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Extent of use of long-acting injectable antipsychotics in children and adolescents within Indiana Medicaid

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Abstract

Introduction: Oral formulations of the antipsychotics aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, quetiapine, and risperidone are indicated for use in pediatrics for several diagnoses. Long-acting injectable (LAI) antipsychotics are of interest in this special population because they may be used due to convenience and desire to improve adherence, despite limited support in the literature. The primary intent of this study is to provide descriptive information on the use of paliperidone palmitate, risperidone microspheres, aripiprazole extended-release injection, and olanzapine pamoate in pediatric patients within Indiana Medicaid.

Methods: This study was a retrospective database analysis, which retrieved information from Indiana Medicaid over a 2-year timeframe spanning from July 1, 2012, through June 30, 2014. The study included the prescription medications filled for all children and adolescents within Indiana Medicaid who received the LAI antipsychotics paliperidone palmitate, risperidone microspheres, aripiprazole extended-release injection, and olanzapine pamoate.

Results: From July 1, 2012, through June 30, 2014, 150 Indiana Medicaid patients younger than 18 years old were prescribed a LAI atypical antipsychotic. A total of 1013 LAI atypical antipsychotic doses were billed to Indiana Medicaid during the study period for pediatric patients. Paliperidone palmitate was billed most frequently.

Discussion: Long-acting injectable atypical antipsychotics are being prescribed for children and adolescents within Indiana Medicaid, despite minimal clinical evidence supporting use. There is a need for further research in this area to increase generalizability of results and aid in implementation of policies to prevent inappropriate use of LAI antipsychotics in children and adolescents.

Keywords: long-acting injectable antipsychotic, children and adolescent, Medicaid

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Introduction

Oral formulations of atypical antipsychotics have Food and Drug Administration (FDA)-approved indications in pediatrics for a variety of conditions. Of these medications, 6 (risperidone, aripiprazole, olanzapine, lurasidone, paliperidone, and quetiapine) are approved for the treatment of schizophrenia (ages 13 to 17). Additionally, 5 (risperidone, aripiprazole, olanzapine, asenapine, and quetiapine) are approved for treatment of bipolar disorder

(ages 10 to 17). Risperidone and aripiprazole are approved for the treatment of irritability associated with autism spectrum disorders (ages 5 to 17).[1-7]

Although atypical antipsychotics are only FDA-indicated for the treatment of 3 psychiatric conditions in the pediatric population, it is not uncommon for these medications to be prescribed off-label. Non-FDA approved indications include attention deficit hyperactivity disorder, oppositional defiant disorder, conduct disorder, major depressive disorder, developmental disorders, and post-traumatic stress disorder.[8,9]

Use of oral formulations of atypical antipsychotics in pediatrics is common, however little is known regarding use of long-acting injectable (LAI) antipsychotics in this population. While a small amount of literature exists for use of some LAI antipsychotics (risperidone microspheres, paliperidone palmitate, aripiprazole extended-release injection, fluphenazine decanoate, and olanzapine pamoate), it is limited to small open label studies, case series, and case reports. Diagnoses contained in these publications include bipolar disorder, schizophrenia, schizoaffective disorder, and eating disorders. These studies concluded that LAI formulations may improve clinical outcomes and adherence with side effect rates similar to oral preparations in the pediatric population; however, there are significant methodological limitations including study design, sample size, and confounding variables that must be taken into consideration.[8,10-13] Because of a lack of data supporting LAI antipsychotic use, the American Academy of Child and Adolescent Psychiatry recommends these dosage forms only for adolescents with schizophrenia and documented chronic psychotic symptoms with a history of poor adherence.[14]

Labeled dosing recommendations for LAI antipsychotics are based on adult populations; therefore, appropriate dosing for the pediatric population is not known. Additionally, pediatric patients have demonstrated greater rates of extrapyramidal and metabolic adverse effects with oral antipsychotics when compared to adults.[15] Long-acting injectable antipsychotic use in the pediatric population lacks long-term safety data regarding these adverse effects. In addition, there is a lack of published pharmacokinetic data for LAI antipsychotics in the pediatric population. It is unclear if differences in muscle mass could alter the release or distribution of the currently available LAI antipsychotics.[16]

As compared to privately insured children, those insured by a state Medicaid program were 4 times more likely to be prescribed an antipsychotic.[17] It was also reported that 12.4% of children in foster care versus 1.4% of non-foster children in Medicaid used antipsychotic prescriptions.[18]

The intent of this study is to provide descriptive information on the use of the LAI antipsychotics in pediatric patients within Indiana Medicaid. Additionally, the study compared data collected from patients designated as *foster* by Indiana Medicaid versus patients without the designation. Long-acting injectable antipsychotic use in this special population is of interest because these formulations may be substituted in place of oral therapy because of convenience and a desire to improve adherence despite limited support for use in the literature. Foster children represent an underserved population that may be more vulnerable to being prescribed multiple psychotropic medications and, consequently, have higher rates of adverse effects.[19,20] This information may serve as a baseline for future studies and assist professional organizations as they develop criteria for the appropriate use of LAI antipsychotics in children and adolescents.

Methods

This study was a retrospective database analysis. Information was retrieved from Indiana Medicaid over a 2-year timeframe, from July 1, 2012, through June 30, 2014. The primary endpoint was to provide descriptive information on the use of paliperidone palmitate, risperidone microspheres, aripiprazole extended-release injection, and olanzapine pamoate in Indiana Medicaid members younger than 18 years. The secondary endpoint of the study was to evaluate the use of these LAI antipsychotics in individuals with the designation of foster child as compared to use in individuals without this designation.

Data recorded within this descriptive analysis included the patient's sex and date of birth; National Drug Code numbers; days supply; Medicaid claim date; National Provider Identifier numbers; and designation of foster child. National Provider Identifier numbers were used to determine prescriber taxonomy.

This study was approved under exempt status by the Indiana University Purdue University-Indianapolis Institutional Review Board because of a lack of personal identifiers collected from the data.

Inclusion criteria involved use of olanzapine pamoate, paliperidone palmitate, risperidone microspheres, or aripiprazole extended-release injection between July 1, 2012, and June 30, 2014; age less than 18 years old; and payer source of Indiana Medicaid. It should be noted that aripiprazole extended-release injection became available on May 1, 2013.

Statistical Package for Social Sciences software (Armonk, NY) was used to analyze both primary and secondary endpoints. Descriptive statistics were performed, including baseline demographics and clinical characteristics for the

TABLE 1: Long-acting injectable antipsychotic use in pediatric patients

Characteristic	Total (%)	Foster (%)	Non-Foster (%)	*P* Value[a]
Patient count	150 (100)	24 (16.0)	126 (84.0)	
Sex				
Male	98 (65.3)	17 (70.8)	81 (64.3)	.537
Female	52 (34.7)	7 (29.2)	45 (35.7)	
Age, y				
Mean ± SD	14.7 ± 2.2	14.8 ± 1.5	14.7 ± 2.4	.618
≤ 2	1 (0.7)	0 (0)	1 (0.8)	.592
3-6	0 (0)	0 (0)	0 (0)	
7-10	5 (3.2)	0 (0)	5 (4.0)	
11-14	52 (34.7)	9 (37.5)	43 (34.1)	
15	31 (20.7)	9 (37.5)	22 (16.7)	
16	33 (22.0)	2 (8.3)	31 (25.4)	
17	28 (18.7)	4 (16.7)	24 (19.0)	
Primary drug				
Paliperidone Palmitate	107 (71.3)	11 (45.8)	96 (76.2)	.005[b*]
Risperidone Microspheres	32 (21.3)	11 (45.8)	21 (16.7)	
Aripiprazole extended-release injection	11 (7.4)	2 (8.4)	9 (7.1)	
Provider				
Psychiatry				
Medical doctor	67 (44.6)	9 (37.5)	58 (46)	
Certified nurse practitioner	23 (15.3)	2 (8.3)	21 (16.7)	.019[c*]
Family medicine				
Medical doctor	1 (0.7)	0 (0)	1 (0.8)	
Certified nurse practitioner	12 (8.0)	3 (12.5)	9 (7.1)	
Pediatrician	1 (0.7)	0 (0)	1 (0.8)	
Multiple providers	46 (30.7)	10 (41.7)	36 (28.6)	

[a]*P* values indicate differences between the foster and non-foster groups.

[b]*P* value for primary drug used indicates differences between primary drug used in the foster group vs non-foster group.

[c]*P* value for provider indicates differences between primary provider in the foster group vs non-foster group.

[*]Statistically significant *P* value.

total population. The foster and non-foster groups were compared using the χ^2 (sex, primary drug), Mann-Whitney *U* (age, grouped age), and Fisher exact (provider) tests.

Results

A total of 150 Indiana Medicaid patients younger than 18 years old were prescribed LAI antipsychotics from July 1, 2012, through June 30, 2014. Patients in the overall study population were aged 14.7 ± 2.2 (mean ± SD) years and were predominantly male (65.3%). Table 1 includes demographic information. A total of 1013 LAI antipsychotic doses were billed to Indiana Medicaid during the study period. Table 2 includes information on LAI antipsychotic doses billed to Medicaid.

Paliperidone palmitate was billed most frequently (72.1%), followed by risperidone microspheres (21.3%) and aripiprazole extended-release injection (6.6%). No doses of olanzapine pamoate were billed during this period. Table 2 summarizes the results relating to the most common dose and administration frequency observed.

Most patients billed therapy from a single provider (69.3%). The largest number of prescribers per patient was 4, which was observed in 2% of patients. Psychiatrists made up the most common taxonomy (44.6%). Within the multiple provider category, prescriber taxonomy included an internal medicine physician and a podiatrist. Of the psychiatrist taxonomy, adult psychiatrists comprised the largest subcategory (49.3%), followed by those specializing in pediatrics (47.7%), and geriatrics (3%). Table 1 includes information on prescriber taxonomy.

Twenty-four patients (16%) were designated as foster children. Patients within this group were aged 14.8 ± 1.5 (mean ± SD) versus 14.7 ± 2.4 (mean ± SD; *P* = .618) years

TABLE 2: Long-acting injectable antipsychotic doses billed to Indiana Medicaid

Age Group, y	<2	3-6	7-10	11-14	15	16	17	Total No. (%) Doses
Total doses billed	1 (0)	0 (0)	47 (4.6)	427 (42.1)	209 (20.6)	206 (20.3)	123 (12.1)	1013 (100)
Paliperidone Palmitate (doses)	0	0	44	317	130	164	75	730 (72.1)
234 mg (1)	0	0	0	8	4	7	4	23
156 mg (1)	0	0	1	8	4	9	4	26
117 mg (1)	0	0	0	4	2	3	5	14
234 mg every 4 wk	0	0	22	60	35	35	18	170
156 mg every 4 wk	0	0	8	131	26	77	26	268
156 mg every 2 wk	0	0	0	1	1	1	0	3
117 mg every 4 wk	0	0	7	92	49	31	14	193
78 mg every 4 wk	0	0	5	12	9	0	4	30
39 mg every 4 wk	0	0	1	1	0	1	0	3
Risperidone Microspheres	1	0	3	81	55	28	48	216 (21.3)
12.5 mg every 4 d	0	0	0	0	2	0	0	2
12.5 mg once weekly	0	0	0	0	2	0	0	2
12.5 mg every 2 wk	0	0	2	6	1	9	0	18
12.5 mg every 4 wk	0	0	0	4	0	2	0	6
25 mg (1 dose)	0	0	0	1	0	0	0	1
25 mg every 2 wk	0	0	1	25	30	12	19	87
25 mg every 4 wk	0	0	0	9	2	0	3	14
37.5 mg every 2 wk	0	0	0	3	15	0	14	32
37.5 mg every 4 wk	1	0	0	32	0	5	4	42
50 mg every 2 wk	0	0	0	0	0	0	8	8
50 mg every 4 wk	0	0	0	1	3	0	0	4
Aripiprazole extended-release injection	0	0	0	29	24	14	0	67 (6.6)
300 mg every 4 wk	0	0	0	14	12	1	0	27
400 mg every 4 wk	0	0	0	15	12	13	0	40

in the non-foster group. Patients in both groups were predominantly male (70.8% in the foster group; 64.3% in the non-foster group; $P = .537$).

Paliperidone palmitate (45.8%) and risperidone microspheres (45.8%) were the primary drugs used by the foster group. When primary drug is compared between the foster and non-foster groups, the difference is statistically significant ($P = .005$).

Multiple providers comprised the most common taxonomy in the foster group (41.7%), followed by psychiatrists (37.5%). Within the psychiatrist taxonomy, adult psychiatrists comprised the largest subcategory (66.7%), followed by those specializing in pediatrics (33.3%). When primary provider is compared between the foster group (psychiatrist) and non-foster group (multiple providers), the difference is statistically significant ($P = .019$).

Discussion

This analysis demonstrates use of LAI antipsychotics in children and adolescents despite lack of compelling clinical data supporting safety and efficacy. Based on the results of this literature review and the clinical experience of the authors, limited clinical circumstances would justify consideration for use of LAI antipsychotics in this patient population. However, these agents could potentially be considered for older adolescents (ages 16 to 18) with documented non-adherence to an oral antipsychotic that is FDA-approved for their diagnosis. Strict monitoring of adverse effects on a routine basis would be indicated.

Paliperidone palmitate was the LAI antipsychotic that was most frequently billed during the study period. Paliperidone palmitate, aripiprazole extended-release injection, and olanzapine pamoate are available in once monthly dosing frequencies, as opposed to risperidone microspheres which requires twice monthly administration. Furthermore, paliperidone palmitate and olanzapine pamoate necessitate no oral antipsychotic overlap upon initiation, in contrast to risperidone microspheres and aripiprazole extended-release injection. Paliperidone palmitate is primarily eliminated as unchanged drug in the urine and has fewer drug-drug interactions than risperi-

done microspheres, aripiprazole extended-release injection, and olanzapine pamoate. Aripiprazole extended-release injection became available 8 months after the start of the study, which most likely contributed to lower use compared to other agents. Additionally, olanzapine pamoate has a Risk Evaluation and Mitigation Strategy for post-dose sedation syndrome that requires the patient to remain in the health care setting for 3 hours after administration because of the risk of symptoms consistent with olanzapine overdose, specifically sedation (including coma) and/or delirium (including disorientation, agitation, anxiety, and cognitive impairment). The majority of cases have occurred within the first 3 hours after injection.[21-24] It is proposed that paliperidone palmitate was the LAI antipsychotic that was billed most frequently during the study period for these reasons.

The paliperidone palmitate package insert recommends a maintenance dose of 117 mg monthly (equivalent to paliperidone tablet 6 mg/d).[21] The most common paliperidone palmitate dose observed was 156 mg every 4 weeks (equivalent to paliperidone tablet 9 mg/d), despite evidence that young patients may be more susceptible to antipsychotic-induced side effects.[21] All LAI antipsychotics included in the study were billed except for olanzapine pamoate, possibly because of post-dose sedation syndrome and the inability to prescribe this medication through the Risk Evaluation and Mitigation Strategy for patients under age 18.[23]

Psychiatrists comprised the most common prescriber taxonomy. Psychiatrists specializing in pediatrics prescribed less frequently than those specialized in adult psychiatry. In clinical practice, many children are seen by a child psychiatrist in consultation and subsequently followed by primary care physicians, especially in rural areas where specialists are not readily available. Indiana Medicaid does cover costs for child psychiatrists, based upon diagnosis of the patient. However, there is a shortage of psychiatrists in Indiana.[25]

Several statistically significant differences were observed between the foster and non-foster groups. The foster group was more likely to receive care from multiple providers than patients without the designation. Additionally, fewer patients received care from pediatric psychiatrists in the foster group than in the non-foster group. Paliperidone palmitate was the primary drug prescribed to patients in the non-foster group, whereas risperidone microspheres was prescribed more frequently in the foster group. These differences may be worthy of further investigation.

In response to the results from this retrospective database analysis, Indiana Medicaid approved a prior authorization policy for patients less than 18 years old. Additionally, 2 expansion studies are in progress to explore diagnoses and concomitant oral antipsychotic therapy of the patients included in this dataset.

Because of the retrospective design of this study, results were limited to injections that were billed to Indiana Medicaid without knowledge of injections that were administered. Extrapolation to other payer sources and states is limited. The number of patients in the original study sample, prior to exclusions (age >18 years and LAI used), was not reported by Indiana Medicaid. It is also unclear how many patients <18 years of age were enrolled in Indiana Medicaid during the study period, which limits assessments of the magnitude of this issue. The data obtained did not identify patients newly started on therapy so that they could be followed over a period of time. The secondary outcome of the study could be considered non-specific, and more specific secondary outcomes were not developed a priori. Appropriateness of the prescriptions was unable to be determined for many reasons including lack of data regarding diagnoses, comorbid conditions, past medication trials, concomitant medications, oral overlap, and side effects. It is unknown how formulary restrictions affected prescribing, and new LAI antipsychotic products have been approved since data analysis was conducted.[26,27]

Long-acting injectable antipsychotics are being prescribed for children and adolescents within Indiana Medicaid despite lack of compelling clinical data supporting safety and efficacy. Some notable prescribing differences were found between the foster group and non-foster group. There is a need for further research in this area to increase generalizability of results and aid in implementation of policies to prevent inappropriate use of LAI antipsychotics in children and adolescents. Areas of interest include pharmacokinetic differences in children and adults, as well as clinical response and tolerability for various conditions.

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