had ER, 54.8% had IP, 17.3% died in follow-up.

¹ Percentages are calculated out of total N=261, N=104 with negative outcome and N=157 without negative outcome.

² From comparing means for age using two group t-test and comparing percentages with the characteristics for other variables using chi-square test between those with vs. without negative outcome. For chart-based variables, comparisons excluded those with missing information on the characteristics.