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ORIGINAL PAPER

The Relationship of Antipsychotic Medication Class and Adherence with Treatment Outcomes and Costs for Florida Medicaid Beneficiaries with Schizophrenia

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Abstract While some studies show a significant advantage in adherence rates with use of atypical versus typical antipsychotic medication, others show no advantage or mixed results (Jones et al. (2006). *Archives of General Psychiatry, 63*, 1079–1087; Rosenheck, (2006). *Archives of General Psychiatry, 63*, 1074–1076). This study examined treatment outcomes and costs associated with adherence rates by antipsychotic medication class for adult Medicaid beneficiaries in Florida diagnosed with schizophrenia. Outcomes examined include arrests, involuntary commitments, and physical and behavioral healthcare costs. Study findings demonstrate that medication adherence for persons with schizophrenia may be as important to treatment costs and benefits as the class of medication used.

Keywords Antipsychotic medication · Adherence · Medicaid · Cost-effectiveness

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Introduction

Although schizophrenia only affects about 1% of the population in the United States, this disorder consumes a disproportionately larger share of total national healthcare expenditures, approximately $35–$65 billion annually (Rice, 1999; Wyatt, Henter, Leary, & Taylor, 1995). Presently, the most effective treatment for schizophrenia involves the use of antipsychotic medications (Rittmannsberger, Pachinger, Keppelmuller, & Wancata, 2004). However, growing concerns over rapidly rising expenditures for these drugs have made benefit versus price a critical issue (Fichtner, Hanrahan, & Luchins, 1998; Gardner et al., 2003; Gibson, Dalmer, Jackson, Wilder, & Ramsey, 2004; Hogan, 1999). Faced with skyrocketing Medicaid expenditures, many states are adopting restrictive prescribing policies (e.g., mandatory generic requirements, prior authorization, medication algorithms, drug formulary restrictions, and preferred drug lists) to contain these costs (Awad & Voruganti, 2004; Becker & Lemrow, 2004; Boyd, 2003; Geddes, Freemantle, Harrison, & Bebbington, 2000).

Since their development in the 1950s, conventional antipsychotic medications also referred to as first-generation or typical antipsychotics (TAs)—have been a primary component of treatment for schizophrenia

(Lehman & Steinwachs, 1998). However, TAs are associated with diminished tolerability and patient compliance due in part to a high incidence of adverse extrapyramidal side effects including parkinsonism and tardive dyskinesia (Brown, Markowitz, Moore, & Parker, 1999; Dolder et al., 2002). TAs are reported to have only partial efficacy against negative, cognitive, and depressive symptoms of schizophrenia and are associated with patients' complaints of reduced quality of life (Csernansky & Schuchart, 2002; Naber et al., 2001). Since 1989, when the Food and Drug Administration (FDA) began approving second-generation or atypical antipsychotic (AA) medications, these newer, more expensive antipsychotics have gained acceptance as the first-line treatment choice for persons with schizophrenia. Some research suggests that AAs may be more broadly effective than TAs; they have better safety profiles, lower relapse rates, enhanced tolerability and increased adherence rates (Csernansky & Schuchart, 2002; Davis, Chen, & Glick, 2003; Dolder et al., 2002). Other research, however, has questioned these advantages (Jones et al., 2006; Rosenheck, 2006). The CATIE study, for instance, failed to find any significant differences between medication classes in time to discontinuation (Lieberman et al., 2005). Nonadherence is a major problem with both classes of antipsychotics (Eaddy, Grogg, & Locklear, 2005; Thieda, Beard, Richter, & Kane, 2003; Weiden, Kozma, Grogg, & Locklear, 2004). Adherence is defined as the extent to which a person's behavior coincides with medical or health advice (Haynes, 1979, p. 2).

While some studies show a significant superiority in adherence rates with AAs, others show little advantage or inconclusive results (Dolder et al., 2002; Lacro, Dunn, Dolder, Leckband, & Jeste, 2002; Rosenheck et al., 2003; Vanelli, Burstein, & Crammer, 2001). Depending on the study design, measurement methods, and success criteria, reported rates of nonadherence to antipsychotic medication range from 11 to 80%, with an average rate of 50% (Dolder, Lacro, & Jeste, 2003; Lacro et al., 2002; Weiden & Olfson, 1995).

Factors contributing to this inconclusive clinical and cost-effectiveness picture include studies that have been too brief (given schizophrenia's long-term treatment prognosis), and outcome variables concentrating on direct medical costs (Rosenheck, 2006). Few studies have examined the impact of AAs on more distal outcomes such as long-term adherence employment, or perceived quality of life (Becker & Diamond, 2005; Lehman & Steinwachs, 1998). Further complicating existing research is the lack of common definitions or standards for clinical improvement, remission, and recovery (Andreason et al., 2005).

Surprisingly, many studies of schizophrenia have neglected to consider medication adherence in their analysis. Even the most effective antipsychotic medication will fail if not taken. Indeed, research suggests that adherence is far more important than medication class in determining treatment outcomes (Valenstein et al., 2004). Partial or nonadherence is strongly associated with hospital readmission, which is a large part of treatment costs (Svarstad, Shireman, & Sweeney, 2001). In prior research showing cost savings for AAs, these cost savings have been partially derived from lower hospitalization rates thought to be due to a higher level of medication compliance associated with the use of AAs (Davis et al., 2003; Foster & Goa, 1999; Glazer, 1998; Hargraves & Shumway, 1996; Lehman & Steinwachs, 1998; McCombs et al., 2000). Unsuccessful management of medication adherence is correlated with suboptimal clinical responses and may be the most common cause of relapses, which increased treatment costs (Weiden, Aquila, & Standard, 1996; Weiden et al., 2004).

Almost 40% of the national annual cost of rehospitalization for persons with schizophrenia is attributed to adherence problems (Weiden & Olfson, 1995). Based on findings from randomized clinical trials, treatment guidelines recommend that antipsychotic medication regimens be followed for at least a year after symptom remission (Mojtabai et al., 2002). Recent data suggest that the majority of patients with schizophrenia considered fully compliant with their antipsychotic medication actually exhibited considerable variation when patient self-reports were contrasted with blood samples or measures such as the Medication Event Monitoring System (Javaid, Holland, & Janicak, 1991; Olivieri, Matsui, Hermann, & Koren, 1991). Further, the prevalence of discontinuous or interrupted use of antipsychotic medication increases over time and is reported to be approximately 50% after 1 year and 75% after 2 years (Weiden & Zygmunt, 1997).

In order to better understand the relationship between antipsychotic medication class, consistent use of a specific medication regime, treatment outcomes and costs, this retrospective intent-to-treat study used administrative data from non-elderly Florida Medicaid beneficiaries with schizophrenia to compare physical health treatment, behavioral health treatment, length of medication adherence, criminal justice outcomes, and service costs among persons taking different classes of antipsychotic medication. To our knowledge, this is the first study to include incarceration and involuntary examination as variables in assessing treatment outcome.

Methods

Participants

The study included all community dwelling Florida Medicaid beneficiaries: (1) between the ages of 18 and 61 during FY 99-00, (2) continuously enrolled in Medicaid for 36 months, including 12 months prior to and 20 months following continuous use of an antipsychotic drug for at least 4 months, (3) diagnosed with schizophrenia in FY 99-00, as indicated by at least one inpatient or two outpatient claims containing that diagnosis, (4) not enrolled in a Medicaid managed care plan, and (5) not living in a nursing home. Persons diagnosed with schizophrenia who were not receiving antipsychotic medications were deleted from the analysis. It is not known whether excluding persons enrolled in a Medicaid managed care plan introduced bias, but previous research comparing fee-for-service and managed care participants within the Florida Medicaid program suggests these populations are comparable (Shern et al., 2005).

Measures

Florida Medicaid paid claims data were used to identify all study subjects and to collect information on the following services: inpatient and outpatient mental health, crisis unit or emergency room, substance abuse, pharmacy, case management, and physical health. Medicaid data were also used to identify pre-existing patient characteristics: age, sex, race, Department of Children and Families (DCF) health planning district, and the existence of other mental health comorbidities. The study utilized the Florida Alcohol, Drug Abuse, and Mental Health Data Warehouse (ADMDW) service event data to capture publicly funded behavioral health services used by the study sample not covered by Florida's Medicaid program. Additionally, we used the Florida Baker Act Data File to identify those who had an involuntary psychiatric (or Baker Act) examination. Arrest data were provided by the Florida Department of Law Enforcement (FDLE). Data on quarters of paid employment were obtained from the Florida Unemployment Insurance Employment Wage File (FUIEWF), a database maintained by the Florida Department of Education. We operationalized the levels of adherence to antipsychotic medications by the frequency with which patients refilled their monthly prescriptions over the study's 24-month follow-up period.

Procedure

After obtaining university IRB approval, we identified Medicaid beneficiaries diagnosed with schizophrenia (as indicated by ICD-9 codes of 295.0–295.9) who had used the same antipsychotic medication for at least four continuous months. (Persons switching medications during this initial 4-month period were not analyzed because the study timeframe could not accommodate adequate follow-up.) Adherence was operationalzed as months on one medication, and was calculated as a proportion of the possible Medicaid prescriptions filled over the 2-year follow-up period. For example, if Medicaid claims data showed an individual received the same antipsychotic medication 18 out of 24 months, that person was rated as having 75% adherence to the medication regime. Both inpatient and outpatient pharmacy records were used to assure complete data. All antipsychotic medications paid for by Medicaid, including clozapine, were included in the analyses.

Beneficiaries were grouped into four categories based on time on their specific medication: (1) maximal adherence (75–100% use over the 2-year study), (2) moderate adherence (50–74.9%), (3) minimal adherence (25–49.9%), and (4) negligible adherence (<25%). We also examined three types of antipsychotic medication users within the study sample: (A) patients who received TAs only, (B) patients who received AAs only, and (C) patients who received a combination of AAs and TAs (i.e., on both types of medication at the same time). The use and cost of behavioral and physical health, pharmacy, criminal justice, and involuntary commitment services received were compared across the three medication class groups and four levels of adherence.

Analyses

We used simple descriptive statistics to describe medication usage, and a multivariate logistic regression analysis to predict maximal adherence. Service costs were calculated thusly: Number of units of services patients used X price per service unit. Previously developed standard unit costs were used for specific services (Jones et al., 2006). These cost standards were applied to ADMDW service events, Baker Act (involuntary) examinations, and arrests. For Medicaid services, including pharmacy, the cost was the amount Medicaid reimbursed. To compare statistically the individual and total service costs associated with the different medication classes, a series of univariate one-way analyses of variance were performed to compare the four adherence levels on each of the service cost variables.

Table 1 Sample characteristics by medication class

Characteristic	Typical only (TA)(N = 3,277)	Atypical only (AA) (N = 6,023)	Both TA & AA (N = 1,030)	Total (N = 10,330)
Mean # months on drug (SD)	17.44 (7.16)	19.75 (6.54)	15.75 (7.44)	18.61 (6.98)
Adherence pattern				
Maximal (75–100%)	1,827 (55.8%)	4,319 (71.7%)	463 (45.0%)	6,609 (64.0%)
Moderate (50–75.9%)	518 (15.8%)	581 (9.6%)	177 (17.2%)	1,276 (12.4%)
Limited (25–49.9%)	755 (23.0%)	892 (14.8%)	293 (28.4%)	1,940 (18.8%
Negligible (0–24.9%)	177 (5.4%)	231 (3.8%)	97 (9.4%)	505 (4.9%)
Age at study entry				
18–30	282 (8.6%)	915 (15.2%)	123 (11.9%)	1,320 (12.8%)
31–44	1,481 (45.2%)	2,827 (46.9%)	523 (50.8%)	4,831 (46.8%)
45–64	1,514 (46.2%)	2,281 (37.9%)	384 (37.3%)	4,179 (40.4%)
Mean age (SD)	43.54 (9.10)	41.17 (9.84)	41.48 (9.28)	41.95 (9.61)
Gender				
Male	1,790 (54.6%)	3,256 (54.1%)	630 (61.2%)	5,676 (54.9%)
Race				
White	1,485 (45.3%)	3,340 (55.5%)	540 (53.4%)	5,365 (51.9%)
Non-white	1,792 (54.7%)	2,683 (44.5%)	490 (47.6%)	4,965 (48.1%)
Comorbidities				
Psychotic disorder otherthan schizophrenia	423 (12.9%)	771 (12.8%)	183 (17.8%)	1,377 (13.3%)
Mood disorder	784 (23.9%)	1,871 (31.1%)	282 (27.4%)	2,937 (28.4%)
Substance abuse diagnosis	414 (12.6%)	820 (13.6%)	179 (17.4%)	1,413 (13.7%)

Note: Cells include raw frequencies and column percents or means followed by standard deviations in parentheses

Results

As shown in Table 1, a total of 10,330 individuals met study inclusion criteria. Over half the participants (58.3%) received AA medication only, slightly less than one third (31.7%) received TA medication only, and 10%, received combination AA & TA treatment. In keeping with study expectations, persons on AAs demonstrated greater adherence, remaining on their medication 2.3 months longer than those on TAs or combination treatment. Further data inspection indicated that ''maximal adherence'' was the most common pattern across all three medication groups, with ''negligible adherence'' the least common.

There were modest differences in age, gender, diagnosis and race across the medication groups (see Table 1). With a mean age of 43.5 years, TA users were on average 2 years older than individuals receiving AAs. The combination drug group had a higher proportion of males than the other groups. Persons in the combination drug group were also more likely to have a co-occurring substance abuse or psychiatric diagnosis other than schizophrenia. In addition, persons with minority status were less likely to receive AAs. These demographic differences were consistent across levels of adherence.

Table 2 presents the service utilization outcome variables by medication class. Physical and behavioral health service data indicate that, regardless of adherence level, individuals receiving typical antipsychotic medications had fewer behavioral-health related hospitalizations, fewer CSU or ER visits, and fewer residential treatment days. Patients on combination therapy had the highest rate of hospitalizations, CSU or ER visits, and residential treatment days. Compared to persons on AAs or combination therapy, persons on TAs had fewer involuntary psychiatric (Baker Act) examinations. As expected, persons on TAs were more likely to take medication for side effects than those on AAs (73.8% vs. 41.3%). Persons taking AAs had fewer arrests than persons taking TAs. All variables in Table 2 were used to compute total costs for each medication class and adherence group.

Figure 1 presents the total mean per-user-per-month (PUPM) service costs for each level of adherence within each medication class. These total costs relate to outcomes listed in Table 2, including expenditures for antipsychotic and side effect medications. Total costs were lowest for persons taking only typical antipsychotics and were highest for persons receiving combined therapy. A series of one-way analyses of variance indicated these results were significant across all four adherence levels (all P's < 0.001). Within each medication class, higher adherence levels were associated with significantly lower total costs, though the correlation was weaker for persons taking only atypical

Table 2 Outcomes by antipsychotic medication class (N = 10,330)

Outcome	Typical only (TA) (N = 3,277)	Atypical only (AA) (N = 6,023)	Both TA & AA (N = 1,030)	Total (N = 10,330)	F or χ^2
Mean months on drug	17.4	19.7	15.7	18.6	<0.0001
Persons hospitalized for behavioral health	552 (16.8%)	1,035 (17.2%)	236 (22.9%)	1,823 (17.7%)	<0.0001
Persons with state psychiatric hospital stays	42 (1.3%)	100 (1.7%)	15 (1.5%)	157 (1.5%)	0.3563
Persons with CSU or ER visits	640 (19.5%)	1,426 (23.7%)	276 (26.8%)	2,342 (22.7%)	<0.0001
Persons with residential treatment	177 (5.4%)	623 (10.3%)	136 (13.2%)	936 (9.1%)	<0.0001
Persons on other psychotropic meds	2,331 (71.1%)	4,901 (81.4%)	826 (80.2%)	8,058 (78.0%)	<0.0001
Persons on side effect meds	2,417 (73.8%)	2,489 (41.3%)	798 (77.5%)	5,704 (55.2%)	<0.0001
Persons with outpatient MH services[a]	3,226 (98.4%)	5,942 (98.7%)	1,018 (98.8%)	10,186 (98.6%)	0.5693
Persons with one or more Baker Act Exams	560 (17.1%)	1,186 (19.7%)	274 (26.6%)	2,020 (19.6%)	<0.0001
Persons with multiple Baker Act Exams	227 (6.9%)	501 (8.3%)	136 (13.2%)	864 (8.4%)	0.0378
Persons with one or more arrests	266 (8.1%)	471 (7.8%)	74 (7.2%)	811 (7.9%)	0.6183
Persons with multiple arrests	117 (3.6%)	205 (3.4%)	42 (4.1%)	364 (3.5%)	0.5471
Persons with addictions services	375 (11.4%)	720 (12.0%)	155 (15.1%)	1,250 (12.1%)	0.0072
Persons with a physical health Medicaid claim	3,122 (95.3%)	5,766 (95.7%)	1,001 (97.2%)	9,889 (95.7%)	0.0298

Note: Percentages represent column percentages

[a] Includes all Medicaid outpatient behavioral health services, including case management

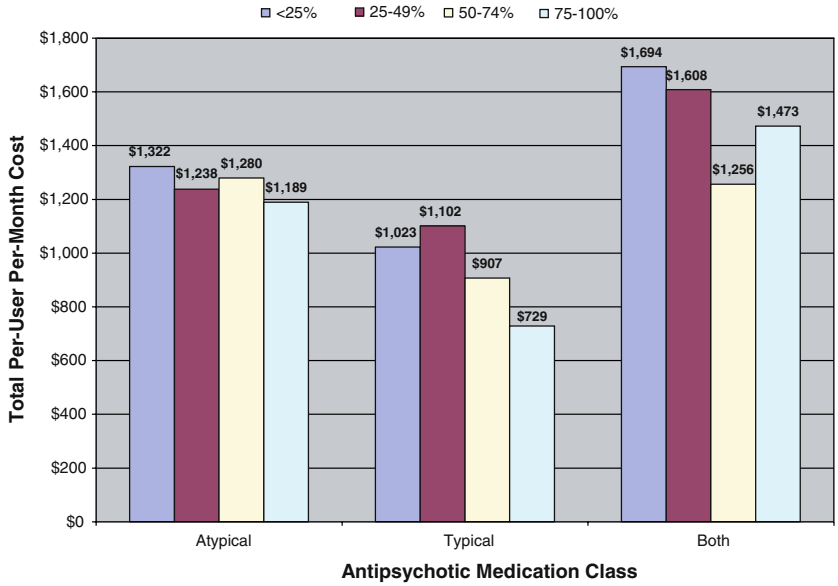

Fig. 1 Total cost by antipsychotic medication class and adherence level

antipsychotics. For persons receiving combination therapy, the lowest costs were associated with the two highest levels of adherence.

Multivariate Analysis

As shown in Table 3, logistic regression analysis revealed that being middle aged or older, male, white, without a co-occurring substance abuse disorder, and being on AA medication all increased adherence rates over the two-year study. Persons on AA medication were more than twice as likely to have maximal adherence than persons on TA medication. Overall, comorbid substance abuse more than doubled the rate of nonadherence. These study findings support previous research that found a relationship between

Table 3 Logistic regression analysis predicting maximal adherence (N = 10,330)

Predictor variable	Values	Odds ratio	95% CI	Wald χ^2	p Value
Age category	31–44 vs. 18–30	1.197	1.050–1.364	7.249	0.0071
	45–64 vs. 18–30	1.396	1.220–1.597	23.578	<0.0001
Gender	Female versus male	0.822	0.755–0.895	20.317	<0.0001
Ethnicity	Non-white versus white	0.737	0.677–0.801	50.519	<0.0001
Comorbid substance abuse	SA versus No SA	0.459	0.404–0.521	144.986	<0.0001
Dual eligibility	Dual versus non-dual	0.955	0.875–1.043	1.033	0.3096
Type of antipsychotic	Atypical versus typical	2.050	1.872–2.246	238.669	<0.0001
	Both versus typical	0.650	0.564–0.751	34.669	<0.0001

medication adherence and age, gender and ethnicity (Fenton, Blyler, & Heinssen, 1997; Ziguras, Klimidis, Lambert, & Jackson, 2001).

Study Limitations

This study has a number of limitations. First, administrative data record-keeping is imperfect and these data lacked measures of illness severity, health status, or role functioning. Second, this study does not include service costs incurred outside of the Medicaid and public behavioral health service system. This includes care provided within the criminal justice system and state hospitals, along with out-of-pocket costs or private pay services. Therefore true behavioral and physical health service costs are underestimated. A third limitation is that we only included beneficiaries continuously enrolled in Medicaid for the 36-month follow-up period. Thus, outcomes for Medicaid drop-outs were not examined in this study. Fourth, there are apparent systematic biases in the decision to place recipients on AA or TA medications. People who are white, have a substance abuse diagnosis or have a mood disorder are more likely to be placed on AA medications (Daumit et al., 2003; Herbeck et al., 2004; Ren et al., 2002). Fifth, our outcome measures were limited. For instance, any improvement in quality of life associated with decreased criminal justice involvement and increased paid employment resulting from increased medication adherence is not reflected in these cost analyses. Finally, this study used pharmacy refill methodology that records only medications dispensed. It is certainly possible that some subjects received but did not take their medication, while others may have received medication from sources outside of Medicaid.

Despite the limitations noted above, large administrative databases are inclusive, cost-effective, and allow investigations of treatment administered in real world settings with diverse populations, including subpopulations rarely included in clinical trials (Pandiana & Banks, 2003). Medicaid datasets offer detailed information on beneficiaries, minimize attrition due to lost contact over time, and can readily be used at minimal cost because the data are already in place.

Discussion

Nonadherence with antipsychotic medication remains a well-recognized but poorly understood problem that threatens the treatment success for schizophrenia and increases costs. When evaluating the cost-effectiveness of antipsychotic medications, clinicians, and researchers should consider the important role of medication adherence. In this study, individuals receiving the more costly AAs were more than twice as likely to achieve maximal or excellent adherence than those receiving TAs. Subjects with co-morbid substance abuse were less than half as likely to achieve maximal adherence than those with no substance use problems. While other variables were associated with increased adherence, AA medication and absence of substance use disorders were the strongest predictors. The more tolerable side effects profile of AAs likely contribute to the increased adherence found in this and other studies. This finding is important as prior research suggests that inconsistent use of antipsychotic medication may negatively impact long-term costs and patient outcomes, particularly if it occurs early in the treatment course (Tandon, 1998; Weiden & Olfson, 1995).

Adherence in this intent-to-treat study was defined by the length of time patients continued refilling prescriptions for their initially prescribed antipsychotic medication regimen. We felt assigning patients to a medication class group based on the initial four-month period was justified; four months provides ample time for pharmacological stabilization and demonstrates a clear intention-to-treat with the identified medication.

Our data indicates that most patients were maximally adherent across drug classes.

Additionally, given that interrupted antipsychotic medication use and polypharmacy have been shown to

contribute to poor treatment outcomes and higher costs for persons with schizophrenia, these variables should be included in future research on the relative merit of specific antipsychotic medications and medication classes (Becker & Lemrow, 2004; Geddes et al., 2000).

Findings indicate that persons with minority status were considerably less likely to receive AAs. These differences are of great concern and are consistent with prior research documenting that racial and ethnic disparities exist in all aspects of psychiatric treatment (Baker & Bell, 1999; Becker, Jang, & Kane, 2006; Moy, Dayton, & Clancy, 2005; Nicole, 2005; Schneider, Zaslavsky, & Epstein, 2002).

To conclude, medication adherence is a critical link between a physician's drug treatment plan and a patient's outcome. Our study suggests adherence may be as important to treatment costs and benefits as the medication type. Additional studies should combine administrative data with quality of life measures to assess the true value of AAs.

Future research would benefit from a design that included extended follow-up periods in order to examine long-term outcomes. Improved understanding of factors that influence patient behavior could facilitate the development of strategies to increase medication adherence and thereby improve treatment effectiveness.

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