Psychiatry Research 265 (2018) 82–86

Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres

All-cause mortality in older adults with affective disorders and dementia under treatment with antipsychotic drugs: A matched-cohort study

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ARTICLE INFO

Keywords:
Antipsychotic agents
Mental health
Cohort study
Pharmacoepidemiology
Older adults

ABSTRACT

We aimed to compare the mortality risk between patients with affective disorders and dementia under treatment with antipsychotics. To do this, a matched-cohort study based on an electronic database of a tertiary teaching hospital in Argentina was performed. Antipsychotic exposure was defined as any antipsychotic drug initiated by the patient. Primary outcome was defined as all-cause mortality during the 5-year follow-up period. To estimate the association between baseline diagnosis (affective disorders vs. dementia) and all-cause mortality, we used a multivariate generalized linear model with robust standard errors. Of 1008 eligible patients, 114 age-matched pairs were included in the present study. The primary event occurred in 23 patients (20%) and 17 patients (15%) in the dementia and affective disorder group respectively. In the adjusted model, the risk of all cause mortality for the affective disorders group was 0.92 times the risk for the dementia group (95%CI, 0.54–1.59, $p = 0.77$). In conclusion, older patients with affective disorders starting antipsychotic treatment presented with a similar risk of all-cause mortality during the 5-year follow-up when compared to older patients with dementia who were also initiating either typical or atypical antipsychotic medications. Closer medical attention to older patients with mental conditions under antipsychotic treatment remains warranted.

1. Introduction

The use of antipsychotic drugs in the treatment of behavioral disturbances that are typically associated with dementia - such as psychosis, agitation, aggression, irritability, and disinhibition - has raised serious concerns regarding the safety of such therapeutic strategy. In 2005, the FDA issued a warning stating that atypical antipsychotics drugs were associated with increased mortality in comparison with placebo in people with dementia (FDA, 2005). In 2008, a similar black-box warning was issued for conventional antipsychotic drugs (FDA, 2010). In general, the increased mortality risk associated with both typical and atypical antipsychotics may be attributed to either infections, arrhythmia or cardiovascular disease (Kuehn, 2005). Furthermore, recent reports have also shown similar results among older adults with other conditions such as Parkinson's disease or stroke under antipsychotic treatment (Frandsen et al., 2014; Jennum et al., 2016).

However, evidence regarding this matter in psychiatric disorders remains both scarce and contradictory. For example, antipsychotic treatment might explain the excess mortality risk observed in patients with schizophrenia (SZ) (Daumit et al., 2008; Goff et al., 2005; Laursen et al., 2014; Raedler, 2010; Saha et al., 2007). Conversely, the FIN-11 study (Tiihonen et al., 2009) did not show an increase in mortality risk when second generation antipsychotic drugs were introduced. Specifically, regarding older adults with Mood Disorders (MD), there is a conspicuous dearth of studies exploring the effects of antipsychotic treatment on mortality. Nevertheless, a recent study has shown higher mortality rates when patients with Bipolar Disorder were receiving antipsychotics rather than anticonvulsants (Bhalerao et al., 2012). This topic remains of special interest since other therapeutic options (i.e., mood stabilizers or antidepressant agents) with proven efficacy are also available for the treatment of such conditions, which contrasts with the scenario in both dementia and SZ. Given that prescription of antipsychotic drugs in MD is rising (Kessing et al., 2016) - and most are using them on a long-term basis (Olfson et al., 2015) - further

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https://doi.org/10.1016/j.psychres.2018.04.034
Received 27 August 2017; Received in revised form 8 April 2018; Accepted 11 April 2018
Available online 19 April 2018
0165-1781/

clarification of the role of these drugs on mortality in patients with MD remains paramount.

Thus, our aim was to delineate the survival experience of older adults with MD starting antipsychotic treatment. For this purpose, we compared the overall mortality risk between patients with MD and dementia under treatment with antipsychotic drugs. We selected dementia patients as the reference group since it stands as the most-validated clinical population in which antipsychotic treatment increases mortality rates.

2. Methods

2.1. Data source and data extraction

The present study was a matched-cohort study based on an electronic database of a tertiary teaching hospital in Buenos Aires, Argentina. The institutional review board provided approval for this study. Health-plan electronic data includes drug prescriptions and its characteristics, including dispensing date, drug name, dose, quantity, and duration of supply - all of which have been shown to be reliable measures of drug treatment (Johnson and Vollmer, 1991; West et al., 1995). Moreover, it contains a fully integrated health-care database with both inpatient and outpatient information regarding baseline comorbidities, clinical outcomes and laboratory measures. We used these health records to gather baseline information on demographics, clinical history and comorbidities, physical examination, and laboratory and radiological data. We also used the registry to capture information on vital status during follow up. Finally, as patients belonging to the present health-plan receive their clinical attention through the tertiary Hospital, all medical care was captured by the present charts.

2.2. Study design and population

We selected 1,229 eligible patients starting antipsychotic treatment in an outpatient basis between January 1 2002 and December 31 2007 (Fig. 1). Patients (with either dementia or affective disorder) were matched by age (± 0.5 years) at the start of follow-up. We identified 114 age-matched pairs and thus, our cohort was comprised of 228 patients. Index date was defined as the calendar time for the first qualifying antipsychotic prescription (i.e., the first refill after the first supply ever received by the patient had ran out).

2.3. Exposure to antipsychotic treatment

Antipsychotic exposure was defined as any antipsychotic drug initiated by the patient with at least one extra expenditure within the first 3 months of prescription. Antipsychotics were divided into either typical (haloperidol, trifluoperazine, levomepromazine and thioridazine) or atypical (olanzapine, aripiprazole, risperidone, quetiapine and clozapine) medications.

Treatment discontinuation was defined by any period of more than, or equal to, 3 months without claiming the prescribed AP drug. In the case that a patient stopped their AP medication, an approximation to an intention-to-treat analysis was performed in which patients were followed until disenrollment, end of follow up or primary outcome regardless of discontinuation of index drug.

2.4. Covariates

Demographic variables including age, gender, and psychiatric diagnosis were recorded. Baseline characteristic regarding prior cardiovascular events (such as ischemic stroke, myocardial infarction, diagnosis of peripheral artery disease and atrial fibrillation) were included. Risk factors (e.g. gender, blood pressure, type 2 diabetes) and laboratory markers associated with cardiovascular disease (low density lipoprotein, high density lipoprotein, total triglycerides, and fasting plasma glucose) were also evaluated. In addition, prevalent chronic pulmonary obstructive disease, heart failure, chronic renal failure, HIV diagnosis, prior pulmonary thromboembolism, liver disease, malignancy and both tobacco and alcohol use were recorded. Finally, the number of hospitalizations during follow-up and number of suicide attempts were measured (Bodén et al., 2015; Gardette et al., 2012).

Regarding concomitant pharmacologic treatment, dispensing of non-AP drugs were also captured if the patient had a documented prescription by the time the AP drug was started. Non-AP drugs included cholesterol-lowering agents, antihypertensive medication, antithrombotic agents, lithium, anticonvulsants, benzodiazepines, antidepressants, cholinesterase inhibitors, corticosteroids, and anti-diabetic agents.

All covariates were measured within a 3-month period prior to or on the index date.

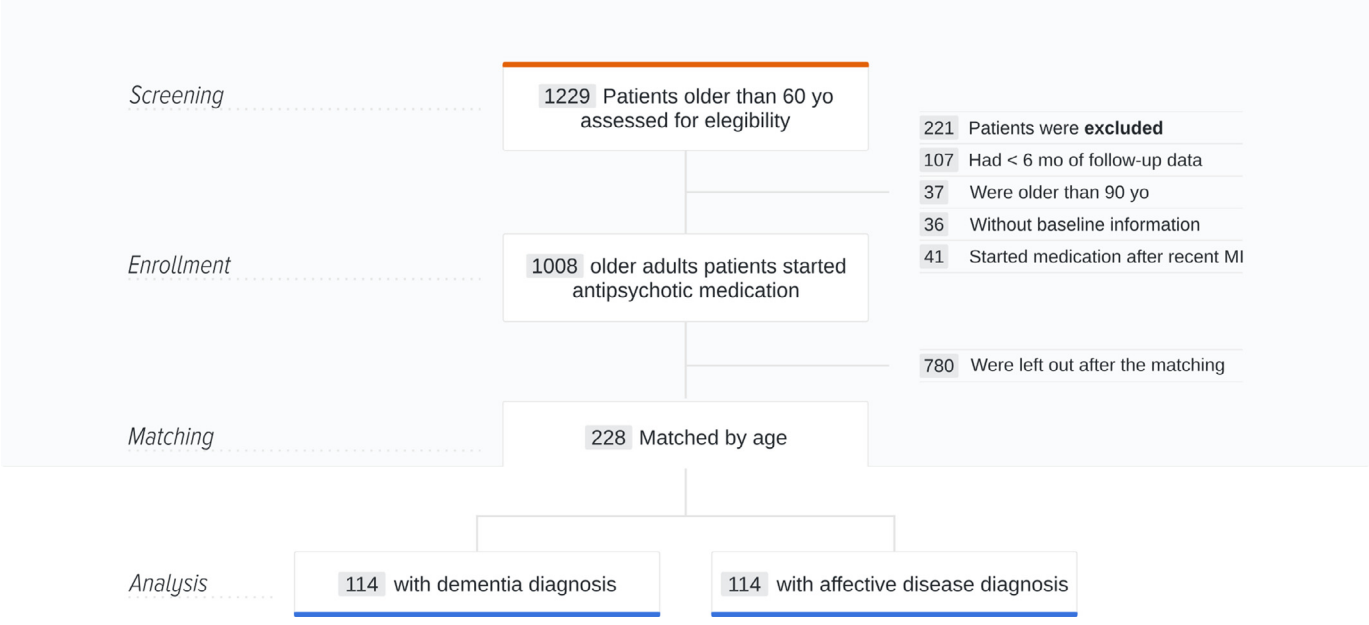

Fig. 1. Flowchart of patients.

2.5. Follow-up and outcome measures

Each patient was followed from the index date to disenrollment from health plan, end of the study period (December 31, 2013) or all-cause mortality. The primary outcome measure was defined as all-cause mortality during the 5-year follow-up period. Mortality in the cohort was captured in the electronic health records either if the death event occurred as an in-patient, as a result of a home-care hospitalization or as an out-patient.

2.6. Statistical analysis

Quantitative variables are presented as mean and standard deviation, or, in case of noticeably skewed data, as the median and interquartile range. Baseline differences between groups were assessed using the McNemar test for categorical variables and paired T test for all continuous variables.

To estimate the association between baseline diagnosis (affective disorders vs. dementia) and all-cause mortality during the 5-year follow up period, we fitted a generalized linear model. This model had a log (link) with a Poisson distribution and confidence intervals were constructed using robust standard errors. This model thus allows to estimate risk ratios (cumulative incidence ratios) and takes into account possible overdispersion. In order to control for measured confounding, we included in this multivariate model all covariates based on subject matter knowledge as well as those statistically significant in the bivariate analysis at the 0.2 level. We used a threshold of 0.05 to declare statistical significance and all reported *p*-values are two-sided. All analysis were performed in STATA v. 14.1 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP).

2.7. Fixed sample size and power calculation

We estimated that, in order to observe a difference of 30% in mortality rates between groups, using a fixed sample size of 228 patients with a two-sided significance level of 0.05, we would obtain 60% statistical power.

3. Results

A total of 114 age-matched pairs were included in the present study. Mean age overall was 74.1 years (standard deviation (SD), 6.9). Main characteristics at baseline are shown in Table 1. Although the measured variables in both groups were similar, statistically significant differences were observed regarding lithium consumption and past psychiatric hospitalization which were - as expected - more prevalent in the MD group. Patients with both diseases had also similar distribution of the type of antipsychotics prescribed (50.9% of dementia patients and 49.1% of affective patients were receiving a typical antipsychotic).

Incidence rate of death among patients with dementia was 6.8/100 person-years and the incidence rate among affective patients was 7.8/100 person-years. The primary event occurred in 23 patients (20%) and 17 patients (15%) in the dementia and MD groups respectively. Of note, none of them was due to suicide. The crude relative risk (RR) of all-cause mortality for the MD group compared to those with dementia was 0.74 (95% CI 0.42–1.31). In the adjusted model, the risk of all cause death for the affective disorders group was 0.92 times the risk for the dementia group (95%CI, 0.54–1.59). A summary of these findings is shown in Table 2.

As a secondary analysis, we evaluated the modification of the aforementioned effect by the type of antipsychotic (either typical or atypical) without any evidence of a statistically significant interaction.

4. Discussion

Our study shows that older patients with MD initiating AP treatment presented with a similar risk of all-cause mortality during the 5-year follow-up period to that of older patients with dementia who were also initiating either typical or atypical AP drugs. The interpretation of our findings should be done with caution and taking into account the limitations of our study.

To the best of our knowledge, there are no previous studies that

Table 1
Baseline characteristics of matched patients with either dementia or affective disorders.

Baseline characteristic	Dementia diagnosis (*N* = 114)	AD diagnosis (*N* = 114)	*p* value[a]
Age - years (mean, SD)	74.1 (6.9)	74.1 (6.9)	1.00
Male sex – no. (%)	40 (35.1)	28 (24.6)	0.11
Systolic blood pressure, mmHg (mean, SD)	130.0 (16.1)	125.7 (22.5)	0.09
BMI, kg/m^2 (mean, SD)	19.0 (12.6)	22.2 (10.5)	0.03
Geriatric residence - no. (%)	97 (85.1)	99 (86.8)	0.84
Psychiatric characteristic - no. (%)			
≥300 mg equivalents of chlorpromazine	10 (8.8)	10.0 (8.8)	1.00
Alcohol abuse	3 (2.7)	5 (4.4)	0.48
Past psychiatric hospitalization	3 (2.6)	18 (16.0)	< 0.01
Use of concomitant medication- no. (%)			
Cholesterol lowering agents	32 (28.1)	28 (24.6)	0.55
Anti-hypertensive	60 (52.6)	50 (43.9)	0.18
Anti-thrombotic	32 (28.1)	20 (17.5)	0.08
Antiepileptic	12 (10.5)	21 (18.4)	0.07
Lithium	0 (0)	9 (7.9)	< 0.01
Benzodiazepines	77 (67.5)	80 (70.2)	0.77
SSRI	1 (0.9)	4 (3.5)	0.37
Corticosteroids	10 (8.8)	12 (10.5)	0.82
Anti-diabetics	6 (5.3)	6 (5.3)	1.00
Comorbid conditions - no. (%)			
COPD	6 (5.3)	15 (13.2)	0.07
Chronic renal failure	12 (10.5)	10 (8.8)	0.82
Heart failure	18 (16.0)	9 (7.9)	0.09
Atrial fibrillation	9 (7.9)	8 (7.0)	1.00
Cancer	19.0 (16.7)	21 (18.4)	0.86
Tobacco use	30 (26.3)	42 (36.8)	0.09
Previous cardiovascular events- no. (%)			
Myocardial infarction	6 (5.3)	8 (7.0)	0.59
Stroke	12 (10.5)	5 (4.4)	0.09
Diabetes	10 (8.8)	9 (7.9)	0.82
Peripheral artery disease	3 (2.6)	2 (1.8)	0.65
Baseline laboratory measures (mean, SD)			
LDL, mg %	109.2 (44.7)	117.5 (43.7)	0.17
HDL, mg %	46.7 (17.8)	49.2 (17.9)	0.27
TG, mg %	100.2 (50.3)	100.6 (48.5)	0.96
Fasting plasma glucose, mg %	95.8 (19.3)	95.0 (24.5)	0.79

AD: affective disorders; SSRI: selective serotonin reuptake inhibitors; COPD: chronic obstructive pulmonary disease; HDL: high-density cholesterol; LDL: low-density cholesterol; TG: triglycerides; BMI: body mass index, SD: standard deviation

[a] Two sided *p* values. Means are compared with paired Student's *T*-test and proportions with the McNemar test.

Table 2
Crude and adjusted relative risk of all cause mortality during 5-year follow up.

Condition	Crude RR (95% CI)	*p* value[a]	Adjusted RR (95% CI)	*p* value[b]
Affective Disorders (vs. Dementia)	0.74 (0.42–1.31)	0.30	0.92 (0.54–1.59)	0.77

Abbreviations: RR: Relative ratio, 95% CI: 95% confidence interval.
Primary outcome: all-cause mortality.

[a] Univariate generalized linear model.

[b] Multivariate generalized linear model including Sex, BMI, SBP, Diabetes, Cancer, Stroke, MI, Peripheral artery disease and Atrial fibrillation.

have directly compared mortality risk among elderly patients with dementia and MD. However, both dementia (i.e. Alzheimer disease) and MD are associated with statistically significant mortality risk compared to the general population (Almeida et al., 2014; Chesney et al., 2014; Lawrence et al., 2013; Todd et al., 2013). This can obscure the potential role of antipsychotic medications on our findings. While it has been well documented that the use of both typical and atypical antipsychotics produces an increase in the mortality in patients with dementia (Gill et al., 2007; Singh and Wooltorton, 2005), its role in patients with MD remains controversial (Barak et al., 2007; Bhalerao et al., 2012). One of the caveats in the evaluation of the mortality risk associated with AP in severe mental conditions is the difficulty in the comparison of users and non-users, or the impossibility to perform studies against placebo. For this reason, we used dementia patients as the comparison group because it remains the most reliable and validated clinical population in which AP treatment increases mortality risk during follow-up. Nevertheless, the assumption that the effect on overall mortality caused by AP drugs on MD and dementia is equal cannot be derived from the present study. In fact, even when mortality in patients with MD who reach old age and those with dementia were similar, and that we controlled for several confounding factors, we cannot rule out that the results of this study were driven primarily by mechanisms related to psychiatric disease rather than drug-related ones. Notwithstanding this limitation, our results reinforce the need for studies specifically focused on the risk of mortality associated with the use of antipsychotics among elderly patients with MD. Studies comparing mortality in specific subgroups of psychiatric patients (such as older adults with BD or MDD) under treatment with AP drugs or other drug classes would be of special relevance to this matter. Moreover, several additional limitations regarding our study have to be acknowledged. Prescription fills can be an imprecise measure of actual drug exposure and may not reflect poor compliance which is associated with MD and dementia in older populations (Barat et al., 2001; Maidment et al., 2002; Sajatovic et al., 2007). However, 91.2% of patients were under antipsychotic treatment when outcome occurred. In addition, age at onset of psychiatric disorders was not available from the current database and it cannot be ruled out that some of the patients were already taking antipsychotic drugs previous to enrollment to health plan. Likewise, while differences in known risk factors and potential confounders were controlled for, residual confounding cannot be excluded as well as confounding by unknown or unmeasured covariates. For example, it may be possible that differences in cognitive status at baseline or during long term follow-up may affect overall survival (Connors et al., 2015), which could not be accounted for. Finally, the MD construct includes different psychiatric diagnoses and it cannot be ruled out that the effect of AP on mortality was the same in all disorders (i.e. MDD and BD). Indeed, a potential risk of non-differential misclassification of the exposure and outcome could have been influential in our finding of no differences between groups. Further studies with a better characterization of affective and dementia diseases should be conducted to endorse our findings.

In summary, our results show that patients with dementia and those with MD initiating antipsychotic treatment show similar long-term outcomes regarding overall mortality. This finding might be due to either drug or diagnosis related mechanisms. Although preliminary, our results warrant the need for further studies on the mortality associated with antipsychotics use in MD, as well as the close medical care of the elderly psychiatric patients treated with these drugs.

Conflict of interest

The authors declare NO potential conflicts of interest.

Author's disclosure

The authors of this paper do not have any commercial associations that might pose a conflict of interest in connection with this manuscript.

Contributors

AGS: designed and wrote the protocol and performed the literature search. AGS, AF, AR, MLG, FM, LCC and FA performed data analysis and drafted the manuscript. DJM and AF provided critical analysis of previous draft versions. All authors contributed to and have approved the final manuscript.

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