

Received: 2016.11.02
Accepted: 2016.11.24
Published: 2016.12.16

A Randomized Comparison of Medication and Cognitive Behavioral Therapy for Treating Depression in Low-Income Young Minority Women

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCDEF 1 **Hyunkeun Cho**
ADF 2 **Sang Joon Son**
CDEF 1 **Sanghee Kim**
ADEFG 3 **Jungsik Park**

1 Department of Statistics, Western Michigan University, Kalamazoo, MI, U.S.A.
2 Department of Psychiatry, Ajou University School of Medicine, Suwon, South Korea
3 Center for Medical Humanities and Convergent Content, Ajou University, Suwon, South Korea

Corresponding Author: Jungsik Park, e-mail: jspark@ajou.ac.kr

Source of support: This work was supported by the National Research Foundation (NRF) funded by the Korean Government (MSIP) (No. 2015R1A5A7037630)

Background: Longitudinal data arise frequently in biomedical science and health studies where each subject is repeatedly measured over time. We compared the effectiveness of medication and cognitive behavioral therapy on depression in predominantly low-income young minority women.

Material/Methods: The treatment effects on patients with low-level depression may differ from the treatment effects on patients with high-level depression. We used a quantile regression model for longitudinal data analysis to determine which treatment is most beneficial for patients at different stress levels over time.

Results: The results confirm that both treatments are effective in reducing the depression score over time, regardless of the depression level.

Conclusions: Compared to cognitive behavioral therapy, treatment with medication more often effective, although the size of the effect differs. Thus, no matter how severe a patient's depression symptoms are, antidepressant medication is effective in decreasing depression symptoms.

MeSH Keywords: **Cognitive Therapy • Depression • Regression Analysis**

Full-text PDF: <http://www.medscimonit.com/abstract/index/idArt/902206>



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Background

According to the US National Institute of Mental Health (NIMH), major depressive disorder is one of the most common mental disorders in the United States. About 6.7% of US adults experience major depressive disorder. This is especially true for women, who are 70% more likely than men to experience depression during their lifetime. Major depression is a disorder typically characterized by early onset and chronic symptoms, including mental pain and anguish, suffering, and disability. This disorder can be found throughout the population, regardless of social class and economic status. There are, however, many potential causes of major depressive disorder, and treatment options thus require research into a patient's background.

In this paper, we focus on young minority women with low income and coming from diverse ethnic backgrounds. There is a need to develop treatment studies for low-income minority women. Often, this group is disenfranchised due to a lack of care either by themselves or by society owing to financial adversity, social negligence, or other challenges in their life. Primary treatment studies focus on the white middle-class population, so this study is important in establishing treatment for this disadvantage population [1]. Poverty is one of the most consistent predictors of depression in women, probably because it imposes considerable stress, anxiety, and deprivation [2]. Economic inequalities within society are strongly related to various negative physical health outcomes. Thus, poverty and economic inequality are major causes of depression, and are the main impediments to receiving treatment due to a lack of time and money to pay for treatment. Therefore, effective care and cost effectiveness need to be established in providing treatment. This also explains the importance of baseline assessment in prescription and diagnosis. When doctors produce a prescription, they normally consider the patient's baseline status. Thus, the goal of this study was optimization of treatment efficiency and providing a guideline for prescription according to a patient's baseline status.

Effective treatment for major depression can be roughly categorized as antidepressant medications and psychotherapies [3,4]. In a randomized controlled trial study conducted in Washington, D.C., 3 treatments were randomly assigned to patients: antidepressant medication, cognitive behavioral therapy (CBT), and community referral. Miranda et al. [5] also confirmed that guideline-based care for depression was more effective than referral to community care. Thus, the objective of this study was to compare medication vs. psychotherapy.

Longitudinal data arise frequently in epidemiology, medical science, and socioeconomic panel studies, where repeated measurements within the same subject are more likely to be correlated [6,7]. The data in this study can be also considered as

longitudinal data since the Hamilton Depression Rating Scale (HDRS) was measured monthly for 6 months, and these measurements within the same patient can be interdependent. The benefit of quantile regression is that it can show diverse trends from high quantile to low quantile [8,9]. Therefore, we utilized quantile regression models for longitudinal data to determine which treatment is most beneficial for patients at different stress levels, as determined by significance over time [10,11].

Material and Methods

Design of experiment

The data used in this study come from the Women Entering Care Study, which is a randomized controlled trial of treatment for major depression in low-income women, including Latinas, blacks, and whites. These women received welfare services and health care from national and local agencies based in Washington, DC, suburban counties of Prince George and Montgomery, MD, and Arlington and Alexandria, VA. First, 16 286 women were screened who live in these areas, along with women receiving services at county-run Title X family planning clinics. Among them, 13 975 women were eligible based on self-reported ethnicity and origin. Approximately 11% of them were positive for Major Depression Disorder based on the Primary Care Evaluation of Mental Disorders [12]. However, among them, only 5.6% of black, 8% of white, and 7.6% of Latina women consented to participate in this program. Finally, we enrolled a total of 267 participants, who were randomly divided into 3 treatment groups (Table 1) and followed up for 1 year regardless of the duration of each treatment. However, we only used the data for the first 6 months because most of the treatment was completed within 6 months.

Cognitive behavior therapy

Patients (n=90) assigned to the cognitive behavior therapy intervention group were treated by experienced psychotherapists supervised by a certificated clinical psychologist with CBT experience. This intervention ran for 8 weeks as a weekly session, either as a group or individually, as necessary based on the patients' circumstances. A CBT manual was distributed to the patients for keeping them informed on treatment progression. These manuals were designed for low-income and young women to appropriately assess the subjects. After 8 weeks in the program, if the patients' score still increased, they were offered 8 more sessions. As shown in Figure 1, the distribution is skewed to the right. The proportion of HDRS scores within the 5–10 group is smaller than the proportion of 20–30 HDRS scores. Neither a symmetric nor normal distribution occurred.

Table 1. Summary of participant specification from Siddique et al. 2012.

Characteristics	Total (N=267)		Medication (n=88)		CBT (n=90)		Referral (n=89)	
Age, mean (SD), y	29.3	(7.9)	28.7	(6.6)	29.8	(7.9)	29.5	(9.1)
Marital status								
Married or living with partner	124	(46.4)	43	(48.9)	40	(44.4)	41	(46.1)
Widowed or separated/divorced	52	(19.5)	17	(19.3)	22	(24.4)	13	(14.6)
Never married	91	(34.1)	28	(31.8)	28	(31.1)	35	(39.3)
No. of children, mean (SD)	2.3	(1.4)	2.2	(1.2)	2.2	(1.5)	2.4	(1.6)
Education								
Less than high school	99	(37.1)	37	(42.0)	27	(30.0)	35	(39.3)
High school or GED	87	(32.6)	31	(35.2)	29	(32.2)	27	(30.3)
Some trade or college	63	(23.6)	15	(17.1)	26	(28.9)	22	(24.7)
College graduate	18	(6.7)	5	(5.7)	8	(8.9)	5	(5.6)
Ethnicity								
Black	117	(43.8)	34	(38.6)	41	(45.6)	42	(27.2)
White	16	(6.0)	6	(6.8)	6	(6.7)	4	(4.5)
Latina	134	(50.2)	48	(54.6)	43	(47.8)	43	(48.3)
Insurance								
Uninsured	173	(64.8)	55	(62.5)	58	(64.4)	60	(67.4)
Medical assistance	40	(15.0)	14	(15.9)	12	(13.3)	14	(15.7)
Private	54	(20.2)	19	(21.6)	14	(15.6)	15	(16.9)
Employment								
Working or looking for work	219	(82.0)	69	(78.4)	76	(84.4)	74	(83.2)
Not working or disabled	48	(18.0)	19	(21.6)	14	(15.6)	15	(16.9)

Community referral

Subjects in the group assigned to community referral (n=89) were educated about depression, and mental health treatments were offered to them in the community. The clinician scheduled an appointment for the patients at the end of the clinical interview to facilitate referral. Approximately one-quarter of patients did not want to use the referral option. Referred patients were contacted to encourage them to attend a scheduled community care program. All patients in this study were followed up for 12 months regardless of whether they continued treatment or not.

The participants in this study were mostly employed and had low levels of education and income. The mean (SD) age of each participant was 29.3 (7.9) years. Less than half of them were living with a partner. More than one-third of the participants

had not graduated from high school and only 6.7% of them had received a college diploma. Sixty percent of them lived at or below the federal guideline for poverty.

Measures

At the baseline assessment, patients from the Women Entering Care project completed a structured version of the HDRS (the Hamilton Depression Rating Scale) by telephone interview [13,14], and after starting the treatment, it was measured monthly for 6 months in addition to assessment at 8, 10, and 12 months. The HDRS was categorized as follows: a score less than 7 was considered "not depressed", 7–13 was considered "mild", 13–18 was considered "moderate", 18–23 was considered "severe", and scores 23 and higher were considered "very severe", as specified by the American Psychiatric Association.

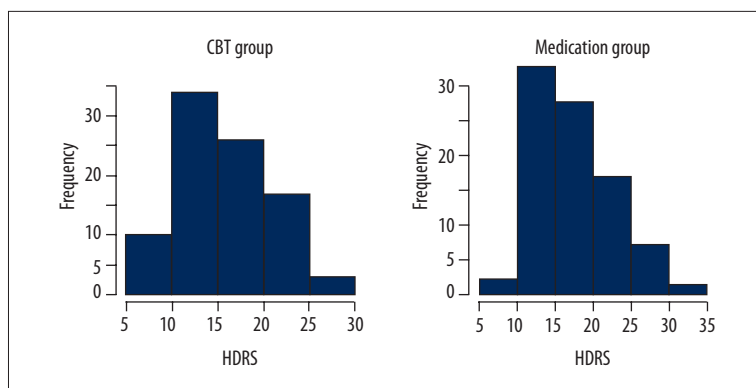


Figure 1. Histogram of HDRS score at baseline in CBT group and medication group.

The rate of participation for the women in care varied with the treatments to which they were assigned. The women in the community referral group showed the lowest rate among the 3 groups, and 83% did not attend any session. Only 8 women attended 4 or more sessions of the community care. The medication group had the best participation rate; 75% attended 9 or more weeks of a guideline-prescribed regimen of medication, and 45% of them took medication for 24 or more weeks. In the CBT group, 53% of women attended 4 or more CBT sessions and 36% of them attended more than 6 sessions. This participation rate persisted regardless of ethnicity [5].

Reasons for the low participation rate in the community referral group included lack of outreach, burden of child care, and lack of transportation. Unlike the community care group, medication and CBT intervention provided intensive outreach, child care, and transportation, and patients could make an appointment at their convenience. Clinicians and therapists offered individual sessions for the women who needed to care for their partner or children. The primary problem facing this group is lack of time, transportation, education, and personal care. This means that without outreach, child care help, and transportation assistance, these women could rarely gain access to treatment. Therefore, to achieve decreasing depression symptoms, outreach and care from the community and clinical service is essential [5].

Methodology

We used longitudinal data analysis, which allowed us to explore each patient’s dynamic change over time. Liang and Zeger [15] proposed the generalized estimating equation approach and Qu et al. [16] developed the quadratic inference function approach on the basis of mean marginal regression models. These approaches are mainly applicable when the responses are normally distributed. In this study, however, the distribution of HDRS score at the baseline was strongly skewed to the right (Figure 1). Therefore, the mean regression approaches were not considered appropriate for analysis of this data set. In data with skewed distribution, median regression is more robust than mean regression. Since the mean was skewed to

right in this data set, we opted for quantile regression as a viable alternative; it estimates diverse effects of independent variables with quantile-specific regression coefficients without imposing any distributional assumption on the responses [8].

The benefit of quantile regression is that it can show diverse trends from high quantile to low quantile. In quantile regression models, a certain percentile can be used as an indicator among various depression levels. Thus, the corresponding percentile is used to observe the trend over time of each depression level. As shown in Table 2A and 2B, the baseline of each quantile (denoted by month 0) is presented: the HDRS score in the 90th percentile was 24.1 in the CBT group and 24 in the medication group. According to the APA classification, the 90th percentile indicates that a patient has severe depression. The score in the 3rd quantile (75%) was 20 in the CBT group and 21 in the medication group. The score in the 2nd quantile (median, 50%) was 16 in the CBT group and 18 in the medication group. These 2nd and 3rd quantile scores indicate that the symptoms are moderate. The score in the 1st quantile (25%) was 13 in the CBT group and 14 in the medication group, indicating mild depression.

Moreover, the assumption that the independent variables similarly affect the different parts of the conditional distribution of the response may make little sense in biomedical applications. For example, in a clinical trial of depression that evaluated effects of different treatments on HDRS scores longitudinally, the treatment effects on study subjects with high HDRS scores differed from the treatment effects on study subjects with low HDRS scores who were less sick. In the present study, given a certain level of quantile $\tau \in (0,1)$, the τ^{th} quantile of the depression score is linearly modeled as:

$$Q(Y|X)=\beta_0+\beta_1 \text{ CBT}+\beta_2 \text{ Time}+\beta_3 \text{ CBT}\times\text{Time},$$

where CBT=1 if a subject received CBT and 0 otherwise. Time is the index of month. We used the model at $\tau=0.1, 0.25, 0.5, 0.75,$ and 0.9 to assess the relative effect of CBT as compared to that of medication treatment. The coefficient β_1 indicates

Table 2A. HDRS score in the medication.

Quantile	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
10%	12.0	6.0	2.3	2.0	1.0	0.0	1.2
25%	14.0	9.0	4.3	5.0	4.0	3.0	3.0
50%	18.0	14.0	10.5	8.0	8.0	7.0	8.0
75%	21.0	17.8	15.8	14.5	16.0	13.0	13.0
90%	24.0	22.1	19.0	17.8	19.0	16.8	15.5

Table 2B. HDRS score in the CBT group.

Quantile	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
10%	10.0	6.0	2.0	2.0	1.0	2.0	3.9
25%	13.0	8.3	5.0	5.0	4.8	5.5	5.0
50%	16.0	13.0	10.0	10.0	7.0	9.0	9.0
75%	20.0	16.8	16.8	14.8	13.0	14.0	15.0
90%	24.1	21.5	21.5	18.6	19.5	20.2	22.1

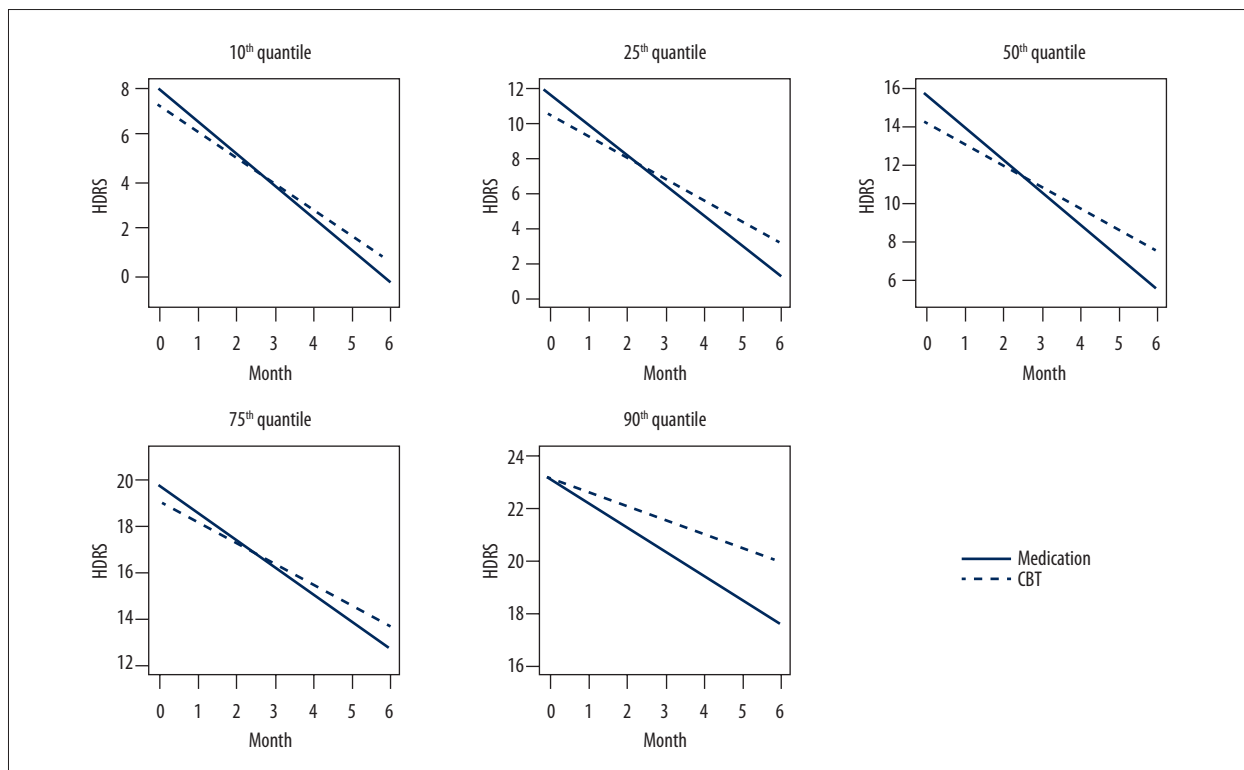


Figure 2. Fitted quantile regression lines for HDRS scores of CBT and medication group.

the overall relative effect, while β_3 corresponds to a time-related change in the relative effect. To fit the model to data, we applied the empirical likelihood procedure proposed by

Cho et al. [17], which allowed us to accommodate the within-subject correlation. Here, we assume an AR(1) correlation structure commonly used for longitudinal data analysis.

Table 3. Rates of lost to follow-up in depression study.

Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
0%	5.1%	10.7%	19.7%	33.7%	46.6%	63.48%

Discussion

The results in Figure 2 show that the patients in both groups had lower HDRS scores and their depression symptoms decreased over time in all quantiles. According to the estimated coefficient of time effect, both treatments were effective in reducing the HDRS score over time, regardless of depression levels, and it is statistically significant in terms of the negative estimate (p -value <0.001). To examine which treatment improved patient condition more significantly over time, we used the interaction term between the treatments, and time in the quantile regression model. Figure 2 indicates that there was a statistically significant interaction in depression outcomes between the treatment and time. According to the positively estimated coefficient of the interaction effect, the medication treatment was always effective but CBT was not always effective over time, although the p -value varied. More specifically, the 25th (1st quartile) and 50th (median) percentiles were statistically significant, and the 10th percentile was marginally significant; the p -values for these were less than .05. In the 75th and 90th percentiles, the medication treatment performed better than the CBT in terms of the rate of score decrease, although the difference was not statically significant. Thus, no matter how severe a patient's depression symptoms are, offering antidepressant medication was always effective in decreasing depression symptoms over time.

Conclusions

Comparing the participation rates for each treatment group, we found that the patients in the medication group show more enthusiasm about their treatment. Taking a prescription drug is much easier for participants and does not require the inconvenience and time of attending sessions through CBT or community referral. In this population, considering that patients are in need of the additional support of daycare and transportation to receive treatment from community or county agencies, medication is an affordable way to receive treatment with less burden to their daily life, therefore yielding better participation rates and superior treatment performance.

Likewise, this result also explains the high rate of patients discontinuing treatment (Table 3). In our study, 74 of the 267 women who were randomly assigned to community referral did not

attend any sessions; 22 of the women failed to attend even one-quarter of the scheduled sessions, and 42 women who were offered CBT attended 4 or fewer CBT sessions. Overall, of the 267 women, 138 women discontinued CBT treatment. This is likely related to the circumstances plaguing this population of women with low levels of income and education, who often lack support from surrounding infrastructure.

The results of this study show that medication interventions are significantly more effective for low-income and minority women than are psychotherapy interventions, although CBT is still helpful in reducing levels of depression. Our results suggest that medication needs to be promptly provided despite economic burdens or lack of resources, because the benefit of medication is immediate and visible. Major depressive disorder in low-income women affects not only these individuals, but also the community and country at large. Since the cause of the disease can be related to social negligence, prompt and effective treatment can help prevent further depression from developing. Particularly, most of the patients are married and have children, and a mother's depression is assumed to lead to parental negligence and may cause further familial and social issues related to their children [18]. Therefore, antidepressant medication for minority women needs to be promptly prescribed.

Siddique et al. [19] estimated the mean of HDRS at each month using marginal mean regression: the mean was measured each month for 6 months, and was in turn compared to the mean of different treatment options at the same month to assess the effectiveness. The estimation, however, cannot provide a predictive model due to the nature of cross-sectional study design. Additionally, for the comparison of the groups, the study utilized partial data with a small sample size where, for example, only 20 severe patients are included among 267 women. Although the study of Siddique et al. [19] was original and insightful in testing the significance of the differences, the sample size could not confirm the relative effectiveness of the 2 treatments. In the case of the quantile regression approach, the test result is based on the analysis of the whole data set, thus yielding a more accurate prediction model.

Conflicts of interest

None.

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