

The Addiction Severity Index in Clinical Efficacy Trials of Medications for Cocaine Dependence

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INTRODUCTION

The Addiction Severity Index (ASI) is a semistructured clinical or research interview (McLellan et al. 1980, 1985, 1992*b*). It was developed more than 15 years ago to fill the need for a standardized, reliable, and valid instrument with which to evaluate substance-abusing patients. More specifically, it was created to enable clinical researchers to evaluate the treatment outcome of drug and alcohol patients. Since that time, it has been widely used and has become a standard. The ASI is used internationally and has been translated into numerous languages. Nationally, a number of States, counties, and cities, in programs that they fund, have mandated the use of the ASI for clinical and program evaluation purposes. Finally, the ASI has become a mainstay in substance abuse research, which is the reason that the role of the ASI in medication trials to treat cocaine dependence is a topic of interest.

Given this kind of popularity, the ASI must have a lot going for it. The ASI is especially valuable as a tool to conduct assessments for clinical purposes and to obtain information to evaluate broad-based rehabilitations. To what extent, however, is the ASI applicable to clinical trials of pharmacotherapy for cocaine dependence? To address this question, first the structure of the ASI will be briefly reviewed. Then the appropriateness and the strengths and weaknesses of the ASI as a baseline assessment instrument and as an outcome measure in clinical efficacy trials of medications for the treatment of cocaine dependence will be addressed.

OVERVIEW OF THE ADDICTION SEVERITY INDEX

The ASI is a semistructured interview that can be administered by trained interviewers. It assesses patient status in seven areas and obtains demographic information as well. The seven following

potential problem areas are evaluated within the ASI: medical, employment, drug use, alcohol use, legal, family/social, and psychological. Questions in each area address lifetime and current functioning (i.e., past 30 days).

Each problem area has several different types of items. The large majority are considered objective items that detail the type, number, and duration of problems and, to a lesser extent, assets. Two more subjective items in each problem area are included: a patient rating of recent problem severity and a patient rating of current need for treatment. The ASI has two summary measures available for each problem area:

1. Interviewer severity ratings are 0- to 9-point estimates of problem severity, defined as the “need for additional treatment.” Each severity rating is a subjective synthesis of all the information in a specific problem area.
2. Composite scores (McGahan et al. 1982) are a second type of summary measure and are considered to be more objective indices of problem severity than interviewer severity ratings. Each composite score is developed from a subset of items that reflect current status in a given problem area.

The items are standardized and summed to produce a mathematically derived composite score, which ranges from 0.00 to 1.00 for each ASI problem area. Baseline composite scores and interviewer severity ratings have been found to be highly correlated (Brown et al. 1993; McLellan et al. 1985). The final items in each area are confidence ratings, two items that are interviewer ratings of the veracity of the information elicited from the patient.

The ASI is designed such that it is capable of repeat administration(s), at least 1 month apart, with a followup version that is essentially a subset of items from the full ASI. Composite scores are calculated using the same items in full and followup ASIs. A baseline or admission ASI used in conjunction with a followup ASI(s) can provide a profile of change.

USE OF THE ADDICTION SEVERITY INDEX TO EVALUATE PSYCHOSOCIAL TREATMENTS

The multidimensionality and breadth of information collected on the ASI are its major strengths as an outcome measure for psychosocial

inter-ventions. These strengths are in some ways handicaps when the ASI is used as an outcome measure to evaluate pharmacologic interventions.

Alterman and colleagues (1994) used the ASI as a primary outcome measure to determine the effectiveness of 1 month of inpatient versus day-hospital cocaine rehabilitation. This was a near-perfect fit of the ASI to evaluate a treatment intervention. These two intensive programs, inpatient and day hospital, would be expected to effect change over a number of dimensions (not just cocaine use), and followup evaluations several months following admission would be appropriate (in this case 4 months and 7 months) insofar as treatment effects would be expected to emerge and persist over time. Since these assumptions apply to many psychosocial interventions, it is no surprise that the ASI is a primary assessment instrument in these types of treatment studies for cocaine dependence. Actually, it is a rare study that has evaluated the efficacy of a psychosocial intervention for cocaine dependence that has not used the ASI.

USE OF THE ADDICTION SEVERITY INDEX TO EVALUATE PHARMACOTHERAPY

General Considerations

Measures other than or in addition to the ASI may be more appropriate to evaluate the efficacy of pharmacotherapy for cocaine dependence. Medications would very likely be expected to effect change in fewer areas, primarily cocaine use and perhaps psychiatric symptomatology. Change in other areas, for example, criminal behavior, employment status, and interpersonal functioning, would likely be secondary to reduced cocaine use or to any psychosocial treatment coupled with the pharmacotherapy. Furthermore, the timing of pharmacologic and psychosocial treatment effects may be different (Carroll et al. 1994*b*). The medications that have been developed are generally expected to have a rapid onset. Since this is the case, evaluations several months apart or even monthly are not sufficient to capture the course of the treatment effect. At least initially, weekly or more frequent evaluations may be needed to adequately monitor change.

It is important to keep in mind that the ASI was developed as a generic instrument for assessing substance abusers. Therefore, its application to cocaine dependence and more specifically to

pharmacotherapy of cocaine dependence will not necessarily address in sufficient detail the nature of the treatment effects. There are actually only three items in the ASI that specifically address cocaine use, i.e., days of cocaine use in the past 30, years of regular cocaine use, and primary route of cocaine administration. One of these items, route of administration, was added in the fifth and most recent edition of the ASI (McLellan et al. 1992*b*), in part because route of administration of cocaine may be an important severity/prognostic variable. A second item, years of regular use, was modified in the fifth edition to include a binge pattern of drug use and not strictly use of three or more times a week. This change was made in part because a typical pattern of cocaine use is bingeing. It is apparent that the ASI does not include important information such as amount of cocaine used and consecutive days of abstinence from cocaine. Furthermore, the interviewer severity rating and composite score for drug use are not cocaine specific. Insofar as these two summary measures of drug use severity are sensitive to and elevated by multiple drug use, they do not necessarily reflect severity of cocaine use.

Weiss and Mirin (1990) have identified four ways in which broad classes of pharmacotherapeutic agents may impact cocaine use. These medications may:

1. Block the effects of cocaine.
2. Treat premorbid, coexisting psychiatric disorders.
3. Treat cocaine withdrawal/craving.
4. Produce aversive reactions following cocaine use.

The ASI does not include items that assess specific variables that may be most relevant to determining whether a medication is producing its anticipated effect. For instance, craving/withdrawal are only addressed on the ASI within the broader item of days of drug problems. Psychiatric symptoms are assessed such that the presence of symptoms such as anxiety and depression are noted, as are the frequency and severity of psychological distress in general. The ASI does not, however, rate the frequency or severity of specific psychiatric symptoms.

This brief review lays the groundwork to outline how the ASI can best be used in clinical efficacy trials of pharmacological treatments for cocaine dependence.

The Addiction Severity Index as a Baseline Measure

At baseline, the ASI can provide a description of the study sample on a standard set of potentially important background characteristics over and above demographics, such as years of cocaine use, number of previous drug treatments, years of alcohol use, arrest history, and psychiatric symptom and treatment history. Current status in the seven problem areas can also be described with individual items as well as with interviewer severity ratings and composite scores. This information creates a multidimensional profile of the subjects.

The scores on ASI individual items and summary measures can be used to determine whether randomization to treatment conditions has been successful, and in multisite trials to evaluate whether intersite comparability has been achieved. ASI variables can also serve as control variables if important differences do exist. To the extent that the ASI is widely used, it supplies a standard set of variables to compare one investigation with another, and thus provides information that may assist in making sense of conflicting results. The ASI also yields a number of severity variables that can be explored as predictor variables.

As mentioned, the ASI collects valuable background and current status information in seven problem areas, including psychiatric status. It does not, however, elicit the necessary information to determine psychiatric diagnoses. Specifically, although frequency of drug and alcohol use and problems are obtained, the individual diagnostic criteria for substance-related disorders are not assessed. Also, although the ASI has questions about legal history and criminal and violent behavior, it does not supply enough information to make a diagnosis of antisocial personality disorder. Similarly, a positive response to the depression or anxiety items in the ASI psychiatric section does not necessarily indicate a diagnosable mood or anxiety disorder.

It is apparent that there are two general types of information in a baseline assessment that would be a helpful supplement to the ASI. First, psychiatric diagnoses, especially substance-related disorders, are necessary to adequately characterize a study sample. Other Axis I disorders and personality disorders may be important descriptors as well. Second, more detailed information on patients' history and current pattern of cocaine use is recommended.

The Addiction Severity Index as an Outcome Measure

With regard to the ASI as an outcome measure, the authors have in many ways already alluded to its strengths and weaknesses. The ASI alone does not provide the information to adequately assess outcome in pharmacotherapy studies. The main areas in which more information may be necessary are those concerning cocaine use and problems— amount of use, craving/withdrawal, abstinence, treatment attendance, urinalysis results, etc. Related to this point, Carroll and colleagues (1994a) have added a few items to the ASI that, in combination with the standard ASI item “days of cocaine use in past 30 days,” can be used to calculate a cocaine composite score. This score is a specific measure of cocaine severity and is unaffected by other drug use (see table 1).

Composite scores and specific items relating to frequency and severity of problems in the seven ASI domains can be compared from admission to varying followup points as measures of change. (Interviewer severity ratings should generally not be used as pre- and postmeasures because they are based on different information at baseline and followup.) For the purposes of pharmacotherapy studies, changes in the ASI problem areas (other than the drug use area), however, are probably best thought of as secondary outcomes. That is, broader changes would most likely be related to a reduction in cocaine use or the psychosocial aspects of the treatment in which the medication is embedded, and not direct results of the medication per se. Insofar as the medications are expected to treat coexisting psychopathology such as depression, the ASI psychiatric scale may be considered a primary outcome measure as well. Nevertheless, in these cases, more syndrome-specific scales may be valuable supplements, e.g., the Hamilton Rating Scale for Depression (Hamilton 1960) or the Beck Depression Inventory (Beck and Beck 1972).

The timeframe reflected in the ASI followup is primarily the past 30 days. If medications are to affect early abstinence, weekly evaluations, at least at first, are probably necessary. The ASI is not designed for such frequent evaluations. There are several other points related to the

TABLE 1. *Questions and formula for the cocaine composite score.*

The cocaine composite score is based on the algorithm for the ASI alcohol composite score.

The cocaine composite includes the first part of question 8 in the ASI Drug and Alcohol Section; i.e., number of days of cocaine use in the past 30. It also requires adding the three following additional cocaine questions to the ASI:

1. How many days in the past 30 have you experienced cocaine problems?
2. How troubled or bothered have you been in the past 30 days by these cocaine problems?__ (Answer = 0-4, not at all - extremely)
3. How important to you now is treatment for these cocaine problems? __ (Answer = 0-4, not at all - extremely)

The formula to compute the cocaine composite score is as follows:

$$\text{Cocaine Composite Score} = \text{Drug and Alcohol Q8} / 120 + \text{Cocaine Q1} / 120 + \text{Cocaine Q2} / 16 + \text{Cocaine Q3} / 16.$$

D & A Q8 = number of days used cocaine in the past 30.

C Q1 = number of days problems with cocaine in the past 30.

C Q2 = how bothered by cocaine problems in the past 30 days.

C Q3 = need for treatment for cocaine problems.

SOURCE: Carroll, personal communication.

timeframe of the evaluation period covered by the ASI. When evaluations are several months apart, the most detailed information collected on the ASI concerns the past 30 days, and that is the information on which the composite scores are based. Regarding the remainder of the followup period, the ASI covers only major events, such as hospitalizations and arrests. Therefore, the course of cocaine use or psychiatric symptoms or alcohol use is not continuously documented unless the ASI is conducted monthly or supplemented by additional timeline followback procedures in the domains of interest. For example, if a baseline ASI and a 3-month ASI followup are conducted, the data available for the comparative analyses are essentially snapshots of the 30 days prior to each evaluation. In this

case, important information such as duration of continuous abstinence and occurrences of relapse episodes is not obtained.

Measuring the Treatment Context

The ASI does not document the treatment services that patients receive. There are important benefits in evaluating the amount and nature of treatment that patients are receiving during the medication trial. The treatment context within which a medication is delivered may well impact on its effectiveness. The Treatment Services Review (TSR) (Alterman et al. 1993; McLellan et al. 1992*a*) is a structured, technician-administered interview designed to assess the type and amount of treatment that patients receive. In this brief interview, treatment services are categorized along the lines of the seven ASI problem areas. The period addressed with the TSR is 1 week. Repeated TSR interviews can therefore detail the course of a patient's treatment over time. The authors have been focusing on patient variables that can be measured with the ASI. Treatment or program variables, in addition to patient variables and type and dose of medication, may account for individual and site differences in response to medication. The TSR can provide a standard evaluation of treatment services in the same way that the ASI can provide a standard set of patient variables. Therefore the TSR items and summary measures can be used to determine whether patients in different treatment conditions (e.g., active medication versus placebo) are receiving similar levels of ancillary services. In multisite trials, the TSR can be used to determine whether treatment among sites is comparable. The TSR can also supply a standard set of variables to compare one investigation with another. Lastly, the TSR can assist in the effort to determine the overall treatment conditions necessary for a medication to show a therapeutic effect.

SUMMARY

In sum, the ASI provides a standard and multidimensional initial evaluation of the subject. Furthermore, a profile of subjects is obtained that can be compared at different evaluation points, providing secondary outcomes. However, for the purposes of clinical trials evaluating pharmacotherapy for cocaine abusers, supplemental measures are needed at both baseline and followup to more specifically address cocaine use and problems.

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[Click here to go to page 192](#)