PATIENT STAGE OF CHANGE PREDICTS OUTCOME IN A PANIC DISORDER MEDICATION TRIAL

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Objective: The authors test the hypothesis that patient readiness to change predicts outcome in a placebo-controlled medication trial. *Method:* Out-patients with panic disorder and agoraphobia completed the Stages of Change (SOC) questionnaire, a measure of readiness to change, before being randomly assigned either sustained release (SR) adinazolam or placebo in a 4 week double-blind trial. *Results:* In the "intent to treat" analysis, for the 202 subjects who made at least one visit after baseline, adinazolam SR was significantly more effective than placebo on most major outcome measures. Of the 126 subjects who completed the SOC questionnaire, regression analyses showed significant correlations between SOC scores and all S outcome measures. In a second analysis, cluster membership based on SOC scores was predictive of outcome on 3 of 5 measures. In each statistical analysis, subjects who were not predisposed to change as measured by the SOC were significantly less likely to change. *Conclusions:* Patient readiness to change was strongly correlated with outcome in a placebo-controlled panic disorder trial with an effective medication. In this study, the SOC category, Precontemplation (i.e., those subjects who reported the belief that they had no problem) were less likely to change compared to those who believed that they had a problem. *Anxiety 1:64–69 (1994).* © 1994 Wiley-Liss, Inc.

Key words: *panic disorder, readiness to change, placebo, self-change*

INTRODUCTION

Several studies have suggested that patients change problematic behaviors without benefit of professional intervention (Schacter, 1982; Shapiro et al., 1984; Verhoff et al., 1981a, b). Readiness to change appears to be a crucial variable in the change process. This concept has a long history and is concerned with changes in patients' receptiveness to self-change during treatment (Meltzoff and Kornreich, 1970). DiClemente et al. (1991) examined a number of variables associated with smoking cessation in smokers who had changed on their own. They found that the less clearly self-changers defined the behaviors as a problem to be solved, the less likely they were to change. In order to measure this construct, they develop a 32-item Stages of Change (SOC) Questionnaire (McConnaughy et al., 1983, 1989) that quantifies varying predispositions to change. The items are listed in Table 1.

The SOC measures four stages with 8 items per stage: Precontemplation, Contemplation, Action, and Maintenance. These stages represent a continuum of predisposition or readiness to change. At one pole, Precontemplators are underaware of their problems and usually feel coerced into entering treatment; e.g., "As far as I'm concerned, I don't have any problems that need changing." Contemplators are aware of their problems but have not yet committed to action; e.g., "I have a problem and really think I should work on it." Individuals in Action have targeted behaviors and/ or thoughts to change and are currently working on them; e.g., "Anyone can talk about changing. I'm actu-

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TABLE 1. Items in Stages of Change questionnaire (SOC)'

Precontemplation
1. As far as I'm concerned, I don't have any problems that need changing.
2. I'm not the problem one. It doesn't make much sense for me to be here.
3. Working on problems is pretty much of a waste of time for me because the problems don't have to do with me.
4. I guess I have faults, but there's nothing that I really need to change.
5. I may be part of the problem, but I don't really think I am.
6. All this talk about psychology is boring. Why can't people just forget about their problems?
7. I have worries, but so does the next person. Why spend time thinking about them?
8. I would rather cope with my faults than try to change them.

Contemplation
1. I think I might be ready for some self-improvement.
2. It might be worthwhile to work on my problems.
3. I've been thinking that I might want to change something about myself.
4. I'm working on my problems in order to better understand myself.
5. I have problems, and I really think I should work on them.
6. I wish I had more ideas on how to solve my problems.
7. Maybe someone will be able to help me.
8. I hope that someone will have some good advice for me.

Action
1. I am doing something about the problems that had been bothering me.
2. I am finally doing some work on my problems.
3. At times my problems are difficult, but I'm working on them.
4. I am really working hard to change.
5. Even though I'm not always successful in changing, I am at least working on my problems.
6. I have started working on my problems, but I would like help.
7. Anyone can talk about changing; I'm actually doing something about it.
8. I am actively working on my problems.

Maintenance
1. It worries me that I might slip back on problems I have already changed, so I am ready to work on my problems.
2. I have been successful in working on my problems, but I'm not sure I can keep up the effort on my own.
3. I'm not following through with what I had already changed as well as I had hoped, and I'm working to prevent a relapse of my problems.
4. I thought once I had resolved my problems I would be free of them, but sometimes I still find myself struggling with them.
5. I may need a boost right now to help me maintain the changes I've already made.
6. I'm working to prevent myself from having a relapse of my problems.
7. It is frustrating, but I feel I might be having a recurrence of a problem I thought I had resolved.
8. After all I had done to try and change my problems, every now and **again** they come **back to** haunt **me.**

'McConnaughy et al. (1983).

ally doing something about it." At the other pole of the continuum, individuals in Maintenance are at-tempting to prevent relapse and to consolidate gains; e.g., "I'm here to prevent myself from having a relapse of my problem." As patients move through the cycle of change, they move from one stage to the next as measured by the SOC (McConnaughy et al., 1983, 1989). This scale has been shown to be reliable (McConnaughy et al., 1983, 1989). Its validity was supported by the finding that the highest correlations between stages occurred for adjacent stages, and the lowest correlations occurred for nonadjacent stages (McConnaughy et al., 1989). Validity is also supported by the finding that patient stage of change has been shown to be significantly predictive of outcome in smoking cessation (DiClemente et al., 1991) and weight control (Prochaska et al., 1992b) programs. In each of these studies, patients who scored high on Precontemplation changed very little, while those who were high on Action were most likely to change. To our knowledge the SOC has never been used in a placebo-controlled medication trial. We report here a test of the hypothesis that stage of change can predict outcome in panic disorder treatment with adinazolam SR.

METHOD

PLACEBO VS. ACTIVE DRUG

This parallel flexible dose study randomized patients either to adinazolam (ADN)-SR tablets or matching placebo (PBO). Adinazolam, a triazoiobenzodiazepine, is a dimethylamino analogue of alprazolam. Subjects were eligible to receive randomized treatment if they met study criteria and had not responded to one week of single-blind placebo lead-in treatment. At the time of randomization (i.e., baseline), subjects were assigned either to ADN or PBO, and returned for evaluation at weeks 1, 2, and 4. Altogether, 206 subjects were randomized to treatment (n = 103 ADN, n = 103 PBO). "Intent to treat" analysis was carried out on 202 subjects (n = 99 ADN, n = 103 PBO) who returned at least one time after randomization. Subjects were required to meet the following conditions: (a) be within the ages of 18 and 65, inclusive; (b) meet DSM-III-R criteria for panic disorder with agoraphobia (American Psychiatric Association, 1987) and have at least one panic attack per week for each of four weeks prior to baseline; and (c) be free of psychoactive medication for at least 14 days before randomization. The following outcome measures were included: Snaith Clinical Anxiety Scale (CAS; Snaith et al., 1982); Hamilton Anxiety Scale (HAM-A; Hamilton, 1969); patient diary reports of panic attack frequency (PANIC); Clinical Global Impression (CGI; Guy, 1976); and Phobia Severity Scale (Sheehan, 1986).

Subjects were initially evaluated and screened by the Structural Clinical Interview for DSM-III-R (Upjohn

version; SCID-UP-R; Spitzer and William, 1987). This was followed by a two week treatment washout and one week single-blind placebo phase, during which a physical examination, EKG, hematologic and urinary assays were conducted. Randomization to treatment occurred after completion of the placebo lead-in phase.

The maximum dose was eight tablets a dav, each tablet containing either 15 mg adinazolam SR or placebo, thus making the theoretical maximum dose of active drug 120 mg per day. Medication was administered b.i.d., and advanced by adding one tablet per day every three or four days, with the larger dose being given in the evening when there was an odd number of tablets involved. It was hypothesized that differences in favor of drug would be found on the outcome measures at weeks 1 and 4.

Response data at weeks 1 and 4 were analyzed by an analysis of covariance (ANOCOVA) with two factors (treatment and investigator) and their interaction, with baseline values serving as covariate. Analysis of categorical data were performed either by means of Chi square testing or by categorical data modeling (CATMOD; Grizzle et al., 1969). Further details of the research designs are provided in Davidson et al. (1994).

Subjects completed the SOC questionnaire prior to being assigned to the drug or placebo treatment.

STAGES OF CHANGE ANALYSES

The four SOC scores (Precontemplation, Contemplation, Action, Maintenance) are simple unweighted sums of eight items comprising each stage. To facilitate interpretation of these data, the four SOC scores were converted to T-scores (M = 50; S.D. = 10).

To examine the relationships between pretreatment Stage of Change scores and clinical improvement, a series of regression analyses using the general linear model (GLM; SAS Institute, Inc., 1985) were performed. Each of the 4 SOC scores served as independent variables, and the Time 1 and Time 4 outcome measures as dependent variables. In the results discussed below, "Time" simply refers to the repeated factor. Use of the repeated measures analysis with this method ensures that the correct error terms are used in calculation and allows examination of unique predictive variance contributed by each independent variable (SAS Institute, Inc., 1985).

The data analysis for the treatment trial itself was done separately from the SOC analysis because of logistical and priority problems involving the sponsor's (Upjohn) data analyst. The outcome data were gathered through the individual initiative of the authors led by R. Maddock who solicited selected data directly from the participating investigators. All data sets had been sent to the sponsor's data analyst and were not directly available to us for this analysis.

RESULTS

PLACEBO VS. ACTIVE DRUG

Two hundred and six patients were enrolled to receive randomized medication, with 103 receiving adinazolam SR and 103 receiving placebo. Mean ages (+ S.E.) for Adinazolam SR and placebo were 36.1 1.0 and 35.5 st 0.8, respectively. Among the Adinazolam SR group, 34% were male and 66% female compared to 33% male and 67% female in the placebo group. Adinazolam SR was significantly more effective than placebo at week 4 on the CGI, panic frequency, HAM-A and CAS. Overall phobia scores were not significantly different between treatment weeks 1 and 4. Further details of these findings are reported in Davidson et al. (1994).

STAGES OF CHANGE REGRESSION ANALYSIS

One hundred rive tv-six of these patients completed and returned the SGC scale with a mean age of 36.5 0.9. Thirty-six percent were male and 64% were female. The major reason for the failure of 40% to complete the SOC lay wit the failure of several investigators to include the SOC in their preliminary package of instruments for some of their patients, since this was an "add-on" study not part of the standardized scales.

The regression analysis (Table 2) on the CAS variable uncovered a significant interaction between the Precontemplation variable and Time ($F(1,110) = 4.41$, $p = .04$). High scores on Precontemplation were associated with little change in CAS scores over the course of the study. None of the other scales (Time x Action, Time x Maintenance) approached significance on this outcome measure.

This pattern was repeated in the analysis of the HAM-A variable, with a significant effect only for Time x Precontemplation ($F(1,110) = 5.59$, $p = .02$). As was the case with the CAS, high Precontemplating scores were associated with little change on the HAM-A.

Another replication of the relationship between Precontemplation and outcome occurred with regard

TABLE 2. Summary of regression analyses based on SOC scores

Variable'	Significant	F	df	p
CAS	Precontemplation	4.41	1,110	.04
HAM-A	Precontemplation	5.59	1,110	.02
Panic	Precontemplation	5.91	1,109	.02
CGI	Precontemplation	2.57	1,110	.11
	Contemplation	4.92	1,110	.03
PHOBIA	Contemplation	8.49	1,102	.004

'CAS = Clinical Anxiety Scale; HAM-A = Hamilton Anxiety Scale; PANIC = panic diary; CGI = Clinical Global Impression; PHOBL-I = ***phobia scale.***

to the Panic Attack Frequency variable. Here, the interaction was again significant (F(1,109) = 5.91, p = .02), with no significant interactions between the other SOC variables and Time.

In the analysis of the CGI data, the interaction between Time and Precontemplation approached but did not achieve significance (F(1,110) = 2.57, p = .11). However, the interaction between Time and the Contemplation variable was significant (F(1,110) = 4.92, p = .03). High scores on Contemplation were predictive of a high degree of change on CGI ratings.

The pattern observed on CGI ratings was replicated in the analysis of the Phobia Severity data scores in that Contemplation again predicted outcome (F(1,102) = 8.49, p = .004). High scores on Contemplation were predictive of high levels of change over time in Phobia Severity.

STAGES OF CHANGE: CLUSTER ANALYSIS

Results from the regression analyses provided evidence that pretreatment Precontemplation scores were inversely associated with clinical outcome on 3 of the 5 outcome measures. On the remaining 2 measures, Contemplation scores were positively associated with improvement during the course of the study. However, regression analyses do not generate specific prescriptions regarding individual patients' SOC profiles.

In order to more precisely and concretely identify the pretreatment SOC profiles of responsive vs. unresponsive subjects for clinical purposes, each subject's SOC T-scores were entered into the SAS FASTCLUS procedure (SAS Institute, Inc., 1985). This disjoint cluster analysis uses an iterative algorithm for minimizing the sum of squared distances from the cluster means. Products of FASTCLUS include a predetermined number of clusters, cluster means (in this case, on the 4 SOC variables), standard deviations, and the number of subjects in each cluster. In order to determine the number of clusters (Aldenderfer and Blashfield, 1984), a range of cluster solutions was examined with 2 to 8 clusters extracted from the data set.

The 3-cluster solution produced a theoretically consistent and interpretable set of clusters. The first cluster consisted of 37 subjects who had exceptionally high scores on Precontemplation. The second cluster consisted of 36 subjects with low scores on Precontemplation and high scores on Contemplation, Action, and Maintenance. The third cluster consisted of 53 subjects with average scores on all 4 SOC scales (See. Fig. 1).

Thus, the 3-cluster solution generated a group of subjects that could be expected to be unresponsive (37 patients with high Precontemplation scores) as well as a group of subjects that could be expected to be highly likely to change (36 subjects with high scores on Contemplation, Action, and Maintenance). For this reason, the 3-cluster solution was chosen for further study in the hope that it might have heuristic value for treatment responsiveness.

In order to examine the relationships between the clusters and outcome, a series of GLM analyses as performed. Each of the 5 outcome measures again served as dependent variables. The independent variable were cluster group members (cluster 1 vs. cluster 2 vs. cluster 3) and drug group membership (drug vs. placebo). Table 3 summarizes the results.

The GLM performed on the CAS indicated a significant Time by Cluster (F(2,109) = 4.64, p = .012). This effect involved greater decreases in CAS scores in cluster 2 subjects (high Contemplation, Action and Maintenance), as compared to subjects in cluster 1 (high Precontemplation. See Table 4 for these and related outcomes.

On the HAM-A, the Time by Cluster (F(2,109) = 3.66, p = .029) interaction was significant. The means indicated that subjects in cluster 2 (the high Contem-

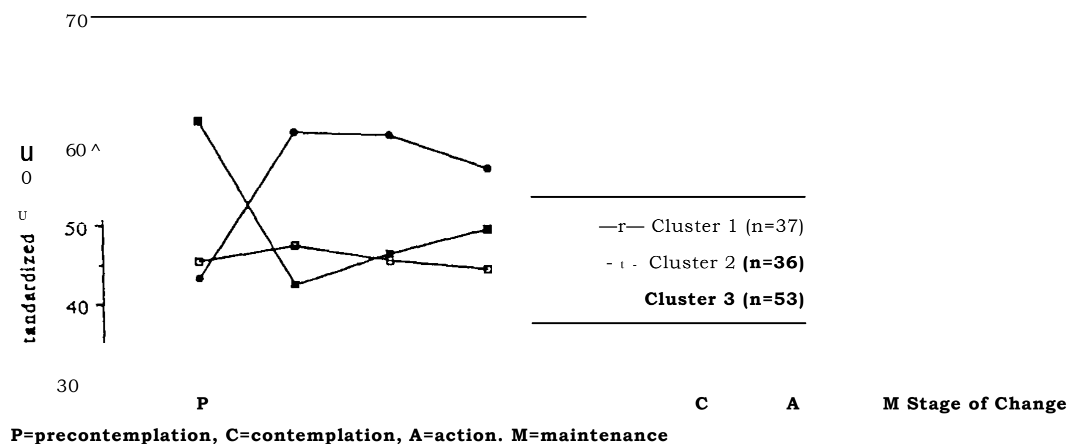

Fig. 1. The three-cluster solution.

TABLE 3. Summary-regression analyses based on clusters

Dependent variable	Effect tested	F	*df*	p
CAS	Time x cluster	4.64	2,109	.01
	Time x drug group	5.46	1,109	.02
HA.'vl-A	Timex cluster	3.66	2,109	.03
	Timex drug group	1.97	1,109	.16
Panic	Time *x* cluster	2.31	2,108	.10
	Time x drug group	0.97	1,108	.33
CGI	Timex cluster	0.14	2,109	.87
	Timex drug group	3.41	1,109	.0[7]
Phobia	Time *x* cluster	6.79	2,101	.001
	Timex drug group	0.15	1,101	.70

plation, Action and Maintenance cluster) manifested greater decreases in HAM-A scores over time than subjects in cluster 1 (the high Precontemplation cluster). Cluster 3 (the cluster with moderate scores on all four SOC scales) fell in between clusters 1 and 2 with regard to change on the HAM-A.

The GLM performed on the Panic Attack Frequency variable yielded a marginally significant effect for Time by Cluster ($F(2,108) = 2.31$, $p = .10$). Here, subjects in cluster 2 manifested somewhat greater de-creases in Panic Attack Frequency over time than did subjects in cluster 1.

The GLM on the Phobia measure generated a significant effect for the Time by Cluster interaction ($F(2,101) = 6.79$, $p < .002$). This interaction involved greater decreases in Phobia scores over time by subjects in cluster 2, as compared to subjects in cluster 1.

In regards to time x drug group analyses, the CGI was marginally significant (F(1,109 = 3.41, p <_ = .0675), and the CAS was significant (F(1,109 = 3.41, p =.0213).

In regards to the question of the interaction between drug x cluster, none of the analyses emerged as significant. However, on all outcome measures, each cluster receiving drug showed greater benefit than each cluster receiving placebo.

DISCUSSION

These results indicate that pretreatment Precontemplation scores predict less favorable outcome among panic disorder patients in a placebo-controlled medication trial. Moreover, regression analyses on both stage of change scores and cluster group means suggest that Precontemplation serves as an indicator of low responsivity to active drug and placebo. Subjects in the Precontemplation cluster did not change significantly over time on 4 of the 5 outcome measures; by way of contrast, both of the other two clusters manifested significant changes on all 5 outcome measures (See Table 4).

The results further indicate that the predictive strength of the pretreatment SOC scores was, according to this analysis, more powerful than drug group assignment since statistical analysis of the full group of 206 subjects showed strongly significant efficacy of drug over placebo. Why was there no significant drug x cluster effect? One possible explanation lies with the suggestion that this subgroup of patients was not as responsive as the entire 206 patients. Another explanation suggests that the larger N showed differences not evident in the smaller sample. Finally, the different statistical methods employed in the outcome analysis of the 206 patients may have yielded a greater significant difference.

Noteworthy is the finding that the CGI did not tend to follow the pattern of the other outcome measures. The CGI differs from the other measures in its relatively strong dependent upon clinician subjectivity. The HAM-A and CAS, while interviewer-based, rely on specific responses to specific questions. The phobia scale is self-rated aitd the panic frequency is primarily self-report. Because the SOC is self-rated, we may be seeing a correlation between self-rating domains.

Several important questions cannot be answered because the SOC analysis was done separately from the treatment analysis on the entire sample. The SOC subset did not differ from the larger sample on sex and age. However, did the SOC subsample differ from the entire sample in terms of placebo response, adinazolam response, adinazolam dose, severity, comorbidity or chroniciry rates? Our inability to answer these and related questions weakens the support for the SOC findings.

It is noteworthy that cluster analyses performed by McConnaughv et al. (1983, 1989), using different clus-

TABLE 4. Testing mean changes on outcome measures across time as a function of cluster group

Variable	Cluster	*n*	Time 1 mean (S.D.)	Time 2 mean (S.D.)	*t*[a]	*p*[a]
CAS	1	34	8.21 (4.73)	7.03 (3.80)	1.81	.08
	2	31	8.94 (3.36)	5.00 (3.80)	5.76	.0001'
	3	50	9.56 (3.76)	6.58 (4.06)	5.44	.0001'
HAM-A	1	34	17.74	14.47	2.45	.02
	2	31	17.94	10.10	6.70	.0001'
	3	50	18.30	11.84	6.54	.0001'
Panic	1	33	4.49 (4.71)	2.91 (4.73)	2.35	.03
	2	31	5.03 (4.21)	1.16 (2.46)	4.96	.0001'
	3	50	4.56 (4.65)	2.30 (4.85)	3.13	.003
CGI	1	34	4.47 (.79)	3.59 (.82)	5.63	.0001'
	2	31	4.19 (.75)	3.26 (1.03)	4.31	.0002'
	3	50	4.34 (.85)	3.34 (.98)	6.29	.0001'
Phobia	1	33	6.55 (2.43)	5.09 (2.42)	3.09	.004
	2	30	8.17 (1.60)	4.37 (2.33)	9.51	.0001'
	3	44	6.61 (2.33)	4.14 (2.60)	6.88	.0001'

".4ll t-tests and associated p-values are tests for change across time within a given cluster. Using a Bonferroni correction procedure, a p-value of .003 indicates significance and are designated with an asterisk.

tering algorithms on patients presenting for psychotherapy, derived three clusters that bear a high degree of similarity to the three clusters extracted in this study. They labeled the subjects with high Precontemplation scores (cluster 1) the "Immotive" cluster; the subjects with low scores on Precontemplation but high scores on the other three measures (cluster 2) the "Participation" cluster, and the subjects with moderate scores on all 4 SOC scales (cluster 3) the "Uninvolved" cluster. Across diverse studies and patient populations, then, these clusters appear to represent robust patterns of varying predispositions to change.

Our data suggest that predisposition to change has a powerful influence on outcome of short-term treatment of panic disorder with a triazolobenzodiazepine with demonstrated effectiveness in the treatment of panic disorder with agoraphobia. This finding is consistent with previous studies (Prochaska et al., 1992a) and with the clinical observation that a patient who is "ready to change" has a better prognosis. Our study shows that this factor can possibly influence the outcome of psychopharmacological treatment. It is unknown to what extent stage of change measures would correlate with out-come of pharmacological treatment of other psychiatric disorders.

The designs of current medication trials have not taken into account this potentially powerful influence on outcome of patient predisposition to change. If our results are replicated in other psychiatric disorders across a range of pharamcological treatments, then the future designs of medication trials for psychiatric disorders will need to include measures of patient predisposition to change in or-der to assess the influence of this factor on treatment outcome.

Panic disorder patients who were not yet predisposed to change were least likely to have a good outcome after four weeks of medication treatment. It may be possible to develop psychotherapeutic techniques which will help these "reluctant changers" progress along the stages of change continuum. If so, such techniques may become an adjunct to pharmacotherapy for selected patients.

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