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ORIGINAL PAPER

Distress with Medication Side Effects among Persons with Severe Mental Illness

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Abstract We examined prevalence and perceived distress resulting from self-reported side effects (SEs) attributed to psychotropic medications among individuals with severe mental illness participating in a study of consumer-operated services. We examined gender and racial differences using logistic regression, conducted factor analyses of SEs, and examined correlations between distress and self-reported symptoms. Over 90% reported at least one SE, and nearly two-thirds reported a high level of distress with at least one SE. The most distressing SEs reported were embarrassment from weight gain, weight gain, dry mouth, and sedation. The likelihood of distress by particular SEs varied by gender and race.

Keywords COSP · Consumer-operated · Medication · Side effects · Serious mental illness

A recent large-scale trial of antipsychotic medications found disappointingly high discontinuation rates across antipsychotic medications (about three-quarters within 18 months). The number of discontinuations due to intolerable side effects or "patient decision" was nearly twice that of discontinuation due to lack of efficacy (Lieberman et al. 2005). Further analyses of these data suggest that it may be more advantageous to stay on a partially effective

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medication regimen than to switch to a different antipsychotic (Essock et al. 2006). Together, these findings suggest that medication intolerance may lead patients to discontinue treatments that ultimately could be beneficial. A clearer understanding of individuals' distress with side effects (SEs) and identification of early symptoms of medication intolerance might enable prescribers and patients to adjust medication dosages and treat side effects before an individual discontinues the antipsychotic medication altogether. The purpose of the present study is to use a large national sample to explore participants' subjective distress from SEs attributed to current psychotropic medications with the aim of identifying particularly distressing side effects that might decrease an individual's willingness to take medications as prescribed.

The use of psychotropic medication has grown dramatically in the last decade, fueled by the introduction of newer antipsychotic and antidepressant agents. These newer medications including the selective serotonin reuptake inhibitors (SSRIs) for depression and the "atypical" or "second generation" antipsychotics for schizophrenia are examples of classes of medications that are widely considered better tolerated than their predecessors (e.g., tricyclic antidepressants for depression and "conventional" antipsychotics for schizophrenia). Researchers have long noted the importance of individuals' subjective response to psychopharmacologic agents (Van Putten 1978). For example, some have noted that the conventional antipsychotic medications can make people feel "weird", "like a zombie", "lazy", or "fuzzy", and can reduce straight thinking, will power, and spontaneity (Awad 1993; Gerlach and Larsen 1999; Naber 1995, 1998).

Among antipsychotic medications, second-generation agents were initially presented as superior because they are less likely to cause motor SEs, including akathisia, Parkinsonian symptoms, and tardive dyskinesia, than are first-generation antipsychotic medications (Casey 1996). However, clinical experience has shown that some of the newer antipsychotic medications are associated with metabolic changes, including clinically significant weight gain, increased risk of diabetes, and hyperlipidemia (Lieberman et al. 2005; Marder et al. 2004), and some agents cause sexual dysfunction (Marder and Meibach 1994; Sanger et al. 1999). The newer antidepressants, used clinically for a variety of mood and anxiety disorders, are less likely to produce anticholinergic SEs such as dry mouth and constipation than the older tricyclic antidepressants. However, many of the newer agents are associated with sexual dysfunction, psychomotor activation, or sleep disturbances (Goldstein and Goodnick 1998; Rivas-Vazquez et al. 2000; Settle 1998). Many anticonvulsant medications, which are often used to treat bipolar disorders, are associated with significant weight gain and sedation (Aronne and Segal 2003; Ketter et al. 2003; Swann 2001). Hence, a new set of SEs, including weight gain, metabolic disturbances and sexual dysfunction appear to have replaced adverse effects associated with the older medications.

Most clinical studies lack information on how much people are bothered by the SEs they experience. Individuals' subjective distress due to SEs is vitally important; it may determine whether or not they take their medication as prescribed, reduce their dosage, or stop taking it completely. Thus, negative subjective response to medication can lead to non-adherence (Awad 1993; Naber 1995, 1998; Cabeza et al. 2000) and subsequent relapse (Weiden and Olfson 1995). Subjective distress is very individual. Some people might be unconcerned by a medication causing a 10 pound weight gain, while others might find it completely unacceptable, even if the medication was effective in treating their illness.

Research has begun to examine individuals' subjective experience more systematically (Awad et al. 1995; Dassori et al. 2003; Day et al. 1995; Finn et al. 1990; Gerlach 2002; Pereira and Pinto 1997; Waserman and Criollo 2000; Weiden et al. 1994, 1989; Weiden and Miller 2001). However, little information is available regarding individuals' subjective experience of SEs commonly associated with newer agents. One study that did assess distress due to weight gain found that among individuals reporting weight gain, 73% found it "quite or extremely distressing" (Wallace 2001). To improve our understanding of individuals' experiences taking psychotropic medications, the steering committee of the SAMHSA multi-site study of consumer-operated service programs (COSP; http://www.cstprogram.org/consumer%20op/index.html), a randomized trial examining the cost effectiveness of the impact of such programs on the lives of individuals with severe mental illnesses, elected to measure study participants' subjective distress from SEs of their current psychotropic medications.

Method

Study Participants

The COSP study recruited 1,827 individuals for participation in a multi-site randomized trial of consumer-operated and controlled service programs designed to use peer support to improve outcomes for people with mental illness. Study sites included urban, suburban, and rural settings across eight states; non-clinical interviewers (many of whom identified themselves as mental health consumers) received training to adhere to a well-defined protocol in administering a common interview. Study participants were persons over age 18 who met the following eligibility

criteria: (1) diagnosis of severe mental illness [an Axis I or II primary diagnosis other than substance abuse or dependence (American Psychiatric Association 1994)], (2) received mental health services at least four times in the past year from a traditional mental health provider, with at least one of those services in the 4 months prior to entry into the study, and (3) no more than three visits to or meetings in a COSP. Individuals with secondary diagnosis of substance use disorders and those who were not taking psychotropic medications were not excluded. Sites were allowed to impose additional inclusion and exclusion criteria as long as they adhered to the multi-site's inclusion and exclusion criteria for study participation (for example, a site offering advocacy education classes would be allowed the additional inclusion criteria of a participant's stated willingness to attend the classes). All participating sites obtained IRB approval. We report results from baseline interviews, which were conducted between January 2000 and October 2001.

Measures

The measures in this report are derived from the baseline assessment of a larger Common Assessment Protocol composed of 27 scales administered at baseline and 4-, 8-, and 12-month follow-ups (http://www.cstprogram.org/consumer%20op/Multi-Site%20Activities/Common%20Protocol/common_research_protocol.htm). We used the Subjective Side Effect Rating Scale, a 21-item scale (23 items for women), to measure patients' report of common SEs of psychotropic medications and their perceived distress from SEs (Weiden and Miller 2001). The SSRS asks whether individuals experienced each potential SE. If the SE was present, it asks whether they were ''not bothered at all'', ''bothered a little'', ''bothered moderately'', or ''bothered a lot'' by the SE.

We used items from the Hopkins Symptom Checklist (Derogatis et al. 1974; Mollica et al. 1987) to examine the relationship of perceived SEs to other symptom measures. Specifically, other symptom measures included faintness, heart racing, feeling low in energy, blaming oneself, crying easily, losing sexual interest, feeling lonely, feeling hopeless, feeling blue, suicidal thoughts, feeling no interest in things, feeling everything is an effort, and worthless feeling, self report of diabetes, arthritis or rheumatism, breathing trouble, heart trouble, hypertension, joint and muscle ache, pain in heart or chest, stroke, swollen ankles, tiring quickly, back or spine pain, and frequent leg cramps.

We used the overall rating for quality of life from the Lehman Quality of Life Interview (Lehman 1988) to measure general quality of life using a 7-point scale ranging from 1 = terrible to 7 = delighted. At all but one site, diagnoses were recorded via chart review; the remaining site conducted structured clinical interviews for DSM-IV Disorders (First et al. 1995) to obtain diagnoses. The COSP study did not collect information about the specific medications study participants were taking.

Statistical Analyses

We applied descriptive statistics to examine report of distress with medication SEs and applied factor analyses to examine whether meaningful patterns of distress with medication SEs emerged. We applied forward stepwise logistic regression to examine whether gender or race [represented by dichotomous variables representing whether a participant was Caucasian (0 = yes, 1 = no) and whether a participant was African American (0 = yes, 1 = no)] were associated with level of distress due to the four most commonly reported SEs (dichotomized as "bothered a little", "moderately" or "a lot" versus "not present" or "not bothered") and distress with sexual difficulties. We repeated these same analyses with the outcome dichotomized as "bothered a lot" versus all other responses. We also examined correlations between the four most distressing SEs and self-reported symptoms and general quality of life. We conducted analyses for this report using the COSP Outcomes Dataset Version 1.0; created on October 6, 2003.

Results

Participants had a mean age of 42.7 years (SD = 10.2, median = 43, range = 18–78). Nearly half (47%) of the participants (n = 857) were diagnosed with schizophrenia-spectrum disorders (31% (n = 570) with schizophrenia and 16% (n = 287) with schizoaffective disorder), with an additional 21% (n = 389) diagnosed with major depressive disorder, 18% (n = 321) with bipolar illness, 4% (n = 66) with depressive or other mood disorder not otherwise specified, 3% (n = 55) with psychotic disorder not otherwise specified, 2% (n = 34) with dsythymic disorder, and with additional diagnoses including post traumatic stress disorder (n = 23), panic disorder (n = 18), obsessive compulsive disorder (n = 13), adjustment disorder (n = 13), delusional disorder (n = 7), dissociative disorder (n = 7), generalized anxiety disorder (n = 6), anxiety disorder not otherwise specified (n = 5), cyclothymic disorder (n = 4), impulse-control disorder not otherwise specified (n = 2), intermittent explosive disorder (n = 2), agoraphobia without a history of panic disorder (n = 1), mental disorder not otherwise specified due to a general medical condition (n = 1), social phobia (n = 1), gender identity disorder not otherwise specified (n = 1), and personality change due to a general medical condition (n = 1).

Additionally, 9% (n = 158) of study participants were diagnosed with co-morbid substance abuse or dependence. More than half of the study participants were women (n = 1,098, 60%), 74% were Caucasian (n = 1,346), 23% African American (n = 421), and 3% Latino (n = 60). With respect to prescribed medications, 1,753 (96%) of 1,822 individuals indicated that they received a prescription for psychotropic medications, 1,417 (81%) of 1,741 indicated that they had been informed about medication SEs, and 1,568 (91%) of 1,717 noted that medications were helpful. We limit the remaining analyses to those 1,753 individuals who reported receiving prescriptions for psychotropic medication.

Of those individuals who reported receiving prescriptions for psychotropic medication, 94% (n = 1,645) reported the presence of at least one SE (n = 1,645). Study participants indicated that a mean of 6.9 SEs (SD = 5.0) caused them at least some distress and a mean of 2.8 (SD = 3.3) bothered them a lot. Sixty-eight percent (n = 1,189) of individuals who reported receiving prescriptions for psychotropic medication indicated that they were bothered a lot by one or more SEs, 52% (n = 910) were bothered a lot by two or more SEs, and 40% (n = 706) were bothered a lot by three or more SEs.

The most commonly reported SEs listed in order of distress were embarrassment with weight gain, weight gain, dry mouth, and sedation (Fig. 1). Over half (52%, n = 916) of study participants reported embarrassment with weight gain and, of these, 74% (n = 678) were bothered moderately or a lot; 57% (n = 999) of the participants reported weight gain, 70% (n = 701) of whom were bothered moderately or a lot; 62% (n = 1,085) of participants reported dry mouth, 59% (n = 643) of whom were bothered moderately or a lot; and 63% (n = 1,112) of participants reported sedation, of whom 49% (n = 543) were bothered moderately or a lot.

Factor analysis suggested the presence of four factors. The first factor accounted for 19% of the variance, the second for 13%, the third for 9%, and the fourth for 7%. Most items loaded on the first factor (akinesia, akathisia, tremor, embarrassment with EPS symptoms, memory loss, cognitive difficulties, depression, change in appearance, embarrassment/stigma from being on medication). With the exception of ''rigidity'', the second factor appeared to capture anticholinergic side effects (dry mouth, blurred vision, constipation, and sedation). While the first factor captured mostly change in appearance, the third and fourth factors seemed to capture weight gain (weight gain, embarrassment with weight gain) and weight loss (appetite loss, weight loss), respectively. Some items loaded on two factors equally (insomnia on the first and fourth, appetite increase on the second and third, and sexual difficulties on the second and third).

Relationship of Gender and Race to Reported Distress with Side Effects

Women and non-Caucasians were more likely to report distress with greater than six side effects (Table 1). Women and men did not differ in their distress from sedation. However, women were more likely than men to report distress with weight gain and embarrassment with weight gain, and distress due to dry mouth (Table 1). On the other hand, men were more likely than women to report distress with sexual difficulties (Table 1). Individuals of different races did not differ in their report of distress with weight

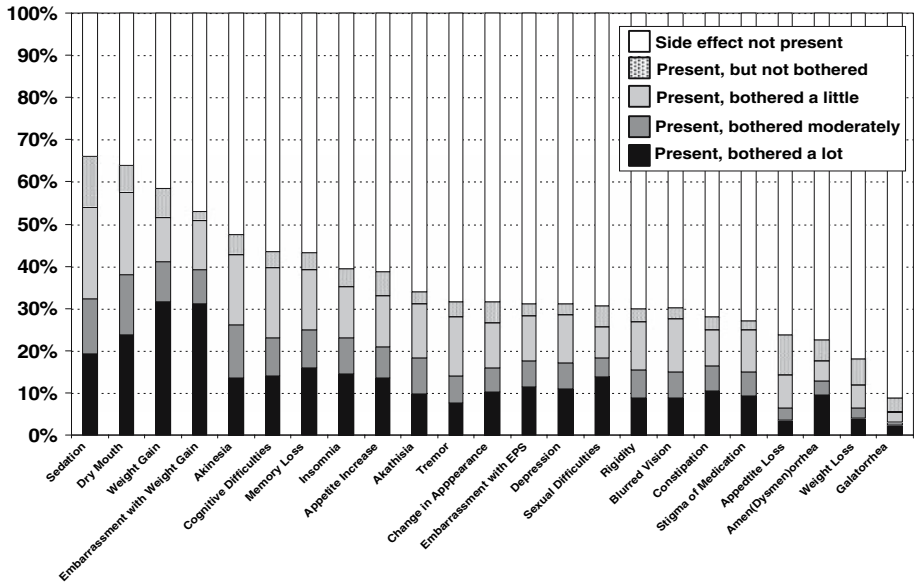

Fig. 1 Percentage of individuals reporting the presence of side effects and the degree to which they were bothered by these side effects

Table 1 Results of logistic regression examining the impact of gender and race on self-reported side effects[a]

Self-reported side effect	Predictor	OR	Wald	*p*-value
Distress with >6 side effects	Gender	1.33	8.0	.005
	Non-Caucasian	1.40	9.0	.003
Weight gain	Gender	1.91	40.1	<.001
Embarrassment with weight gain	Gender	2.98	107.7	<.001
	Non-African American	1.89	27.2	<.001
Dry mouth	Gender	1.43	12.4	<.001
Sexual difficulties	Gender	0.69	10.1	.001
Sedation	Non-Caucasian	1.42	9.7	.002

[a] For "Gender", 1 = female and 0 = male; for "Non-Caucasian", 1 = non-Caucasian and 0 = Caucasian; for "Non-African American", 1 = non-African American and 0 = African American

gain, dry mouth, or sexual difficulties. However, non-Caucasians were more likely than Caucasians to report distress due to sedation (Table 1). Additionally, non-African Americans were more likely than African Americans to report distress due to embarrassment over weight gain (Table 1). This same pattern of results emerged when the cut-off criteria for distress was narrowed to include only severe distress.

Because we observed both race and gender effects for embarrassment due to weight gain, we constructed an additional logistic regression model including terms for gender, whether the participant was African American, and the interaction between African American and gender as they predicted embarrassment due to weight gain. The interaction between race and gender was not significant.

Relationship Between Distress with Side Effects and Other Symptom Measures

We found an association between distress due to embarrassment with weight gain and feelings of self blame ($r = .28$, $p < .001$), loneliness ($r = .26$, $p < .001$), hopelessness ($r = .28$, $p < .001$), feeling blue ($r = .27$, $p < .001$), feeling no interest in things ($r = .22$, $p < .001$), feeling worthless ($r = .28$, $p < .001$), tiredness ($r = .21$, $p < .001$), having everything feel like an effort ($r = .23$, $p < .001$), feeling low in energy ($r = .27$, $p < .001$), and a lower self-reported quality of life ($r = –.21$, $p < .001$). Greater distress due to weight gain was associated with feeling low in energy ($r = .21$, $p < .001$).

Level of distress due to dry mouth was related to racing heart ($r = .22$, $p < .001$) and level of distress due to sedation was related to feeling low in energy ($r = .21$, $p < .001$), and tiring very quickly ($r = .22$, $p < .001$). All other relationships between perceived SEs and other symptoms measures were not significant.

Discussion

This study has several limitations that affect the interpretation of findings. First, lack of prescription data precludes linking distress from SEs to particular classes of psychotropic medications, specific agents, specific dosage ranges, treatment durations, or medication adherence. Similarly, lack of rigorous diagnostic information across sites precluded examining the impact, if any, of diagnosis on distress from SEs. Second, this study is a naturalistic, cross-sectional observation of what is happening in a large and varied outpatient sample of people with SMI who expressed a willingness to participate in a consumer-operated program. While the participants may not be fully representative of all individuals with SMI, the high rate of troubling SEs in this large real-world population should be noteworthy to clinicians. Third, these data represent self-attributed SEs that are not clinically validated with objective measures (e.g., distress with weight gain can not be compared to a measure of weight or calculated body mass index). However, the purpose of our analysis is to examine participants' subjective perception of distress due to SEs, rather than to provide clinical prevalence rates. Individuals' beliefs about their medications may affect their willingness to take the medications, regardless of whether these beliefs can be verified objectively.

With these limitations in mind, the present findings suggest that perceived SEs cause significant distress for individuals prescribed medications to treat severe mental illness. Although over 90% of the participants in our study reported that medications were helpful, the same proportion also experienced SEs they attributed to their medication. Nearly two-thirds of the participants reported a high level of distress with at least one SE, and, on average, individuals reported distress from 6 or 7 SEs, with a wide range of SEs contributing to distress (Fig. 1). Participants reported that embarrassment from weight gain, weight gain itself, dry mouth, and sedation were the most distressing adverse effects they experienced. It is important to note here that, compared to other studies including individuals with serious mental illness, the present study recruited more women (60%) than men, possibly because the inclusion criteria allowed a wide range of diagnoses and there were no limits on enrolling women of childbearing age. Because women were significantly more likely than men to report distress with greater than six side effects, it is important to be mindful of the proportion of women in this and future studies examining rates of self-reported side effects.

In addition to being bothersome, some SEs pose significant health risks (Marder et al. 2004). Weight gain is a well-known risk factor for cardiovascular disease and diabetes, as well as a potential source of physical and

psychological discomfort (Bakx et al. 1999; Kannel et al. 1996; Kawachi 1999; Sakurai et al. 1997; Solomon and Manson 1997), and non-adherence to antipsychotic medication (Weiden et al. 2004). Perhaps less obvious is that individuals' concerns over actual or potential weight gain can prompt them to behave in ways that sabotage their overall health. For example, a smoking cessation study demonstrated that weight-concerned women were less likely to maintain abstinence from smoking after completing a smoking cessation program than were other participants (Meyers et al. 1997). A study examining insulin omission among women with insulin dependent diabetes demonstrated a worrisome link between weight preoccupation and intentional insulin omission (Polonsky et al. 1994). Weight gain is particularly problematic for individuals with serious mental illness because nearly two-thirds are already overweight (Allison et al. 1999; Covell et al. 2004; Umbricht et al. 1994) and weight gain has been associated with many psychotropic agents (Allison et al. 1999; Aronne and Segal 2003; Keck and McElroy 2003). In the current sample, more distress and embarrassment with weight gain was related to a lower self-reported quality of life and more reports of symptoms consistent with depression. However, it is important to note that although significant in this large sample, these relationships were somewhat weak (correlations between .2 and .3); further, we were not able to determine causality given the cross-sectional nature of the analyses.

Dry mouth can cause soreness, ulcers, infections, and loss of teeth (Daniels and Wu 2000) and was one of the more distressing SEs reported, especially among women. Hence, it is important for prescribers to ask about this symptom directly. Dry mouth may be responsible for many of the dental problems experienced by people taking psychotropic medications, rather than lack of adequate self-care. Perceived poor dental health may contribute to low self-esteem, avoidance of social interactions, and reluctance to seek employment. To minimize these consequences, ensuring access to dental treatment for individuals who report experiencing dry mouth is indicated.

Our study demonstrated gender and racial differences in distress from particular SEs. Significantly more women than men reported distress over weight gain and embarrassment with weight gain. Additional evidence suggests that women may be more susceptible than men to weight gain when taking clozapine (Covell et al. 2004), and gender differences in susceptibility to weight gain may exist for other psychotropic medications as well. On the other hand, men reported more distress about sexual difficulties as a SE of psychotropic medications.

African-Americans reported less distress with embarrassment over weight gain than individuals of other race. This finding is consistent with numerous studies indicating that compared to other racial and ethnic groups in the United States, African-American women do not place as much value on thinness, and show less discrepancy between their current size and their ideal desired size (Gluck and Geliebter 2002; Palmer 2003). African American females also generally report less concern about body shape or other body concerns than other racial and ethnic groups in many studies (Barry and Grilo 2002; Neumark-Sztainer et al. 2002; White et al. 2003).

Our results underscore that, in addition to obtaining objective measures of problematic side effects, it is important to address a wide spectrum of potential subjective SEs as part of an ongoing dialogue between clinicians and consumers. In this way, both objective and subjective SEs can be acknowledged and entered into the benefit/cost assessment people make when they decide whether to take medication and how much to take. Clearly, an overwhelming majority of individuals feel that medications are helpful and so addressing these issues forthrightly may lead to a greater likelihood of finding well-tolerated treatments to which individuals can adhere, and also reinforces better communication, respect for individuals' subjective experience, and ultimately should lead to better clinical outcomes. Future randomized trials of the effectiveness of psychotropic medications should examine predictors of distress with SEs, and pharmaceutical manufacturers should monitor and consider these findings as they develop new agents so that consumers and prescribing physicians have information at hand on the relative SE burden of medications to minimize the SEs most troubling to a given consumer as they decide what to try next.

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