Adverse Effects of Psychotropic Medications

A Call to Action

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KEYWORDS

• Adverse effects • Side effects • Psychiatric medications • Psychotropic medications • Clinical trials • Rating scales • CONSORT

KEY POINTS

- Clinicians need to fully appreciate the extent to which nonadherence is a pervasive problem that vitiates the effectiveness of psychotropic medications.
- Adverse effects need to be viewed not as a necessary and unavoidable price to be paid for the benefits of treatment but as a major cause of suffering and nonadherence that need to be energetically prevented, reduced, and managed.
- The methodology for identification, assessment, and reporting of adverse events in clinical trials needs to be improved and standardized.
- A substantial increase in research into management of various adverse effects is needed. Many strategies to reduce and manage adverse effects, however, are already available but need to be used more often to reduce nonadherence to medications.

Adverse effects (a more appropriate term than *side effects*) of psychotropic medications are often viewed by clinicians as the unfortunate, unwanted, and perhaps inevitable accompaniments of the benefits of these medications. To the persons taking these medications, however, the distress caused by these adverse effects is as important as that caused by the symptoms of the disorder being treated. Patients are put in the unfortunate position of having to weigh the benefits of the medications against the burden of adverse effects. Given how important adverse effects are to patients, and often to their families, and given the central role they play in nonadherence to medication, it is astonishing how little attention has been paid to the identification and management of these adverse effects.

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I start by reviewing some of the reasons why adverse effects are so important, then discuss the various problems faced with regard to adverse effects, and, finally, propose a plan of action to address some of those problems.

ADVERSE EFFECTS ARE BOTH COMMON AND BOTHERSOME

A great majority of persons taking a psychotropic medication have 1 or more adverse effects of that medication. Are most of these adverse effects, isolated, mild, and of little clinical significance? In a survey of patients prescribed a selective serotonin reuptake inhibitor (SSRI), 52% of patients reported that they had had 3 or more adverse effects, and 55% reported that they had had at least 1 adverse effect that was either "a lot" or "extremely" bothersome.[1,2]

The drug-placebo differences for the most common adverse events occurring in clinical trials of psychotropic medications, as noted in the prescribing information for these medications, are shown in **Table 1**. The numbers show that adverse effects occur in a substantial number of patients who take these medications. Individual adverse events are reported by 3% to 39% more patients on the medication versus on placebo. These numbers are probably an underestimate of the true incidence of these adverse events because in clinical trials adverse events are identified mainly or entirely based on spontaneous reporting.

ADVERSE EFFECTS OFTEN LEAD TO DISCONTINUATION OF TREATMENT

A majority of persons prescribed a psychotropic medication soon stop taking it, vitiating the effectiveness of treatment. For example, in 1 study, 28% of patients completely discontinued taking any antidepressant within the first 3 months after starting on an antidepressant; in addition, others switched the antidepressant and more discontinued the medication later in treatment.[3]

Why do they discontinue the medications? The most common reason for discontinuing or switching an SSRI within the first 3 months is adverse effects.[3] Similar findings were more recently reported in patients treated with reboxetine or citalopram.[4] The most common reason for discontinuation was adverse effects; these were reported as the reason for discontinuing the medication by 61%, 57%, and 43% of patients who discontinued the antidepressant at 2, 6, and 12 weeks, respectively.[4] For patients with bipolar disorder taking mood stabilizers, adverse effects are the leading cause of nonadherence to medication.[5] In a survey of patients around the world, 43.5% of respondents reported that at some point in their life, they had discontinued their psychotropic medication due to adverse effects.[6] In clinical trials, the most commonly stated reason for discontinuing antidepressants is adverse events.[7] Thus, the extent to which nonadherence to psychotropic medications is a pervasive problem and seriously hampers the potential utility of treatment needs to be fully appreciated.

ADVERSE EFFECTS ARE CONSIDERED IMPORTANT BY BOTH PATIENTS AND CLINICIANS

In a study using trade-offs, patients considered adverse effects of antidepressants as important as their benefits of symptom relief and relapse prevention.[8] A systematic survey of psychiatrists' prescribing found that the most frequent reason they reported for selecting particular antidepressants was the adverse effects of that antidepressant.[9] Thus, the incidence and nature of adverse effects of an intervention can be a major factor in deciding whether that intervention is considered acceptable and worthwhile.[10] It is, therefore, important to have fairly accurate estimates of the absolute and relative prevalence of various adverse effects with different psychotropic medications.

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