Monitoring Metabolic Side Effects when Initiating Treatment with Second-Generation Antipsychotic Medication

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Abstract

Objective: Published guidelines recommend metabolic monitoring for patients prescribed second-generation antipsychotic (SGA) medications. This study determined monitoring rates, and examined predictors of monitoring, for total cholesterol and weight among patients prescribed SGAs during a period when awareness of metabolic side effects was emerging, but prior to the wide promulgation of guidelines. **Methods:** This retrospective study used administrative data from four Veterans Health Administration facilities to examine monitoring rates for total cholesterol and weight during baseline and follow-up periods from October 1, 2000–September 30, 2003 among patients with schizophrenia initiating SGA treatment. The study used logistic regression to identify characteristics that predicted monitoring. Background monitoring rates during routine care were estimated using a resampling procedure. **Results:** Initiating SGA treatment did not appear to trigger annual monitoring above estimated background rates of 54% for total cholesterol and 47% for weight. Patients with metabolic risk factors were monitored at higher rates independent of the start of treatment with an SGA. **Conclusions:** This paper provides a window into side effect monitoring practices prior to the widespread promulgation of guidelines and associated quality improvement efforts and serves as a benchmark for future interventions. Prior to publication of monitoring guidelines, patients initiating treatment with SGAs did not receive adequate metabolic monitoring routinely, nor did SGA treatment appear to trigger additional monitoring. Some studies that have assessed the impact of monitoring guidelines on clinical practice show only limited impact. Quality improvement strategies to increase metabolic monitoring over the rates seen here and in other studies should be developed and implemented.

Key Words: Monitoring Metabolic Side Effects, Cholesterol, Weight, Second-Generation Antipsychotic Medications, Secondary Data, Resampling

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Introduction

Second-generation antipsychotics (SGAs) increase the risk of developing the metabolic syndrome (1-6), which has prompted several groups to recommend routine concurrent monitoring for metabolic side effects (7-9). In response, medical specialty groups and researchers have developed guidelines for metabolic monitoring for individuals prescribed SGAs. Examples include guidelines published jointly by the American Diabetes Association, the American Psychiatric Association and others in 2004 (7), guidelines developed by a group of psychiatric and medical researchers convened at Mount Sinai School of Medicine (8), and monitoring recommendations by Canadian specialists in psychiatry and endocrinology (9). Increased metabolic

Clinical Implications

Monitoring rates for total cholesterol and weight were low prior to the introduction of monitoring guidelines for treatment with SGAs, even in a healthcare system where psychiatric and medical care are integrated and recorded in a single medical record. Initiating second-generation antipsychotic treatment did not appear to trigger monitoring above and beyond rates observed in routine clinical practice. However, lipid monitoring rates were higher in the VA compared to studies conducted in non-integrated health systems. Diagnoses related to metabolic issues—diabetes and hyperlipidemia—were the strongest predictors of monitoring. Studies examining the impact of monitoring guidelines have been disappointing so far. In addition to the clinical characteristics we examined, future studies should analyze provider characteristics, patient characteristics not recorded in administrative data (e.g., assertiveness, knowledge, attitudes toward medical treatment), or other environmental characteristics such as family involvement that might affect monitoring rates. Identifying factors that predict metabolic monitoring could potentially provide clues to improving other aspects of clinical care. Finally, public mental health authorities can summarize administrative data to generate benchmarks prior to policy changes and monitor practice following the initiation of such policies.

risk associated with SGA treatment is especially worrisome because individuals with schizophrenia and related disorders are already at increased risk for developing the metabolic syndrome (10-12).

Recent studies examining rates of metabolic monitoring among individuals treated with SGA medications report low rates of metabolic monitoring in commercially insured (13-15), Medicaid (16, 17) and veteran populations (18), as well as in a United Kingdom-based cohort (19). The highest rates for lipid monitoring were reported by Hsu et al. in a Veterans Affairs Heathcare System-based population, with nearly 40% of individuals having at least one lipid measurement in the six months prior to initiating a new SGA, and nearly 60% of individuals having at least one lipid measurement in the year following a switch to a new SGA (18). Monitoring rates for serum glucose exceeded rates for lipids; however, random glucose measurements are difficult to interpret and the majority of glucose measurements were part of serum chemistry panels rather than fasting blood glucose measurements or hemoglobin A1C measurements. A preliminary study from our research group examining data from a Veterans Administration hospital showed that patients prescribed SGAs who had at least one lipid measurement received follow-up lipid monitoring sooner if their initial lipid levels were abnormally elevated, compared with patients whose initial lipid levels were in the normal range. However, even among patients with elevated lipid levels, median time to follow-up monitoring was approximately ten months (20).

This study is an extension of the VA study cited above that examines monitoring rates for total cholesterol and weight among outpatients treated with SGAs at four VHA sites in the New York/New Jersey metropolitan region. Because the VA is an integrated healthcare system, monitoring may be provided either in the psychiatric setting or elsewhere in the system, with the results of such monitoring available to all VA clinicians via a single electronic medical record. Therefore, the VA is a good place to examine rates of metabolic monitoring absent the constraints present between psychiatric and nonpsychiatric clinics that do not share an electronic medical record.

The aims of the study were: 1) to examine rates of baseline and follow-up monitoring for total cholesterol and weight among patients initiating treatment with an SGA during a period prior to the widespread promulgation of monitoring guidelines; 2) to determine whether demographic or clinical characteristics were associated with differential monitoring rates; and, 3) to assess whether initiating an SGA triggered monitoring above background monitoring rates. The present study examined physicians' monitoring practices at a time when awareness of metabolic side effects was growing, but prior to the publication of the guidelines noted above. Hence, these data extend the benchmark information against which the impact of monitoring guidelines can be assessed.

Methods

The study is a retrospective analysis conducted using administrative data extracted from local databases at four sites in the Veterans Administration New York/New Jersey VISN 3 Healthcare Network. We conducted the study under a waiver of informed consent from the Institutional Review Board at each site (James J. Peters Bronx VAMC, Hudson Valley Healthcare System, New Jersey Healthcare System and New York Harbor Healthcare System).

We extracted data for all individuals who received a prescription for antipsychotic medication during the period from October 1, 1999 through September 30, 2003. We obtained demographic data, service utilization data, prescription data, and laboratory data from the relevant VA local databases. The study population included individuals under age 65 who were treated for schizophrenia or schizoaffective disorder diagnosed at two or more mental health visits and

Table 1 Patient Characteristics, Overall and By Site

	Total Sites N=1,626	Site 1 N=610	Site 2 N=175	Site 3 N=489	Site 4 N=352	Site Difference
Gender (% male)	95.9	95.9	93.1	96.7	96.3	NS
Age (Mean, SD)	48.1 (7.7)	47.9 (7.4)	46.2 (8.8)	48.2 (7.7)	49.4 (7.7)	*
Race† (% white)	50.1	43.4	19.7	60.0	59.7	**
Service Connection‡ (%)	65.6	61.0	58.3	72.4	67.6	**
Diabetes Diagnosis§ (%)	16.0	19.2	18.3	13.5	12.8	***
Hypercholesterolemia‖ (%)	31.6	34.6	26.3	30.3	31.0	NS
Substance Abuse Diagnosis¶ (%)	34.3	32.6	37.1	42.3	24.7	**

*Students t-test, p<.001 **Chi-square, p<.001 ***Chi-square, p<.05

† Due to missing values, for Race, N=1,413
‡ Proportion of individuals receiving compensation for service-connected disability
§ Proportion of individuals diagnosed with diabetes mellitus at an outpatient visit or receiving prescriptions for hypoglycemic agent or insulin treatment
‖ Proportion of individuals diagnosed with hyperlipidemia, receiving prescriptions for lipid-lowering agents or whose total cholesterol level ≥240 mg/dL
¶ Proportion of individuals with visits to substance abuse specialty clinics or diagnosed with substance abuse at an outpatient visit

who started a "new" SGA treatment during the study period (as described below); if visits for bipolar disorder or other psychotic disorders occurred, schizophrenia or schizoaffective disorder represented the preponderance of diagnoses.

Treatment with a "new" SGA medication was defined as receiving an index prescription for an SGA not prescribed previously during the study period, including a one-year lead-in period (October 1, 1999–September 30, 2000), and receiving at least 60 days' supply of the medication during the 90-day period following the index prescription. Prior to starting the "new" SGA, patients could have been taking any other antipsychotic medication, including first- and second-generation antipsychotics. Analyses were limited to individuals who received at least one new SGA, as defined above, during the study period from October 1, 2000–September 30, 2003. Only the first episode of treatment with a "new" SGA was analyzed for each individual.

We examined monitoring for total cholesterol and weight. We examined monitoring rates for total cholesterol whether total cholesterol was measured as part of a lipid panel or as a separate test (thereby providing a more generous estimate of lipid monitoring than would lipid panels alone). We defined baseline and follow-up periods as follows. For cholesterol, the baseline period was defined as the period from 180 days preceding until 29 days after the index prescription; follow-up period for cholesterol included days 30 through 180 after the index prescription. For weight, the baseline period was defined as 30 days preceding until 14 days after the index prescription; follow-up period included days 15 through 90 after the index prescription. We examined the proportion of individuals receiving measurements for baseline cholesterol, baseline weight, follow-up cholesterol and follow-up weight, and the proportion of individuals with baseline/follow-up measurement pairs (i.e., both a baseline and f/u cholesterol or weight for comparative purposes). For these and subsequent analyses, the sample was limited to individuals with sufficient observation time following the index SGA prescription to meet the definition for total cholesterol and weight follow-up periods (180 days and 90 days, respectively).

To determine whether any demographic, clinical or environmental characteristics were associated with an increased likelihood of monitoring, we performed logistic regression analyses. Separate analyses examined predictors for baseline cholesterol monitoring, follow-up cholesterol monitoring, baseline weight monitoring, and follow-up weight monitoring. Covariates included age, race, hyperlipidemia, diabetes mellitus, substance abuse diagnosis, service connection, date of index prescription, and site. For follow-up monitoring, presence/absence of baseline monitoring was an additional covariate. Gender was not included due to the small number of women in the study population. Race was dichotomized as white/nonwhite based on the available data.

Hyperlipidemia diagnosis was defined by at least one of the following prior to the index SGA prescription: hyperlipidemia diagnosis at any medical or mental health visit, receiving a prescription for a lipid-lowering agent, or total cholesterol measurement ≥240 mg/dL. Diabetes diagnosis was defined by receiving a prescription for either an oral hypoglycemic agent or insulin prior to the index SGA prescription or having a diabetes diagnosis at any medical or mental health visit before the index prescription. Substance abuse diagnosis was defined by either receiving specialized substance abuse services or having a visit (including medical) with a substance abuse diagnosis. Site was entered into the logistic regression as a dummy variable.

Service connection, a measure of VA disability based on illness or injury that occurs during, or is a result of, military duty, was dichotomized as present/absent. Service connection served both as a proxy for severity of illness and as a measure of involvement in the VA system. We repeated

these analyses in a stepwise fashion to determine whether diagnosis and other clinical characteristics had an impact on monitoring over and above that seen from demographic characteristics.

In order to examine whether monitoring was triggered by initiating treatment with a new SGA, rather than reflecting background rates of measuring weight and cholesterol levels, we examined monitoring rates linked to randomly selected visits. Using resampling methodology, we examined monitoring during simulated baseline periods constructed around ten randomly selected visits for each individual subject. To determine the background monitoring rates, we calculated the mean likelihoods of receiving monitoring during these simulated baseline periods. We then performed a chi-square analysis to determine whether the observed monitoring rates at the time the SGA was initiated differed from the background (i.e., expected) monitoring rates.

Table 2 Number and Percent of Individuals Starting a Second-Generation Antipsychotic Agent Receiving Baseline and Follow-Up Monitoring for Total Cholesterol

Site (N)	Baseline N (%)	Follow-Up N (%)	Both Baseline and Follow-Up N (%)
Total (1,525)	804 (52.7)	604 (39.6)	359 (23.5)
Site 1 (562)	272 (48.4)	209 (37.2)	114 (20.3)
Site 2 (167)	85 (50.9)	48 (28.7)	25 (15.0)
Site 3 (463)	261 (56.4)	192 (41.5)	118 (25.5)
Site 4 (333)	186 (55.9)	155 (46.5)	102 (30.2)

Table 3 Number and Percent of Individuals Starting a Second-Generation Antipsychotic Agent Receiving Baseline and Follow-Up Monitoring for Weight

Site (N)	Baseline N (%)	Follow-Up N (%)	Both Baseline and Follow-Up N (%)
Total (1,601)	718 (44.8)	746 (46.6)	434 (27.1)
Site 1 (604)	214 (35.4)	221 (36.6)	116 (19.2)
Site 2 (172)	88 (51.2)	93 (54.1)	53 (30.8)
Site 3 (480)	205 (42.7)	214 (44.6)	114 (23.8)
Site 4 (345)	211 (61.2)	218 (63.2)	151 (43.8)

Results

Of 4,468 individuals who met our diagnostic criteria, 4,194 received antipsychotic treatment during the observation period. Of these, 1,955 received only one antipsychotic during the study and 2,239 received treatment with 2 or more different agents. 1,626 individuals met all criteria for inclusion in the study population: schizophrenia/schizoaffective disorder diagnosis, receipt of an index prescription for an SGA not received previously during the lead-in or the study period, and prescribed for a minimum of 60 days during the 90 days following the index prescription.

As shown in Table 1, the great majority of individuals in the study population were male (96%), approximately half were white, and the mean age was 48 years (SD=7.7). About two-thirds met the VA criteria for service-connected disability, reflecting a population with significant disability. Comorbidity was common: 34% had diagnoses indicating current substance abuse, 32% had hyperlipidemia, and 16% had diabetes. Demographics and prevalence of diabetes varied significantly by site.

As shown in Table 2, 53% of patients received cholesterol monitoring during the baseline period (range across sites: 48–56%), and 40% (range across sites: 29–47%) received follow-up monitoring for total cholesterol. Only 24% of patients (range across sites: 15–30%) had total cholesterol measurements during both the baseline and follow-up periods. As shown in Table 3, 45% of patients had weights recorded during the baseline period (range across sites: 35–61%) and 47% (range across sites: 37–63%) had weights recorded during the follow-up period. Only 27% of patients (range across

Table 4 Predictors of Monitoring Total Cholesterol Levels and Weight among Patients with Schizophrenia Initiating Treatment with Second-Generation Antipsychotic Agents

	Cholesterol Baseline (N=1,352)		Cholesterol Follow-Up (N=1,352)		Weight Baseline (N=1,413)		Weight Follow-Up (N=1,413)	
	B (OR)	Sig	B (OR)	Sig	B (OR)	Sig	B (OR)	Sig
Race		NS		NS	.308 (1.36)	.01		NS
Age		NS		NS		NS		NS
Hyperlipidemia Dx	1.121 (3.07)	.000	.775 (2.17)	.000		NS	.398 (1.49)	.002
Diabetes Dx	.519 (1.68)	.001	.572 (1.77)	.000	.268	NS	.563 (1.76)	.000
SA Dx	.288 (1.33)	.02		NS	.388 (1.47)	.001		NS
Service Connection		NS		NS		NS		NS
Baseline Measure	—	—	.220	NS	—	—	.777 (2.18)	.000

sites: 19–44%) had weight measurements during both the baseline and follow-up periods.

Increased likelihood of monitoring cholesterol was associated with clinical, but not demographic, characteristics (see Table 4). During the baseline period, having a hyperlipidemia diagnosis (OR=3.07, 95% CI=2.37–3.97, p<.001), diabetes diagnosis (OR=1.68, 95% CI=1.22–2.31, p<.001), or substance abuse diagnosis (OR=1.33, 95% CI=1.05–1.7, p<.02) was significantly associated with higher rates of cholesterol monitoring. During the follow-up period, having a hyperlipidemia diagnosis (OR=2.17, 95% CI=1.69–2.79, p<.001) or diabetes diagnosis (OR=1.77, 95% CI=1.31–2.4, p<.001) was significantly associated with higher rates of cholesterol monitoring. Significant site differences were observed for both baseline and follow-up monitoring (see Figure 1).

Increased likelihood of monitoring weight was associated with racial and clinical characteristics. During the baseline period, race=nonwhite (OR=1.36, 95% CI=1.08–1.76, p=.01) and having a substance abuse diagnosis (OR=1.47, 95% CI=1.17–1.86, p<.001) were significantly associated with monitoring. During the follow-up period, hyperlipidemia diagnosis (OR=1.49, 95% CI=1.16–1.90, p<.001), diabetes diagnosis (OR=1.76, 95% CI=1.29–2.38, p<.002), and having a weight measurement during the baseline period (OR=2.18, 95% CI=1.74–2.73, p<.001) were significantly associated with higher rates of monitoring. Significant site differences were observed for both baseline and follow-up monitoring.

Figure 1 Likelihood of Monitoring Cholesterol Levels at the Time After Second-Generation Antipsychotic (SGA) Medication is Started Compared with the Base Rate of Monitoring at the Time of Random Visit Dates

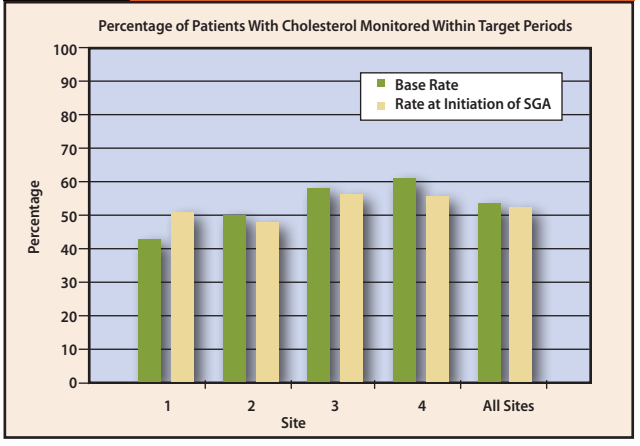

Figure 1 graphically displays respective likelihoods for monitoring cholesterol at each of the 4 sites in this sample, as well as for all sites combined; likelihood of monitoring weight showed a similar pattern. In every case, the base rate of monitoring mirrored the likelihood of monitoring after a second-generation antipsychotic was initiated, yielding nonsignificant chi-square statistics for each of the 8 site-level comparisons, as well as for overall.

Observed monitoring rates for weight and cholesterol during the baseline periods did not differ from background monitoring rates estimated using the resampling simulation (weight: chi-square=1.45, n.s.; cholesterol: chi-square=0.53, n.s.; see Figure 1).

Discussion

Metabolic monitoring rates were relatively low in clinical practice during 2000–2003, a time before the wide promulgation of practice guidelines promoting such monitoring. Furthermore, SGA initiation was *not* associated with an increase in metabolic monitoring over the base rate of such monitoring. Only half of the patients initiating SGA treatment had contemporaneous cholesterol or weight measurements, and only one-fourth of patients had a pair of measurements for the baseline and follow-up periods. Thus, the vast majority of patients' records contained inadequate data to assess the impact of their starting the SGA on cholesterol level or body weight. The good news is that individuals known to be at higher risk for metabolic side effects (i.e., those with pre-existing diabetes or hyperlipidemia) were more likely to be monitored. These data reflect practice of several years ago in a relatively well-financed, integrated healthcare system. Monitoring in community mental health settings is likely to be even lower, and innovative methods will be needed to assure that individuals who receive SGA medications are appropriately monitored and treated.

Our results demonstrate similar annual rates of lipid monitoring as those found by Hsu et al., also describing practices in a VA setting (54 vs. 59%) (18). In a commercially insured population, the annual rate for lipid monitoring was 23% (13); in a community sample, the lipid monitoring rate over 16 months was 32% (14). One hypothesis for the higher rate of metabolic monitoring in the VA setting compared to other clinical settings is that use of a single electronic medical record facilitates coordination of care between primary care physicians and psychiatrists. Another possible explanation is related to population differences (e.g., older age in the veteran populations). We were unable to compare our results to metabolic monitoring rates reported for Medicaid populations because annual rates were not reported in the studies using Medicaid data (16, 17). Comparisons of baseline and follow-up monitoring rates across studies are problematic because different studies have used different definitions for baseline and follow-up periods.

Unlike previous studies examining metabolic monitoring, the current study examines body weight monitoring, but not glucose monitoring. VA datasets capture weight measurements reported in the electronic medical record, information not typically available in insurance or pharmacy-based datasets. Height is almost always recorded at least once in patients' records, so physicians are able to calculate

body mass index, an important component of the metabolic syndrome. We chose to analyze weight monitoring instead of glucose monitoring. Glucose measurements are often conducted as part of comprehensive metabolic panels that are not necessarily collected in the fasting state. Interpretation of nonfasting, random glucose values is problematic. Thus, in our administrative dataset, weight (a proxy for body mass index [BMI]) is a better clinical indicator for the metabolic syndrome than (potentially nonfasting) glucose measures. We defined timeframes for baseline and follow-up periods differently for weight and for total cholesterol because weight is more likely to fluctuate in the short term.

We wondered whether starting a new SGA triggered clinicians' purposeful measuring of total cholesterol or weight, or if the monitoring rates we observed were a reflection of routine medical practice in the VA system. More generally, under what circumstances can one infer intent using administrative data? Our analysis showed no difference between estimated monitoring rates during simulated baseline periods constructed around randomly selected visits and actual monitoring rates during baseline periods linked to prescribing a new SGA. Based on our data, it appears that prescribing an SGA did *not* trigger clinicians to obtain baseline metabolic measurements. They may have looked at the electronic record for pre-existing total cholesterol and weight measurements, but they did not obtain additional cholesterol levels or weight if they were absent from the chart. The monitoring rates we observed may simply reflect ongoing practice. Patients often are weighed as a matter of course in primary care and other medical clinics, and lipids are measured as part of a routine annual medical exam.

The question of effective strategies to improve monitoring is still largely unaddressed. Disappointingly, recent studies examining metabolic monitoring before and after the publication of monitoring guidelines did not find increased rates of monitoring associated with guideline introduction, despite modest secular increases in monitoring (13, 16), or found statistically significant increases, but still unacceptably low monitoring rates subsequent to guideline introduction (15). The use of devices such as "pop-ups" in electronic medical records is widespread, but clinicians may become inured to their presence unless action is required as opposed to recommended. The linkage of clozapine prescriptions to required testing for reduction in white blood cell count has been effective in ensuring side effect monitoring in the United States, but may also serve as a disincentive to prescribing clozapine.

Recently, the New York State Office of Mental Health (OMH) mandated that all adult state-operated outpatient clinics regularly monitor three health indicators (BMI, blood pressure and smoking status). One of the driving forces behind this initiative was OMH's ability to regularly review its administrative data to determine what proportion of the patients at each clinic was being monitored for these health indicators. OMH also supplemented these data reports with implementation wrap-arounds, such as learning collaboratives, to help clinics support each other in their effort to increase monitoring of important health indicators. The initial results have been very promising: after only four months of this coordinated effort, approximately half of NYS OMH outpatients have been screened for these three physical health indicators (21). The important lesson learned from this experience is that it is possible for large public mental health authorities to use data in ways that can effect change in routine practice.

Our results underscore the importance of interpreting administrative data cautiously when assessing impact of an intervention. It is critical to establish a benchmark against which the intervention can be compared. Studies using pre-/post-designs use pre-intervention data as a benchmark. However, in situations where pre-/post-comparisons are problematic (e.g., insufficient data prior to the intervention or secular changes in practice), our simple resampling method provides a novel way to establish concurrent benchmarks.

Conclusions

Monitoring rates for total cholesterol and weight were low prior to the introduction of monitoring guidelines for treatment with SGAs, even in a healthcare system where psychiatric and medical care are integrated and recorded in a single medical record. Initiating SGA treatment did not appear to trigger monitoring above and beyond rates observed in routine clinical practice. However, lipid monitoring rates were higher in the VA compared to studies conducted in non-integrated health systems. Diagnoses related to metabolic issues—diabetes and hyperlipidemia—were the strongest predictors of monitoring. Studies examining the impact of monitoring guidelines have been disappointing so far. In addition to the clinical characteristics we examined, future studies should analyze provider characteristics, patient characteristics not recorded in administrative data (e.g., assertiveness, knowledge, attitudes toward medical treatment), or other environmental characteristics such as family involvement that might affect monitoring rates. Identifying factors that predict metabolic monitoring could potentially provide clues to improving other aspects of clinical care. Finally, public mental health authorities can summarize administrative data to generate benchmarks prior to policy changes and monitor practice following the initiation of such policies.

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