7-2010

A randomized comparison of online and paper mood charts for people with bipolar disorder.

Daniel Z Lieberman

Tammas F Kelly

Lanny Douglas

Frederick K Goodwin

A Randomized Comparison Of Online And Paper Mood Charts For People With Bipolar Disorder

Daniel Z. Lieberman, M.D.,[a] Tammas F. Kelly, M.D. [b], Lanny Douglas, A.P.R.N.,[b] Frederick K. Goodwin, M.D.[a]

Journal of Affective Disorders 124.1-2 (2010): 85-89.
doi: 10.1016/j.jad.2009.10.019

[a] Department of Psychiatry and Behavioral Sciences, George Washington University School of Medicine and Health Sciences, United States

[b] The Depression and Bipolar Clinic of Colorado, 315 West Oak Street, Fort Collins, Colorado 80521, United States

Corresponding author:
Daniel Z. Lieberman, M.D.
Department of Psychiatry and Behavioral Sciences
George Washington University
2150 Pennsylvania Ave, NW Rm 8-421
Washington DC 20037
Telephone (202) 741-2900
Fax (202) 741-2891
Email dlieberman@mfa.gwu.edu

Abstract

Background: Longitudinal mood instability is the essential feature of bipolar disorder, however most rating scales are cross sectional in nature, and focus on acute symptoms. By contrast, the NIMH Life Chart Methodology (LCM) characterizes in detail the severity, duration, and frequency of mood episodes. Adherence to daily rating, however, tends to be low. In this study an online version of the LCM, designed to enhance adherence, was compared to the standard paper version. Methods: Patients from a mood disorders specialty clinic were randomized to the standard LCM or an online, open source adaptation. The online version used hypertext links embedded in a daily email as the primary rating interface. Participants rated for 90 days. The total number of days rated and the number of days with complete data were compared for the two groups. Results: Forty-eight patients participated in the study. The online group rated approximately twice as many days compared to the standard group (44.3 versus 20.4, p=.029). The online group also entered complete data for a larger portion of days (55.2% versus 27.7%, p=.039). Limitations: This was a small, short-term study. The implications for longer-term rating are unclear. Conclusions: Despite the advantages of documenting mood fluctuation on a daily basis, the LCM is not commonly used, in part because ensuring adequate adherence can be resource intensive. An easily accessible online adaptation that utilizes email checking behavior can make this tool available to a wider range of patients.

Key words: NIMH Life Chart Methodology, adherence, Internet

Introduction

Bipolar disorder is a complex illness characterized by long-term mood instability. Mood can fluctuate on a daily basis, and is influenced by multiple interacting variables including social support, environmental stress, medication use, sleep disruption, and internal cyclic processes. Optimal treatment management requires data that is both accurate and comprehensive, however patient recall is often unreliable and subject to inaccuracies and biases.

Rating scales have been developed that attempt to characterize abnormal mood with greater reliability and validity compared to an unstructured clinical interview. However, even these structured assessment instruments fail to adequately capture bipolar psychopathology. Comprehensive data on bipolar disorder requires a longitudinal approach that includes measures of the severity, duration, and frequency of manic, mixed, and depressive episodes. However, commonly used rating scales are cross sectional in nature. They are typically administered weekly, and the scoring of each item represents a synthesis of the past seven days. Scores can rate the average over the past week, the most severe pathology, or some other way of combining multiple days. In each case the weekly synthesis of symptoms precludes measurement of day-to-day fluctuation.

The NIMH Life Chart Methodology (LCM) (Leverich and Post, 2002a) provides an alternative to cross sectional rating scales. Mood is rated daily, so instability can be measured more precisely. Severity scoring is based on functioning rather than on

symptoms which simplifies the process of rating, and supports its reliability and validity (Denicoff et al., 2000).

Advantages of daily rating were seen in a study that compared an antidepressant and a placebo in patients with bipolar II disorder. There were no differences between the two arms as measured by the HAM-D, Beck Depression Inventory (BDI), Young Mania Rating Scale (YMRS), and the Social and Occupational Functioning Scale (SOFAS). The LCM, however, was able to detect significant differences in the number of days depressed or elevated, the average severity of the days ill, and the number of episodes of abnormal mood (Parker et al., 2007). In general, the details of longitudinal mood instability is seldom studied, but it represents the quintessential feature of bipolar disorder (Goldberg et al., 2008).

The greatest difficulty with daily mood rating is adherence. In a short-term study of the use of a daily diary to record chronic pain symptoms, participants reported 90 percent adherence, but the actual adherence was only 11 percent (Stone et al., 2002). Adherence to the NIMH-LCM has not been specifically measured, however the use of this instrument in clinical studies, in which a high level of adherence is required to obtain valid data, is resource intensive. In a study of the relative efficacy of lithium and carbamazepine that used the NIMH-LCM as an outcome measure, Denicoff and colleagues found that daily ratings were often not completed by study participants, and regular meetings with an investigator were required to fill in the missing values (Denicoff et al., 2002).

In order to make charting easier, various proprietary electronic mood charts have been developed including versions that run on hand-held (Scharer et al., 2002) and desktop computers (Bauer et al., 2005). These programs have demonstrated good concordance with standard measures (Bauer et al., 2008), and high satisfaction ratings by patients. The current study addressed the issue of adherence through the use of an Internet-based, open-source adaptation of the LCM in which a daily email served as the primary interface between the patient and the chart. Adherence rates to the online LCM were compared to adherence to the traditional paper-based LCM.

Methods

This was a single site, randomized comparison of a standard paper mood chart with an online mood charting program. The study was approved by the George Washington University Institutional Review Board and all participants provided written informed consent before enrollment.

Participants

Men and women 18-years and older with a diagnosis of bipolar I, II, or NOS based on a psychiatric interview using the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition were eligible for study participation. Participants were required to have bipolar disorder as the primary diagnosis, be outpatients at the time of enrollment, and

have an established and ongoing treatment relationship with a psychiatrist or nurse practitioner. Participants were required to have a history of at least six months of treatment with their clinician in order to increase the likelihood of completing the study, and adhering to the protocol.

Participants were required to have access to an Internet-connected computer, and feel comfortable using web browser and email software. Participants who were psychotic, who experienced symptoms that interfered with their ability to give informed consent, or who were felt to be too unstable for participation in the opinion of their primary treating clinician were excluded.

Materials

Following enrollment participants were randomized to either the standard NIMH Life Chart or an open-source online adaptation (www.moodchart.org; the source code can be obtained from the corresponding author). Those randomized to the paper chart were given a copy of a blank retrospective chart, four blank prospective monthly charts, the *NIMH Life Chart Manual for Recurrent Affective Illness: Retrospective: The LCM - S/R Retrospective (Self-Version)* (Leverich and Post, 2002b), and the *NIMH Life Chart Manual for Recurrent Affective Illness: The LCM - S/P (Self-Version/Prospective)* (Leverich and Post, 2002a). These participants were instructed to read the manuals, complete a retrospective chart, and chart prospectively for 90 days.

Participants assigned to the online version of the mood chart were given instructions on how to sign in to the application. Once they registered, the application guided them through the creation of retrospective, and prospective mood charts. Retrospective charts were created using a three-step process. The first step was to enter significant life events related to relationships beginning or ending, jobs beginning or ending, diplomas, degree, or certificate programs beginning or ending, and geographical moves that occurred during the past two years. These events were placed in the appropriate location on the chart in order to help participants anchor specific periods of time as they entered mood episodes.

Participants viewed a multimedia presentation on identifying and entering mood episodes prior to recording them on the chart. Common symptoms of each of the mood states were reviewed, and participants were instructed on the conventions for determining the severity of the episode in order to correctly choose mild, low moderate, high moderate, or severe. A mild episode is defined as a mood distinctly different from normal with associated subjective distress (in depression, but not hypomania). Low moderate is a syndromal mood episode with some noticeable impairment in usual roles. High moderate is associated with much impairment, and the patient has considerable difficulties with usual activities. A severe rating reflects incapacitation, and inability to function (Denicoff et al., 2000). The instructional content and rating standards matched the instructions in the self-report version of the NIMH Life Chart Manual.

After entering mood episodes, participants viewed a second multimedia instructional module, and then entered medications they had taken during the time period charted. Like

mood episodes, medications were also entered directly on the chart so that participants had the benefit of significant life events and mood episodes to assist recall. Mood episodes could be edited when entering medications so that memory cues brought about by the work done on the medication section of the chart could be used to improve the accuracy of the mood episode section.

Participants randomized to the online chart received a daily email to assist in prospective charting. Embedded within the email were nine links that could be clicked to record a normal mood, or a mild, low moderate, high moderate or severe depression or mania. Each email contained a brief summary of the NIMH Life Chart Methodology rating conventions to help participants choose the most appropriate rating. The links embedded in the email encapsulated information on the participant's study code, the date that was being rated, and the mood severity selected. Consequently, recording daily mood could be completed with a single click in the email.

Clicking on the mood-recording link opened a page in which subjects were able to optionally record hours slept, levels of irritability and anxiety, and monthly weight. Daily events could be recorded in free-form text. Participants could also modify the rating that was recorded with the email click, or rate both depression and mania for the same day. The rating web page also had a brief summary of the rating conventions adjacent to the mood rating area. Participants were allowed to rate mood from previous days, and also to use the online chart to modify ratings from previous days. The date that each rating was made was recorded.

No personal data was included in the email or on the web page that opened in response to clicking the mood link within the email. In order to view their charts, subjects had to sign in with a user name and password. The only piece of identifying information that was stored online was the email address, which was encrypted using the triple DES algorithm (Data Encryption Standard) (Kilian and Rogaway, 1996). All communication between the server and the participants' computers was encrypted using RC4 128 bit Secure Sockets Layer (SSL) in order to provide security and data integrity (Golic, 2000). Participants were advised not to use work computers to access the site because some employers monitor the Internet use of their employees.

In order to evaluate the concordance of clinician assessment with participant self rating, the Clinical Global Impression – Severity (CGI-S) was administered at each routine follow-up visit.

Data analysis

Summary statistics were calculated as means and standard deviations for continuous variables. All analyses were two-tailed and conducted at a significance level of 5 percent. Analysis of variance was used to compare the total number of days charted, and the number of days charted that included complete data in each group. Regression analysis was used to evaluate the degree to which participant ratings predicted clinician-rated

CGI-S scores, and an interaction test was used to determine if one method of patient charting was more successful at predicting clinician ratings than the other.

Results

Between March and September, 2008 48 participants were enrolled and randomized to either the online or paper chart. There were no significant differences between the two groups' gender, marital status, or diagnosis (Table 1). Participants who used the online chart rated significantly more days than those who used the paper chart (Table 2). Looking only at the days rated, a greater percentage contained complete data in the online group compared to the paper chart group.

Two thirds of the participants who were assigned to paper charts, returned them blank, while nearly 80 percent of the online participants rated at least one day (Table 2). Among the participants who rated at least one day, there were no significant differences in total days rated or percentage of rated days with complete data.

Although participants assigned to the online chart were allowed to respond to old emails to rate mood for previous days, 77.0 percent of the days rated were done the same day, and 92.3 percent were recorded within 2 days of the date being rated. It was not possible to calculate the percent of same-day ratings for users of the paper chart.

Only 2 (8%) participants assigned to the paper chart, and 5 (22%) participants assigned to the online chart completed retrospective charts. Among the participants who completed retrospective charts, users of the paper charts recorded more mood episodes than users of the online chart (43.5 versus 5.2, $p<.001$), and more total data (82 versus 21, $p=.006$).

There was no difference in the mean CGI scores between the participants who used the paper charts (2.70, SD 0.76), and those who used the online chart (2.67, SD 0.73). In order to evaluate the level of agreement between the clinician and patient ratings, the mood chart ratings were compared to the CGI scores. Mood chart ratings significantly predicted the clinician-rated CGI scores among those who used the online chart ($R=.495$, $p=.019$), but not among those who used the paper chart ($R=.202$, $p=.55$). An interaction test, however, did not find one method to be significantly better at predicting clinician ratings than the other.

Discussion

Patients using the online chart rated significantly more days than patients using the traditional paper chart, and more of the days contained complete data. The latter finding indicates that after rating mood with a single click in the daily email, online chart users followed it up by entering additional information on the web page that opened in response to the click.

An email interface has the potential to improve task adherence in a number of ways. The first is simplicity. Participants rated mood with a single click by choosing the link that corresponded to the appropriate mood severity level which was embedded in the email. Rating via email eliminated the need for the rater to incorporate a new routine into his or her life. As long as the participant was already using email, the mood chart accommodated to his or her routine rather than forcing the participant to accommodate to the program.

The email interface also capitalized on the fact that checking email is generally performed on a highly consistent basis, and is subject to strong behavioral reinforcement. Like slot machines, email checking follows a variable interval reinforcement schedule, which creates a steady rate of response (Skinner, 1965). Most emails are mundane, but occasionally and unpredictably one arrives that is novel, important, and rewarding.

Unlike alarms, text messages, or automated phone calls, email is not disruptive. It remains in the background until a convenient time. Therefore it is less likely to be discontinued as a result of becoming aversive as can happen with an alarm or other notification that demands full and immediate attention.

Most of the users who were given the traditional paper chart did not use it at all, whereas 78 percent of the online users rated at least one day. Among the paper chart users who rated at least one day the average number of days rated and the percentage of days in which complete data was provided was numerically greater than those rated by the online

chart users, however the differences did not reach statistical significance (Table 2). This subset of paper chart users (32%) represented a group that had the highest levels of motivation for charting. The small number of participants in this subanalysis makes it difficult to draw conclusions due to the risk of a type II error. It is possible that paper chart users who were motivated enough to rate at least one day produced more data, however it is also possible that the online chart allowed the typical user to rate in a way that was comparable to the most highly motivated users of the paper chart.

No specific reinforcement strategies were programmed into the online retrospective LCM, and completion rates were low. Numerically more users of the online LCM completed retrospective charts (22%) compared to users of the paper chart (8%), possibly reflecting greater ease of use, but the difference was not significant. Although the cumulative work required to maintain a prospective chart is large, retrospective charts can be daunting because they require more concentrated effort at one time. The retrospective chart takes approximately one to three hours to complete, and some patients report reluctance to document their history in a retrospective chart because the exercise evokes too many negative emotions (Honig et al., 2001). The small number of users who completed a paper retrospective chart entered significantly more data than the online users, possibly reflecting a selection bias for the most highly motivated participants. More online retrospective charts may have been completed if a system of periodic reminders had been incorporated into the program.

Although most mood rating scales use symptom severity, the LCM uses functioning as a basis for determining episode severity, which can make it easier to select the most appropriate rating (Denicoff et al., 2000). Nevertheless, making the correct selection can still be difficult for some patients. Comparison of the clinician rated CGI-S to the patient rated LCM suggests that it may be important to continually reinforce rating conventions to patients. Users of the online chart were exposed to the rating conventions at least once and often twice during every rating, but users of the standard paper chart did not receive the same level of reinforcement. Regression analysis of patient ratings as predictors of clinician ratings found a higher correlation coefficient for the online group (R=.495) compared to paper chart group (R=.202), however this difference was not statistically significant.

The limitations of this study include a relatively small sample size that was drawn from a stable population. It is possible that sicker patients would have had more difficulty with the online chart as a result of neglecting to check email, and that a paper chart would be more accessible, and lead to higher levels of adherence under conditions of greater psychopathology. Overall, there was low to moderate adherence to the charting task. Because adherence was the primary outcome measure, encouragement to rate consistently was not used because it would have been difficult to give it completely uniformly, and might have skewed the results. Also, one of goals of the study was to determine what could be achieved with the lowest resource utilization level, therefore clinician involvement in the rating task was kept to a minimum. Finally, when patients were consented, it was emphasized to them that there were no specific minimal

requirements for study entry. They could rate as many days as they chose, and drop out of the study at any time. Consequently, recruitment did not select for a predominantly motivated sample as is usually the case in clinical studies in general.

Conclusion

Although the LCM documents the unique psychopathology of bipolar disorder better than cross sectional assessments, only the most motivated patients are able to maintain adherence over the long-term. The use of an online adaptation led to more days rated over a 90 day period as well as the acquisition of more complete information. By bringing the chart directly to the patient via email, and leveraging the behaviorally reinforcing properties of email checking, an Internet-based chart reduces the effort needed to record moods, and makes this tool available to a broader range of patients.

References

Bauer, M., Rasgon, N., Grof, P., Gyulai, L., Glenn, T., Whybrow, P.C., 2005. Does the use of an automated tool for self-reporting mood by patients with bipolar disorder bias the collected data? MedGenMed 7, 21.

Bauer, M., Wilson, T., Neuhaus, K., Sasse, J., Pfennig, A., Lewitzka, U., Grof, P., Glenn, T., Rasgon, N., Bschor, T., Whybrow, P.C., 2008. Self-reporting software for bipolar disorder: Validation of ChronoRecord by patients with mania. Psychiatry Research 159, 359-366.

Denicoff, K.D., Ali, S.O., Sollinger, A.B., Smith-Jackson, E.E., Leverich, G.S., Post, R.M., 2002. Utility of the daily prospective National Institute of Mental Health Life-Chart Method (NIMH-LCM-p) ratings in clinical trials of bipolar disorder. Depress Anxiety 15, 1-9.

Denicoff, K.D., Leverich, G.S., Nolen, W.A., Rush, A.J., McElroy, S.L., Keck, P.E., Suppes, T., Altshuler, L.L., Kupka, R., Frye, M.A., Hatef, J., Brotman, M.A., Post, R.M., 2000. Validation of the prospective NIMH-Life-Chart Method (NIMH-LCM-p) for longitudinal assessment of bipolar illness. Psychol Med 30, 1391-1397.

Goldberg, J.F., Bowden, C.L., Calabrese, J.R., Ketter, T.A., Dann, R.S., Frye, M.A., Suppes, T., Post, R.M., 2008. Six-Month Prospective Life Charting of Mood Symptoms with Lamotrigine Monotherapy Versus Placebo in Rapid Cycling Bipolar Disorder. Biological Psychiatry 63, 125-130.

Golic, J.D., 2000. Iterative Probabilistic Cryptanalysis of RC4 Keystream Generator. Australasian Conference on Information Security and Privacy, pp. 220-233.

Honig, A., Hendriks, C.H., Akkerhuis, G.W., Nolen, W.A., 2001. Usefulness of the retrospective Life-Chart method manual in outpatients with a mood disorder: a feasibility study. Patient Educ Couns 43, 43-48.

Kilian, J., Rogaway, P., 1996. How to Protect DES Against Exhaustive Key Search. Advances in Cryptology - CRYPTO '96, pp. 252-267.

Leverich, G.S., Post, R.M., 2002a. The NIMH Life Chart Manual. for Recurrent Affective Illness: The LCM - S/P (Self-Version/Prospective). NIMH Biological Psychiatry Branch, Bethesda, MD.

Leverich, G.S., Post, R.M., 2002b. The NIMH Life Chart Manual. for Recurrent Affective Illness: The LCM - S/R Retrospective (Self-Version). NIMH Biological Psychiatry Branch, Bethesda, MD.

Parker, G., Tully, L., Olley, A., Barnes, C., 2007. The validity and utility of patients' daily ratings of mood and impairment in clinical trials of bipolar disorder. Acta Psychiatr Scand 115, 366-371.

Scharer, L.O., Hartweg, V., Hoern, M., Graesslin, Y., Strobl, N., Frey, S., Biedermann, C., Walser, S., Walden, J., 2002. Electronic diary for bipolar patients. Neuropsychobiology 46 Suppl 1, 10-12.

Skinner, B.F., 1965. Science And Human Behavior. The Free Press, New York, NY.

Stone, A.A., Shiffman, S., Schwartz, J.E., Broderick, J.E., Hufford, M.R., 2002. Patient non-compliance with paper diaries. BMJ 324, 1193-1194.

Table 2. Number of days rated, and percent of days with complete data on the prospective chart for subjects using a paper chart and those using the online chart. SD=standard deviation.

	Paper Chart	Online Chart	P
All subjects (n)	25	23	
Number of days rated (mean, SD)	20.4, 35.7	44.3, 37.6	.029
Percent with complete data (%)	27.7, 45.4	55.2, 44.0	.039
Subanalysis of subjects who rated at least 1 day			
Number of subjects with at least 1 day rated	8 (32%)	18 (78%)	.001
Number of days rated (mean, SD)	63.8, 34.8	56.6, 33.1	.621
Percent with complete data (%)	86.6, 35.1	70.5, 36.8	.307