EXAMINING THE IMPACT OF THE PSYCHIATRIC PHARMACIST

mhc MENTAL HEALTH CLINICIAN

ORIGINAL RESEARCH Open Access

Re-implementation of a pharmacist-managed metabolic syndrome clinic in an outpatient mental health clinic setting

Nicole Ganzer, PharmD, BCPS[1]; Brandon Utter, PharmD, BCPS[2]; Beth DeJongh, PharmD, BCPS[3]; Michael Behrens, PharmD, BCPS, CGP[4]; Guadalupe Garcia, PharmD, BCPP[5]; Rebecca Graham, PharmD, BCPP[6]

How to cite: Ganzer N, Utter B, DeJongh B, Behrens M, Garcia G, Graham R. Re-implementation of a pharmacist-managed metabolic syndrome clinic in an outpatient mental health clinic setting. 2015;5(1):57-62. DOI: 10.9740/mhc.2015.01.057.

Abstract

Introduction: Second-generation antipsychotics (SGA) are often prescribed prior to first-generation antipsychotics (FGA) for mental health disorders by reason of proposed improved tolerability. Patients on SGA are not always appropriately screened for metabolic parameters in the clinical setting. A metabolic clinic was previously established for a limited time period at the West Palm Beach Veterans Affairs Medical Center (WPB VAMC) with beneficial outcomes. Re-implementation expanded the clinic to assess the impact when patients were referred from outpatient mental health and primary care providers. The objectives of this quality improvement initiative were to evaluate pharmacologic and nonpharmacologic interventions and compare the patient load preexpansion and postexpansion of the metabolic clinic.

Methods: Patients receiving SGA at the WPB VAMC who met the criteria for metabolic syndrome were referred to the metabolic clinic. Preclinic data variables collected include demographics, social history, SGA, and assessment for presence of hypertension, diabetes, or dyslipidemia. Pharmacologic and nonpharmacologic intervention variables were collected throughout clinic involvement. The patient load post clinic expansion was reported.

Results: Of the 17 patients evaluated, 88.2% had hypertension, 94.1% had dyslipidemia, and 88.2% had diabetes mellitus. The average number of components of metabolic syndrome was 3.7 out of 5 possible components. Most patients were taking risperidone (47.1%). An average of 1.5 medication interventions were made per patient. Only 28 patients were referred during reimplementation phase.

Discussion: Metabolic syndrome commonly occurs in patients receiving SGA. Appropriately trained clinical pharmacists can help fill a gap in care by providing the recommended monitoring criteria and interventions for patients taking SGA.

Keywords: atypical antipsychotics, metabolic monitoring, pharmacist interventions, outpatient mental health clinic, pharmacist impact

[1] (Corresponding author) Clinical Pharmacy Specialist, Mental Health
Veterans Affairs Medical Center, West Palm Beach, Florida
nicole.ganzer@va.gov

[2] Clinical Pharmacy Specialist, Mental Health
Veterans Affairs Medical Center, West Palm Beach, Florida

[3] Assistant Professor of Pharmacy Practice
School of Pharmacy
Concordia University, Mequon, Wisconsin

[4] Clinical Pharmacy Specialist, Primary Care
Veterans Affairs Medical Center, West Palm Beach, Florida

[5] Clinical Pharmacy Specialist, Mental Health
Veterans Affairs Medical Center, West Palm Beach, Florida

[6] Clinical Pharmacy Specialist, Mental Health
Philadelphia VA Medical Center, Philadelphia, Pennsylvania

Introduction

Antipsychotics are used for a number of mental illnesses including schizophrenia, bipolar disorder, refractory depression, autism spectrum disorder, personality disorders, and posttraumatic stress disorder.[1] There are 2 classes of antipsychotics, first-generation antipsychotics (FGA) and second-generation antipsychotics (SGA) (Table 1), both with unique mechanisms of actions and adverse effect profiles. While the FGA are primarily antagonists at dopamine (D_2) receptors, SGA have moderate to high D_2 receptor antagonism as well as serotonin (5-HT) receptor antagonism.[1,2] The differing mechanisms of action may explain some of the side effects associated with each class of antipsychotics. The FGA have been associated with an increased risk of extrapyramidal side effects, including dystonia, akathisia, drug-induced Parkinsonism, and tardive dyskinesia because of the high receptor affinity for the dopaminergic receptors in the nigrostriatal region of the brain. SGA are closely linked to metabolic side effects, including weight gain, insulin resistance, dyslipidemia, and hypertension.[3] Both FGA and SGA also have the propensity to cause anticholinergic side effects, sedation, cardiac arrhythmias, and even sudden cardiac death.[1] In general, both FGA and SGA are effective in treating the positive symptoms (eg, delusions, hallucinations) of psychosis and the negative symptoms (eg, blunted affect, avolition, anhedonia) associated with psychosis.[4]

In current practice, SGA are commonly prescribed as first-line agents for the treatment of mental health disorders owing to their proposed improved tolerability profile and the decreased risk of extrapyramidal symptoms; however, the associated metabolic complications pose a concern for the development of cardiovascular (CV) disease. Patients with mental illnesses are at an increased risk of morbidity and mortality, with cardiovascular disease being responsible for approximately 50% of all causes of death.[5] Lifestyle and genetic predisposition are likely contributing factors to the increased CV death in these patients, as people with mental illness often have poor dietary habits, sedentary lifestyles, and are more likely to smoke.[3,6] The side effects of psychotropic medications have the potential to put patients with existing risk factors at higher risk for CV complications. Of the SGA, clozapine and olanzapine are more likely to cause metabolic syndrome, while aripiprazole and ziprasidone are the least likely.[3,7] Quetiapine, risperidone, and paliperidone fall somewhere between these two extremes.[3,7] Other SGA with low propensity to cause metabolic syndrome include lurasidone, asenapine, and iloperidone.[8]

TABLE 1: Antipsychotic medications

Generic Name	Trade Name	Generic Available
Commonly Used First-Generation Antipsychotics		
Chlorpromazine	Thorazine	Yes
Fluphenazine	Prolixin	Yes
Haloperidol	Haldol	Yes
Perphenazine	Trilafon	Yes
Thiothixene	Navane	Yes
Trifluoperazine	Stelazine	Yes
Commonly Used Second-Generation Antipsychotics		
Aripiprazole	Abilify	No
Asenapine	Saphris	No
Clozapine	Clozaril	Yes
Iloperidone	Fanapt	No
Lurasidone	Latuda	No
Olanzapine	Zyprexa	Yes
Quetiapine	Seroquel	Yes
Risperidone	Risperdal	Yes
Ziprasidone	Geodon	Yes

While the management of mental illness is just as important as the prevention of CV disease, the risk and benefits of the use of psychotropic medications must be thoroughly established.[7] Not treating patients with mental illness because of the concern for metabolic complications may place the patient at higher risk for other problems, including suicide. Providers who treat these patients must be aware of the medical side effects associated with the use of SGA and treat these side effects accordingly. Changing antipsychotic therapy is an option in some patients, although it may not always be appropriate given the potential risk for destabilization of the patient if taken off of the medication or switched to another agent.[7] Lifestyle modifications and behavioral modifications are also beneficial when managing these patients.[3] The American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, and the North American Associations for the Study of Obesity have established guidelines for the screening of these patients, both at baseline and periodically, to help minimize the risk of metabolic syndrome.[3,9]

While these consensus guideline recommendations for the screening and monitoring of these risk factors are in place, many patients are not appropriately screened and monitored in clinical practice.[10,11] Implementation of a pharmacist-managed metabolic syndrome clinic in a mental health setting has previously been established at the West Palm Beach Veterans Affairs Medical Center (WPB VAMC) with beneficial outcomes. The clinic was established from December 2010 through February 2011 but then closed because of a lack of staff able to continue managing the clinic. Further expansion and reopening of this clinic may allow clinical pharmacists to improve

patient care and appropriately screen and monitor more patients for metabolic syndrome while taking SGA.

Objectives

The objectives of the re-implementation of the clinic were to evaluate the number of pharmacologic pharmacist interventions, assess the number of nonpharmacologic interventions, and compare the patient load post expansion to the pilot implementation of the metabolic clinic.

Methods

Clinic Description and Participants

Patients receiving SGA at the WPB VAMC were referred to the metabolic clinic by outpatient mental health care providers and/or primary care providers via a computerized patient record system (CPRS) clinic consult. Both mental health providers and primary care providers were informed of the consult by an inservice presented by a clinical pharmacist at the monthly meetings for each department. The consult was previously created during a pilot implementation of this project and was reopened during this project. The CPRS consult was entitled "Pharm/MH Metabolic Syndrome Monitoring." Patients were referred to the metabolic clinic if they met criteria for metabolic syndrome according to the American Heart Association (AHA) parameters and were currently prescribed an SGA.[12] The AHA defines metabolic syndrome as having at least 3 of the following parameters: (1) waist circumference $\geq$ 40 inches in men and $\geq$ 35 inches in women; (2) fasting triglycerides (TG) $\geq$ 150 mg/dL or on drug treatment for elevated TG; (3) high density lipoprotein (HDL) $<$ 40 mg/dL in men and $<$ 50 mg/dL in women or on drug treatment to elevate HDL; (4) blood pressure $\geq$ 130/85 mm Hg or on drug treatment for hypertension; or (5) fasting blood glucose $\geq$ 100 mg/dL or on drug treatment for elevated blood glucose. The clinic consult listed all 5 parameters for metabolic syndrome and the mental health care and/or primary care providers were responsible for checking any applicable metabolic parameters for their patients. All consults for eligible patients were reviewed by the mental health clinic pharmacists for metabolic syndrome and acted upon within 72 hours. Patients and referring providers were notified of the appointment date and time and of the laboratory tests required prior to the first appointment. Patients that were cared for by the private sector for mental health needs and/or metabolic parameters were not eligible for consult.

Clinic Process

The pharmacist was responsible for the ordering and monitoring of laboratory work, patient education, and any psychiatric and primary care medication adjustments based on metabolic parameters. A review of the patient's medical history, medication history, allergies, diet, lifestyle habits, and laboratory parameters was completed. Additionally, blood pressure was measured at each office visit according to recommendations from The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure—Complete Report.[13] Waist circumference was measured as described in the Diagnosis and Management of the Metabolic Syndrome—An AHA/National Heart, Lung, and Blood Institute Scientific Statement.[12] Additionally, the clinical pharmacist reviewed other medications that may contribute to metabolic abnormalities to assess the likelihood of the SGA causing/worsening the metabolic syndrome since medication initiation. All initial findings, recommendations, and adjustment to medications were documented in the CPRS under the note titled "Pharmacotherapy Metabolic Syndrome Consult." The note title was previously created during the initial implementation of the project and was reopened during this project. Future appointment findings and recommendations were documented in CPRS under the note titled "Pharmacotherapy." Consultation and/or referral to clinical pharmacy specialists in mental health and primary care were available for patients with complex medication regimens or those who required multiple interventions. Patients who had difficulty exercising or maintaining healthy lifestyle habits were offered the option to be referred to the MOVE program. The MOVE program is a national weight management program developed by the Veterans Health Administration National Center for Health Promotion and Disease Prevention to help veterans lose weight and improve their health. Patients who smoke were offered a referral to the smoking cessation clinic and/or prescribed medications to aid with smoking cessation.

Data Collection

Data collected from the WPB VAMC included preclinic and postclinic data. All pharmacist interventions were collected and tracked via the PharmD Tool in CPRS. The PharmD Tool is a tool that was created at the WPB VAMC to track outcome measures for patients. Preclinic data included the patient's age, sex, race, social history (eg, smoking status, substance abuse), name of SGA, and assessment for the presence of hypertension, dyslipidemia, and diabetes, participation in formal exercise routine, and the number of criteria for metabolic syndrome. Postclinic data included the number of pharmacologic and nonpharmacologic interventions made, the number of patients referred to the MOVE program, the number of patients referred to the smoking cessation clinic, the name of the SGA at the end of data collection, and the

number of "no-show" appointments. All data were analyzed using descriptive statistics.

This evaluation has been approved by the Scientific Advisory Committee as part of the facility's ongoing performance improvement efforts, as defined by the *Veteran's Health Administration Handbook 1058.05*. Institutional review board approval was not required for this project.

Results

During the postexpansion phase of the metabolic clinic (from November 2013 through May 2014), 28 patients were referred to the clinic and 17 consults were completed. Nine consults were discontinued because patients did not meet the necessary criteria for referral to the clinic or they were actively being followed by another pharmacotherapy clinic, and 2 consults were discontinued as they were entered in error. During the pilot implementation of the metabolic clinic (December 2010 through February 2011), 40 patients were referred to the clinic: 25 consults were completed; 14 consults were discontinued because the veterans did not meet criteria for the clinic or they were actively being followed by another pharmacotherapy clinic; and 1 patient's data were not included because he was psychiatrically unstable at the time of the interview.

Overall, 88% of the patients were men and 65% were Caucasian. The average age was approximately 58 years. The average number of components for metabolic syndrome was 3.7 out of 5 possible components, with 88.2% of patients with hypertension (or receiving treatment), 94.1% of patients with dyslipidemia (or receiving treatment), and 88.2% with diabetes mellitus (or receiving treatment). There was 1 patient using illicit substances (marijuana and cocaine monthly), and 47% of the patients used tobacco products. A majority of the patients (58.8%) reported no formal exercise routine and of those who reported exercising, they reported walking or jogging 2 to 3 times per week, with the exception of 1 patient who was a personal trainer and exercised for 3 hours per day (Table 2).

A majority of the patients (47.1%) were taking risperidone at the time of their visit. Three patients were on dual antipsychotics at the time of initial visit. Each patient had an average follow up of 1.8 appointments during the data-collection period with follow-up appointments scheduled at 4- to 8-week intervals. There were 25 pharmacologic interventions made for the 17 patients evaluated in the clinic, with a majority being new medication starts or titrating the doses of a current medication for diabetes, dyslipidemia, or hypertension. There was one change in the antipsychotic regimen. There were 33 nonpharmacologic interventions made (eg, education on carbohydrate counting, exercise regimens), an average of 1.9 interventions per patient, with 3 patients referred to the MOVE program, and 1 patient referred to the smoking cessation clinic (Table 3). All but 1 patient remained on their initially prescribed SGA during their last visit; 1 patient's antipsychotic medication was discontinued due to lack of efficacy. There were a total of 12 (22%) "no-show" appointments during the re-implementation of this clinic.

TABLE 2: Patient demographics

Patient Characteristics	Value
Age (mean)	58
Male, %	15 (88.2)
Female, %	2 (12)
Race, %	
Caucasian	11 (65)
African American	6 (35)
Diabetes, %	15 (88.2)
Dyslipidemia, %	16 (94.1)
Hypertension, %	15 (88.2)
Smokers, %	8 (47.0)
Exercise, %	7 (41.1)
Current Atypical Antipsychotic	
Aripiprazole, %	4 (23.5)
Olanzapine, %	1 (5.8)
Risperidone, %	8 (47.1)
Quetiapine, %	4 (23.5)

Discussion

The metabolic clinic consult was originally opened for mental health care providers and primary care physicians; however, as time advanced, primary care pharmacists were also able to place the metabolic clinic consult.

Data from this project demonstrated that patients referred to the metabolic syndrome clinic had multiple components of metabolic syndrome and ample opportunity for pharmacist intervention. This is consistent with other data within the VA system. A study conducted by Patterson et al[12] found that 87% of patients enrolled in a pharmacist-run clinic versus 67% of control patients received monitoring for all 5 components of metabolic syndrome in the previous year. Cost-benefit analysis favors implementation of pharmacist-run metabolic syndrome clinics as they contribute to prevention of cardiovascular events and diabetes.[13] Observations from outside the VA system also demonstrate that there may be ample opportunity for pharmacist-run metabolic syndrome clinics in patients receiving antipsychotics. In

TABLE 3: Pharmacologic and nonpharmacologic interventions

Intervention Type	No. of Interventions
Medication Changes	25
Nonpharmacologic Interventions	33
Referral to Smoking Cessation	1
Referral to MOVE Program	3
Other (eg, carbohydrate counting, exercise regimen)	29

MOVE = The MOVE program is a national weight management program developed by the Veterans Health Administration National Center for Health Promotion and Disease Prevention to help veterans lose weight and improve their health.

a 2009 review of Medicaid beneficiaries who had been prescribed an SGA that had a risk of causing metabolic abnormalities, only 40% had received metabolic monitoring in the previous year.[14] A review of baseline data from subjects enrolled in the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study found that 30.2% of patients with diabetes, 62.4% of patients with hypertension, and 88% of patients with dyslipidemia were not receiving treatment.[15]

Clinicians have variable awareness regarding the metabolic side effects of antipsychotic medications. Barriers to providing metabolic care include, but are not limited to, uncertainty as to who is responsible for monitoring (ie, mental health team or primary care), uncertainty regarding what and when to monitor, lack of confidence in interpreting test results, lack of communication with primary care, limited access to equipment, the severity of the psychiatric illness, and concern about decreasing adherence if awareness is raised regarding metabolic side effects.[14,16] A 2013 survey of primary care providers suggested that nearly 40% were unaware of consensus guidelines for the metabolic monitoring of SGA. There were also variable responses as to which providers (ie, primary care or psychiatrists) should be monitoring the metabolic risks in these patients.[14]

This project demonstrated appropriately trained clinical pharmacists can help decrease some of the barriers to metabolic syndrome monitoring in mental health patients and increase patient access to care. Many of the patients preferred to be seen in a mental health setting, rather than primary care, owing to their comfort level with the mental health providers. We found the metabolic syndrome clinic allowed us to provide direct patient care to the veterans and improve the monitoring of the metabolic parameters associated with SGA. It was also noted that some patients were referred from the primary care pharmacotherapy clinics, and this may potentially ease the burden in these clinics in the future. Despite the lower number of referrals after the expansion of the clinic, the clinic is needed as it was still utilized by patients and providers after it was reopened.

There are some limitations to this project in an outpatient mental health setting. First, only outpatient mental health and primary care providers at the WPB VAMC were able to place the metabolic syndrome clinic consult. Many of the veterans at the WPB VAMC receive their mental health or primary care needs at community-based outpatient clinics (CBOCs) in the surrounding area. Many of these providers may not have been properly educated regarding the referral process for the metabolic syndrome clinic at the WPB VAMC. Another limitation to this project was the high no-show rate to appointments; however, the no-show rates in the metabolic clinic appear to be consistent with the overall no-show rates of the outpatient mental health clinic. Last, there was a small number of patients evaluated in clinic for an initial visit. Even though the majority of patients were seen for multiple follow-up appointments, it would likely still be beneficial to continue to educate providers about the metabolic syndrome clinic.

The prescribing patterns observed in this project reflect the formulary preferences of the WPB VAMC. Risperidone is used first line, while quetiapine, olanzapine, aripiprazole, and ziprasidone require medication approvals to be approved by the mental health clinical pharmacy specialist. Patients with metabolic syndrome may be prescribed ziprasidone and aripiprazole more often than the average patient population because these agents are associated with fewer metabolic abnormalities.[2,7] Lurasidone is also available at the WPB VAMC, but it requires a medication approval, and it is not currently being prescribed at this time for patients with metabolic syndrome.

Future areas of improvement for this project include documenting changes in glycated hemoglobin (HbA1c), lipids, blood glucose, weight, and waist circumference. The primary outcome was the measure of the number of interventions made in the clinic, which may or may not lead to a direct decrease in CV risk. Once these objective measures are known, then a total decrease in risk could be calculated. Positive trends were seen during the re-implementation of the metabolic clinic, although because of the short duration of the clinic, the overt changes in the objective measures were not tracked. In addition, services can be expanded to allow rural VA areas to place consults for the metabolic clinic, possibly even by providing patient care via clinical video telehealth (CVT).

Conclusion

The metabolic clinic at the WPB VAMC was successfully re-implemented in an outpatient mental health setting.

Metabolic syndrome monitoring clinics appear useful for providing the necessary screening and monitoring recommended for patients prescribed SGA. Appropriately trained clinical pharmacists can identify both patients at risk for and those with metabolic syndrome, allowing for interventions. The available data provide a good starting point and indication for continuing the metabolic syndrome monitoring clinic.

Acknowledgments

We acknowledge David Parra, PharmD, FCCP, BCPS, for his contributions to the establishment of the metabolic clinic during the pilot implementation phase of this quality improvement project.

References

1. Muench J, Hamer AM. Adverse effects of antipsychotic medications. Am Fam Physician. 2010;81(5):617-22. PubMed PMID: 20187598.
2. Freedman R. Schizophrenia. N Engl J Med. 2003;349(18):1738-49. DOI: 10.1056/NEJMra035458. PubMed PMID: 14585943.
3. Consensus development conference on antipsychotic drugs and obesity and diabetes. Diabetes Care. 2004;27(2):596-601. PubMed PMID: 14747245.
4. Lieberman JA, Stroup TS, McEvoy JP, Swartz MS, Rosenheck RA, Perkins DO, Keefe RS, Davis SM, Davis CE, Lebowitz BD, Severe J, Hsiao JK. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. N Engl J Med. 2005;353(12):1209-23. DOI: 10.1056/NEJMoa051688. PubMed PMID: 16172203.
5. McEvoy JP, Meyer JM, Goff DC, Nasrallah HA, Davis SM, Sullivan L, Meltzer HY, Hsiao J, Stroup TS, Lieberman JA. Prevalence of the metabolic syndrome in patients with schizophrenia: baseline results from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) schizophrenia trial and comparison with national estimates from NHANES III. Schizophr Res. 2005;80(1):19-32. DOI: 10.1016/j.schres.2005.07.014. PubMed PMID: 16137860.
6. Meyer JM, Nasrallah HA, editors. Medical illness and schizophrenia. Arlington (VA): American Psychiatric Press Inc; 2003.
7. Lieberman JA. Metabolic changes associated with antipsychotic use. Prim Care Companion J Clin Psychiatry. 2004;6(Suppl 2):S8-13.
8. Citrome L. Iloperidone, asenapine, and lurasidone: a brief overview of 3 new second-generation antipsychotics. Postgrad Med. 2011 Mar;123(2):153-62.
9. National Heart, Lung, and Blood Institute [Internet]. Bethesda (MD); 2002 [cited 2014 May 21]. Expert panel report 3: guidelines for the diagnosis and management of dyslipidemia. Available from: http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf.
10. Druss BG, Zhao L, Von Esenwein S, Morrato EH, Marcus SC. Understanding excess mortality in persons with mental illness: 17-year follow up of a nationally representative US survey. Med Care. 2011;49(6):599-604. DOI: 10.1097/MLR.0b013e31820bf86e. PubMed PMID: 21577183.
11. Druss BG, Bradford WD, Rosenheck RA, Radford MJ, Krumholz HM. Quality of medical care and excess mortality in older patients with mental disorders. Arch Gen Psychiatry. 2001;58(6):565-72. PubMed PMID: 11386985.
12 Patterson S, Moore E, Hasson N. Outcomes of a pharmacist-run mental health metabolic syndrome clinic. Poster presented at ASHP Midyear Clinical Meeting; 2007 Dec 2-6; Las Vegas, NV.
13. Schenk A, Leonard S, Schaefer M. Development of a metabolic syndrome management clinic. Poster presented at KCHP-MSHP Joint Spring Meeting; 2010 Apr 8-10; Overland Park, KS.
14. Mangurian C, Giwa F, Shumway M, Fuentes-Afflick E, Pérez-Stable EJ, Dilley JW, Schilinger D. Primary care providers' views on metabolic monitoring of outpatients taking antipsychotic medication. Psychiatr Serv. 2013;64(6):597-9. DOI: 10.1176/appi.ps.002542012. PubMed PMID: 23728604.
15. Nasrallah HA, Meyer JM, Goff DC, McEvoy JP, Davis SM, Stroup TS, Lieberman JA. Low rates of treatment for hypertension, dyslipidemia and diabetes in schizophrenia: data from the CATIE schizophrenia trial sample at baseline. Schizophr Res. 2006;86(1–3):15-22. DOI: 10.1016/j.schres.2006.06.026.
16 Barnes TRE, Paton C, Cavanagh M-R, Hancock E, Taylor DM. A UK audit of screening for the metabolic side effects of antipsychotics in community patients. Schizophr Bull. 2007;33(6):1397-403. DOI: 10.1093/schbul/sbm038. PubMed PMID: 17483101.