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Barry W. Rovner
Thomas Jefferson University, barry.rovner@jefferson.edu

Robin J. Casten
Thomas Jefferson University, robin.casten@jefferson.edu

Trust and Glycemic Control in Blacks with Diabetic Retinopathy: A Pilot Study

Barry W. Rovner, MD

Departments of Neurology, Psychiatry, and Ophthalmology

Sidney Kimmel Medical College of Thomas Jefferson University

Philadelphia, PA

E-mail: barry.rovner@jefferson.edu

Robin J. Casten, PhD

Department of Psychiatry and Human Behavior

Sidney Kimmel Medical College of Thomas Jefferson University

Philadelphia, PA

E-mail: robin.casten@jefferson.edu

Corresponding Author:

Barry W. Rovner, MD

Jefferson Hospital for Neuroscience

900 Walnut Street, Suite 200

Philadelphia, PA 19107

E-mail address: barry.rovner@jefferson.edu

(T): 215-503-1243

(F): 215-503-1992

Abstract

Diabetic retinopathy (DR) is more prevalent in blacks than whites because, compared to whites, blacks have worse glycemic control. Both of these racial disparities reflect differences in sociocultural determinants of health, including physician mistrust.. This pilot randomized controlled 6-month trial compared the efficacy of a culturally tailored behavioral health/ophthalmologic intervention, Collaborative Care for Depression and Diabetic Retinopathy (CC-DDR), versus Enhanced Usual Care (EUC), to improve glycemic control in blacks with DR (N=33). The mean age of participants was 68 years (SD 6.1); 76% were women; and mean hemoglobin A1c level (HbA1c) was 8.7 (1.5). At baseline, 14 participants (42%) expressed mistrust about ophthalmologic diagnoses. After 6 months, CC-DDR participants had a clinically meaningful decline in HbA1 of 0.6 (SD 2.1), whereas EUC participants had an increase of 0.2 (SD 1.1); [f (1,28) = 1.9; p = .176]. Within CC-DDR, participants with trust had a reduction in HbA1c [1.4 (2.5)], whereas participants with mistrust had an increase in HbA1c [0.44 (0.7)]; f (1, 11) = 2.11; p = .177]. EUC participants with trust had a reduction in HbA1c [0.1 (1.1)] whereas those with mistrust had an increase in HbA1c [0.70 (1.1)]; f (1,16) = 2.01; p = .172]. Mistrust adversely affected glycemic control independent of treatment. This finding, coupled with the high rate of mistrust, highlights the need to target mistrust in new interventions to improve glycemic control in blacks with DR.

Rates of diabetic retinopathy (DR) and uncontrolled diabetes are higher in blacks than whites in the United States..[1, 2] Both of these racial disparities reflect differences in sociocultural determinants of health, including physician mistrust.[3] Mistrust arises when patients doubt physicians' motivations (e.g., conflicts of interest), when patient and physician understanding of symptoms and treatment are discordant, and when patient low health literacy encounters physician cultural insensitivity to degrade the therapeutic relationship. As an example of the latter, blacks cite problems with trust and communication with eye doctors as obstacles to care, whereas eye doctors cite blacks' lack of understanding of treatment.[4] This mismatch contributes to poor glycemic control - blacks with poorly controlled diabetes are more likely to report negative healthcare experiences than whites.[5] These data implicate mistrust as an important determinant of racial health disparities, and suggest that culturally relevant interventions may help to achieve health equity.

We developed a culturally tailored behavioral health/ophthalmologic intervention, Collaborative Care for Depression and Diabetic Retinopathy (CC-DDR), to improve glycemic control in blacks with DR, and compared its effectiveness with Enhanced Usual Care (EUC) in a pilot single-masked, randomized controlled trial. In CC-DDR, race-concordant community health workers (CHWs) provided health information [e.g., hemoglobin A1c (HbA1c) level, diabetes self-care] to ophthalmologists to guide their discussions with participants on glycemic control, and delivered 6 in-home treatment sessions to participants to develop goals and action plans to improve glycemic control. EUC was usual ophthalmologic care plus the provision of diabetes educational materials at baseline. Here we report treatment effects on glycemic control and the influence of mistrust.

Methods

CHWs recruited participants from the retina clinic of Wills Eye Hospital, Philadelphia, PA, who met the following eligibility criteria: 1) African-American race; 2) age ≥ 65 years; 3) type 2 diabetes; 4) mild or moderate nonproliferative DR; 5) depressive symptoms (i.e., Patient Health Questionnaire-9 score ≥5)[6]; and 6)HbA1C ≥ 7.0%. Institutional review board approval was obtained and all participants provided written informed consent. The CHWs received training to conduct clinical assessments and deliver the study interventions. They received 15 hours of didactic and skills-based training on diabetes, DR, and lifestyle strategies for glycemic control, and 4 hours on interviewing and supportive psychological techniques (e.g., empathy), managing time, and gathering research-quality data. Training for the CHWs who delivered CC-DDR consisted of a daylong workshop, including readings and supervised role-play, and supervision of 5 training cases. The investigators met twice a month with the CHWs to discuss ongoing cases. To maintain treatment masking, different CHWs collected follow-up data and delivered the intervention.

Prior to randomization, a CHW used a standardized protocol to assess the following variables:

Personal Characteristics: Collected data included age, sex, education, marital status, duration and type of diabetes , socioeconomic status, and health literacy (using the Literacy Assessment for Diabetes, which tests pronunciation of diabetes-related terms).[7]

DR stage and Visual Acuity: These data were abstracted from medical records. DR was staged as background, mild, moderate or severe nonproliferative disease, proliferative, or indeterminate. Visual acuity was based on Snellen charts, which was converted to the logarithm of the minimum angle of resolution (logMAR) scores to facilitate statistical analyses.

Trust: A single item tapping trust in ophthalmologists' diagnoses (i.e., "Sometimes eye doctors make me wonder if their diagnosis is correct.") was taken from the Duke Eye Clinics Patient Satisfaction Questionnaire, and rated as strongly agree, agree, uncertain, disagree, or strongly disagree.[8] Mistrust was considered present if a participant agreed or strongly agreed with the statement.

Diabetes Self-Care: The Diabetes Self-Care Inventory-Revised was used to assess self-reported adherence to 12 diabetes self-care behaviors (e.g., glucose monitoring, exercise, diet). Items are rated on a 5-point Likert scale (i.e., 1 = "never do this" to 5 = "always do this"). Scores range from 0 to 100; higher scores indicate better adherence.[9]

Depressive Symptoms: The Patient Health Questionnaire-9 was used to assess depression. This instrument yields a continuous measure of symptoms and has known reliability and validity in older blacks.[6, 10] Scores range from 0 to 27, with higher scores indicating worse depression.

Functional Vision: The 39-item National Eye Institute Visual Function Questionnaire plus Supplement (NEI VFQ) was used to assess difficulty with vision-related activities, social functioning, mental health, role difficulties, and dependency. Scores range from 0 to 100; higher scores indicate better function.[11]

Hemoglobin A1c (HbA1c) [Primary Outcome]: HbA1c level represents glycemic control over the preceding 3 months and provides a valid surrogate marker of DR progression.[12] The CHWs used the DCA Vantage point-of-care device per study protocol to measure HbA1c at baseline and 6 months masked to treatment assignment. The CHW who delivered CC-DDR provided the result to the ophthalmologist to inform their care of the patient.

Statistical Methods: Continuous and categorical data were analyzed using one-way analysis of variance (ANOVA) and chi-square, respectively. To determine if trust moderated treatment effects, a

2 (CC-DDR vs. EUC) X 2 (trust vs. mistrust) ANOVA was computed in which change in HbA1c level was the dependent variable.

Results

Thirty-three participants with complete data were recruited and randomized to CC-DDR (n=16) or EUC (n=17). Their mean age was 68 years (SD 6.1); 76% were women. The mean HbA1c level was 8.7 (1.5). There were no treatment group differences at baseline in any study variable (data not shown). Fourteen participants (42%) expressed mistrust about their ophthalmologic diagnoses. Table 1 shows that the demographic and clinical characteristics of participants with and without trust did not differ significantly.

Four participants (3 CC-DDR; 1 EUC) withdrew from the study protocol by 6 months (2 with mistrust). Table 2 shows treatment group differences in HbA1c level over time, and treatment group differences by trust. CC-DDR participants had a clinically meaningful decline in HbA1c of 0.60 (SD 2.1), whereas EUC participants had an increase of 0.20 (SD 1.10); [f (1,28) = 1.90; p = .176]. Within CC-DDR, participants with trust had a reduction in HbA1c [1.40 (2.50)], whereas participants with mistrust had an increase in HbA1c [0.44 (0.70)]; f (1, 11) = 2.11; p = .177]. EUC participants with trust had a reduction in HbA1c [0.10 (1.10)] whereas those with mistrust had an increase in HbA1c [0.70 (1.10)]; f (1,16) = 2.01; p = .172]. Table 2 also shows a statistically significant main effect for trust. This finding indicates that mistrust adversely affected glycemic control independent of treatment effects.

Discussion

This pilot clinical trial suggests that a CHW-ophthalmologist intervention that is culturally relevant to blacks with DR can improve glycemic control to a greater extent than usual care that is enhanced with diabetes educational materials. Neither treatment, however, improved glycemic control in participants who mistrusted their ophthalmologic diagnosis. These participants doubted the accuracy and veracity of ophthalmologists' diagnoses; some participants believed that ophthalmologists wanted them to take more medications so that doctors and pharmacies could make more money. In general, if a patient doubts that diabetes has damaged their eyes and mistrusts the goals of treatment, they are unlikely to perceive the need to control their diabetes. This perception is important because 42% of participants held this view, and their glycemic control worsened over time regardless of treatment.

These findings are limited by the small sample size, short duration of follow-up, the absence of information that might relate to study outcomes (e.g., type of diabetes care provider and prescribed medications, prior work with a diabetes educator, living arrangements, and anthropomorphic data), and the uncertain psychometric properties (i.e., reliability and validity) of a single item assessing trust in the diagnosis of DR. Nevertheless, the high rate of mistrust is notable, and is similar to the 44.7% rate of low trust in physicians reported by blacks (vs. 33.5% in whites) in a national study of race, ethnicity, and medical care in the United States.[13]

Trust in physicians depends on appreciating patients' knowledge, beliefs, and attitudes and, for blacks in particular, on perceived racism.[14] The latter predicts lower rates of physician visits, medication adherence, and preventive care, which compromise glycemic control and increase risk for progression of DR to blindness.[15] Because blindness is the most feared complication of diabetes, ophthalmologists have the opportunity to collaborate with other diabetes health professionals to emphasize the importance of glycemic control to prevent vision loss. Mistrust, however, undercuts

that opportunity, as does a lack of time, expertise, and resources available to ophthalmologists to address this problem.

We devised and tested a retina clinic-to-community intervention to improve glycemic control in blacks with DR. Although the small sample size precludes definitive conclusions, this pilot study suggests that the experimental intervention, , despite its cultural relevance, failed to improve glycemia in participants with mistrust. For this reason, these participants remain at increased risk for progressive vision loss. By contrast, preserving vision can prevent medication errors and reduce hospitalizations and the considerable costs of vision loss.[16-18] These benefits are relevant to new outcomes-based reimbursement strategies in which ophthalmologists, as well as primary care providers (e.g., physicians, physician assistants, and nurse practitioners) , will be responsible for vision outcomes. Our data highlight the need to target mistrust in interprofessional collaborative clinical interventions that aim to improve glycemic control in blacks with DR. Larger studies are needed to establish the efficacy and cost-effectiveness of this approach, which may improve care quality and prevent progressive vision loss.

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Table 1. Baseline Characteristics of Participants with High and Low Trust

	High Trust (n = 19)	**Low Trust (n = 14)**	**p**
Age (mean, SD)	66.8 (3.7)	69.9 (8.2)	.165
Education (mean, SD)	12.4 (2.2)	12.0 (3.4)	.707
Female (n, %)	14 (74%)	11 (79%)	.746
Hemoglobin A1c (mean , SD)	8.8 (1.8)	8.6 (1.1)	.703
PHQ-9 (mean, SD)[1]	10.2 (4.5)	10.2 (5.1)	.993
MoCA (mean, SD)[2]	22.7 (3.7)	20.7 (4.2)	.152
DSCI (mean, SD)[3]	55.9 (14.1)	59.4 (11.7)	.448
LogMAR (mean, SD)[4]	.16 (.16)	.20 (.15)	.532
NEI-VFQ total score (mean, SD)[5]	73.1 (17.3)	75.6 (18.9)	.693

[1] Patient Health Questionnaire; range is 0 to 27; higher scores indicate more severe depressive symptoms.

[2] Montreal Cognitive Assessment; range is 0 to 30; higher scores indicate better cognitive function.

[3] Diabetes Self-Care Inventory; range is 0 to 100, higher scores indicate better adherence to diabetes self-care behaviors.

[4] Best eye visual acuity expressed as the logarithm of the minimum angle of resolution; higher scores indicate worse visual acuity.

[5] National Eye Institute Visual Function Questionnaire; range is 0 to 100; higher scores indicate better self-reported vision function.

Table 2: Two (CC-DDR[1] vs. EUC[2]) by Two (Trust vs. Mistrust) ANOVA of Change in Hemoglobin A1c from Baseline to 6 Months[3]

	N	Baseline	6 Months	Mean Change[4]	F	p
CC-DDR, total group:	12	8.7 (2.1)	8.1 (.9)	- 0.6 (2.1)		
Trust subgroup	7	9.1 (2.7)	7.7 (.8)	- 1.4 (2.5)		
Mistrust subgroup	5	8.2 (1.1)	8.5 (.9)	0.36 (0.7)		
Enhanced Usual Care, total group	17	8.5 (.9)	8.7 (1.6)	0.2 (1.1)		
Trust subgroup	10	8.5 (1.0)	8.4 (1.8)	- 0.1 (1.1)		
Mistrust subgroup	7	8.4 (0.8)	9.1 (1.2)	0.7 (1.1)		
Main effect of treatment group					1.7	.202
Main effect of trust group					4.5	.044
Treatment by trust interaction					0.6	.441

[1] Collaborative Care for Depression and Diabetic Retinopathy

[2] Enhanced Usual Care

[3] Numbers shown are means. Standard deviations are in parentheses.

[4] 6 months minus baseline; a negative sign represents improved glycemic control.