Original Investigation | CLINICAL SCIENCES

Underuse of the Health Care System by Persons With Diabetes Mellitus and Diabetic Macular Edema in the United States

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IMPORTANCE Thickening of the center of the retina, diabetic macular edema (DME), is the most common cause of visual loss due to diabetes mellitus. Treatment of DME has improved dramatically, and the prompt diagnosis of DME and referral of these patients have become more critical. Nonetheless, awareness of and care for DME in the US population is uncharacterized.

OBJECTIVE To characterize eye care and awareness of eye disease among persons with DME in the general US population.

DESIGN, SETTING, AND PARTICIPANTS Cross-sectional analysis of data from participants in the 2005 to 2008 National Health and Nutrition Examination Survey 40 years or older with diabetes mellitus and fundus photographs.

MAIN OUTCOMES AND MEASURES Among persons with DME, (1) awareness that diabetes has affected their eyes; (2) report on the last time they visited a diabetes specialist; (3) report on their last eye examination with pupil dilation; and (4) prevalence of visual impairment.

RESULTS In 2010, only 44.7% (95% CI, 27.0%-62.4%) of US adults 40 years or older with DME reported being told by a physician that diabetes had affected their eyes or that they had retinopathy; 46.7% (95% CI, 27.5%-66.0%), that they had visited a diabetes nurse educator, dietician, or nutritionist for their diabetes mellitus more than 1 year ago or never; and 59.7% (95% CI, 43.5%-75.9%), that they had received an eye examination with pupil dilation in the last year. Among persons with DME, 28.7% (95% CI, 12.7%-44.7%) were visually impaired (defined as visual acuity worse than 20/40 in the eye with DME) based on visual acuity at the initial examination and 16.0% (95% CI, 2.5%-29.4%) based on best-corrected visual acuity.

CONCLUSIONS AND RELEVANCE Many persons with diabetes mellitus in the United States are not getting care that can prevent visual impairment and blindness. Strategies to increase awareness are warranted, especially given the recent availability of improved therapies for DME.

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Diabetic retinopathy is the most common cause of new cases of blindness in working-age Americans,[1] usually as a result of proliferative diabetic retinopathy or diabetic macular edema (DME). Diabetic retinopathy is also the most common cause of less severe levels of visual impairment in this age group,[2-4] most often due to DME.[5] Because DME can lead to substantial visual loss if left untreated for 1 year or longer,[6,7] health care providers need to ensure that individuals with diabetes mellitus are aware that the condition can affect their eyes, especially those with DME. According to the American Diabetes Association[8] and the American Academy of Ophthalmology,[6] an eye examination with pupil dilation is needed at least annually to identify the presence of diabetic retinopathy, including DME, even in the absence of visual loss.

Treatment of DME has improved dramatically during the past few years. Recent government- and industry-sponsored trials[9-14] have shown that injections of anti-vascular endothelial growth factor drugs, sometimes in combination with laser photocoagulation, safely provide superior visual outcomes compared with the previous standard of care of laser photocoagulation alone in eyes in which DME is causing visual impairment. For example, the National Institutes of Health–funded Diabetic Retinopathy Clinical Research Network reported in 2012 that ranibizumab therapy with prompt or deferred laser photocoagulation in eyes with DME causing visual loss resulted in approximately 50% of treated eyes gaining substantial vision and less than 5% losing substantial vision through at least 3 years of follow-up compared with laser photocoagulation alone.[9] However, prompt diagnosis of DME and referral of patients with these complications are critical to initiate treatment before substantial visual loss has occurred. Despite these recent advances, awareness and care of DME in the US population, to our knowledge, is uncharacterized. We undertook this study to characterize the prevalence of eye care and the awareness of eye disease and visual impairment among persons with DME in the general US population.

Methods

Study Population

The National Health and Nutrition Examination Survey (NHANES) is a series of cross-sectional surveys conducted by the National Center for Health Statistics, a part of the Centers for Disease Control and Prevention.[15] Participants are selected from the noninstitutionalized civilian population in the United States by using a stratified, multistage, probability sampling design. This study analyzed data from the 2005 to 2008 NHANES cycles, when retinal photographs were obtained among participants 40 years or older. Persons were excluded from the retinal imaging examination for blindness, eye infections, or eye patches on both eyes.[16] The present analysis includes persons who completed a mobile examination visit (n = 6797), those with complete retinal imaging data (n = 5351), and those who had self-reported diabetes mellitus (defined below) (n = 798). The NHANES protocol was approved by a human subjects review board, and written informed consent was obtained from all participants.[17]

Assessment of Diabetes Mellitus and Diabetic Retinopathy

Persons were classified as having diagnosed diabetes mellitus if they answered yes to the question: "Have you ever been told by a doctor or health professional that you have diabetes or sugar diabetes?" Diagnosis of diabetic retinopathy, including DME, was based on the grading of fundus photographs by masked graders at the University of Wisconsin Ocular Epidemiologic Reading Center, Madison, using a single nonmydriatic image of the optic nerve and macula in each eye from an ophthalmic digital imaging system (CR6-45NM; Canon, Inc) and a digital camera (EOS 10D; Canon, Inc).

Assessment of Eye Care and Visual Acuity

Persons who reported a diagnosis of diabetes mellitus were asked the following questions during the interview: (1) "Have you been told by a doctor that diabetes has affected your eyes or that you had retinopathy?" (2) "When was the last time you saw a diabetes nurse educator or dietitian or nutritionist for your diabetes?" and (3) "When was the last time you had an eye examination in which the pupils were dilated?" For the question regarding a visit to a diabetes specialist, the response options of "13 to 24 months," "greater than 2 years," and "never" were aggregated in this analysis to improve the precision of the estimate for a combined group response of longer than 1 year or never. Likewise, responses were aggregated for question 3 (the last time the individual had an eye examination in which the pupils were dilated). In addition, presenting and best-corrected visual acuity (VA) of eyes diagnosed with diabetic retinopathy and DME were determined. Presenting VA was measured using a digital lensometer (model LM-990A; Nidek), allowing individuals to use any necessary usual correction, including eyeglasses, contact lenses, or both. For eyes with usual correction of 20/30 or worse, best-corrected VA was determined after refraction of these eyes using a commercially available autorefractor (model ARK-760; Nidek). For eyes with usual correction better than 20/30, the usual correction was considered the best-corrected VA. If both eyes had diabetic retinopathy and DME, the VA of the worse-seeing eye was used in the analysis.

Statistical Analysis

All analyses were performed incorporating the sampling weights to account for the complex NHANES sampling design. The standard errors for all estimates were obtained using the Taylor series (linearization) method following recommended procedures.[18] Any estimate with an associated relative standard error greater than 30% of the estimate may be unreliable and should be interpreted with caution.[19] Statistical analyses were conducted using commercially available software (SAS, version 9.2; SAS Institute, Inc).

Results

Characteristics of the population 40 years or older with diabetes mellitus are summarized in the **Table**. Among 798 persons with self-reported diabetes mellitus in the analytic sample, 238 had diabetic retinopathy without DME and 48 had DME.

Table. Demographics and Clinical Characteristics of Study Participants With Self-reported Diabetes Mellitus Stratified by DR and DME Status[a]

Characteristic	Diabetes Without DR or DME (n = 512)		DR Without DME (n = 238)		DME (n = 48)	
	Unweighted Frequency	Weighted Estimate (95% CI)[b]	Unweighted Frequency	Weighted Estimate (95% CI)[b]	Unweighted Frequency	Weighted Estimate (95% CI)[b]
Age at screening, mean, y	512	60.1 (58.9-61.4)	238	61.7 (59.8-63.5)	48	62.8 (59.5-66.0)
Race/ethnicity[c]						
Non-Hispanic white	216	66.3 (57.0-75.6)	91	64.8 (55.4-74.3)	10	44.1 (23.8-64.3)
Hispanic	143	12.7 (8.0-17.3)	62	13.4 (8.4-18.3)	15	16.7 (4.1-29.3)
Non-Hispanic black	138	14.7 (9.0-20.4)	80	20.0 (14.0-26.0)	23	39.3 (20.4-58.1)
Educational level						
Less than college education	332	57.2 (48.9-65.4)	158	56.0 (48.0-64.0)	31	68.6 (52.4-84.9)
Any college	180	42.8 (34.6-51.1)	80	44.0 (36.0-52.0)	17	31.4 (15.1-47.6)
Gender						
Women	276	56.8 (50.3-63.3)	104	44.3 (36.3-52.2)	24	51.0 (32.7-69.4)
Men	236	43.2 (36.7-49.8)	134	55.8 (47.8-63.7)	24	49.0 (30.6-67.3)
BMI, mean	502	32.7 (32.1-33.4)	237	31.9 (30.8-33.0)	48	33.6 (30.4-36.9)
Hypertension present						
Yes	381	72.9 (67.5-78.4)	184	68.4 (59.6-77.2)	41	89.9 (79.4-100.0)
No	131	27.1 (21.6-32.5)	54	31.6 (22.8-40.4)	7	10.1 (0-20.6)[d]
History of CVD[e]						
Yes	138	27.7 (23.0-32.4)	72	28.1 (21.6-34.5)	13	22.0 (11.4-32.6)
No	374	72.3 (67.6-77.0)	166	71.9 (65.5-78.4)	35	78.0 (67.4-88.6)
HbA_{1c} level, mean, %	491	6.8 (6.6-6.9)	226	7.8 (7.5-8.1)	44	8.1 (7.7-8.4)
Duration of diabetes, mean, y						
<10	381	76.6 (73.2-80.1)	87	36.4 (26.5-46.2)	10	18.5 (6.7-30.3)[d]
≥10	128	22.7 (19.2-26.1)	151	63.6 (53.8-73.5)	38	81.5 (69.7-93.3)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CVD, cardiovascular disease; DME, diabetic macular edema; DR, diabetic retinopathy; HbA_{1c}, hemoglobin A_{1c}.

[a] Participants include adults 40 years or older. Unless otherwise indicated, data are expressed as weighted proportions.

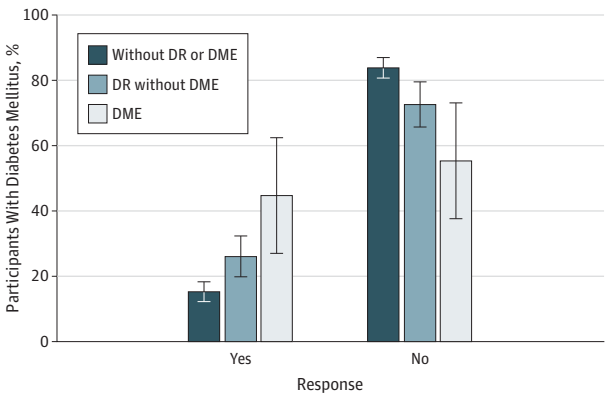
[b] Accounts for multistage sampling design, oversampling, and survey nonresponse.

[c] The category "other" was excluded because there were no DME cases in this group.

[d] Standard error is more than 30% of the estimate; estimate may be unreliable.

[e] Based on self-report of congestive heart failure, coronary heart disease, angina pectoris, or heart attack.

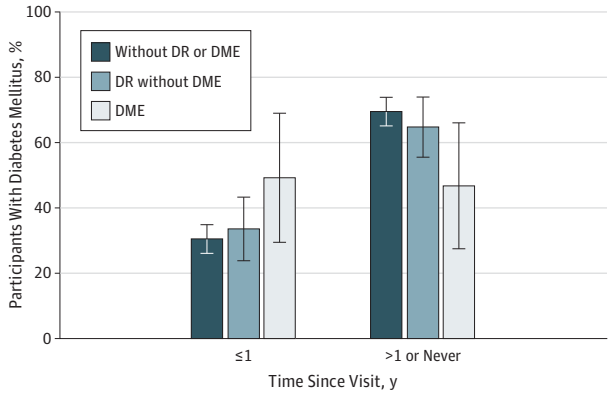
Figure 1. Awareness of Eye Diseases Among Study Participants With Self-reported Diabetes Mellitus



Participants 40 years or older were asked, "Have you been told by a doctor that diabetes has affected your eyes or that you had retinopathy?" Unknown responses were not reported. Error bars represent 95% confidence intervals. DME indicates diabetic macular edema; DR, diabetic retinopathy.

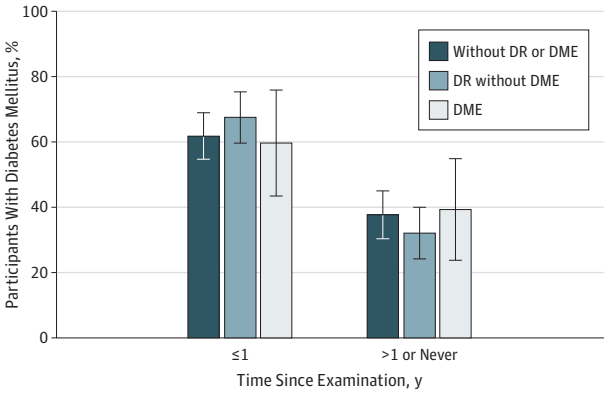
Persons with DME had higher glycated hemoglobin A_{1c} levels and longer duration of diabetes mellitus compared with persons with diabetes mellitus without macular edema. Among those with diabetes mellitus and DME, only 44.7% (95% CI, 27.0%-62.4%) reported being told by a physician that diabetes mellitus had affected their eyes or that they had retinopathy (**Figure 1**) compared with 26.1% (95% CI, 19.8%-32.3%) with diabetic retinopathy but no macular edema and 15.3% (95% CI, 12.3%-18.3%) with diabetes mellitus but no retinopathy. Only 49.2% (95% CI, 29.4%-69.0%) with DME reported seeing a diabetes nurse educator, a dietician, or a nutritionist for their diabetes mellitus within the past year compared with 33.5% (95% CI, 23.8%-43.3%) with diabetic retinopathy but no macular edema and 30.5% (95% CI, 26.1%-34.9%) with diabetes mellitus but no retinopathy. In contrast, 46.7% (95% CI, 27.5%-66.0%) with DME reported seeing a diabetes specialist more than 1 year ago or never (**Figure 2**) compared with 64.7% (95% CI, 55.5%-74.0%) with diabetic retinopathy but no macular edema and 69.5% (95% CI, 65.1%-73.9%) with diabetes mellitus but no retinopathy. Furthermore, only 59.7% (95% CI, 43.5%-75.9%) of persons with DME reported having had an eye

Figure 2. Self-reported Last Visit to a Diabetes Mellitus Specialist Among Study Participants With Diabetes



Participants 40 years or older were asked, "When was the last time you saw a diabetes nurse educator or dietitian or nutritionist for your diabetes?" The total for each cohort equals 100%. If not, the difference represents participants who responded "don't know" to this question (not shown). Error bars represent 95% confidence intervals. DME indicates diabetic macular edema; DR, diabetic retinopathy.

Figure 3. Self-reported Last Examination With Pupil Dilation Among Study Participants With Diabetes Mellitus

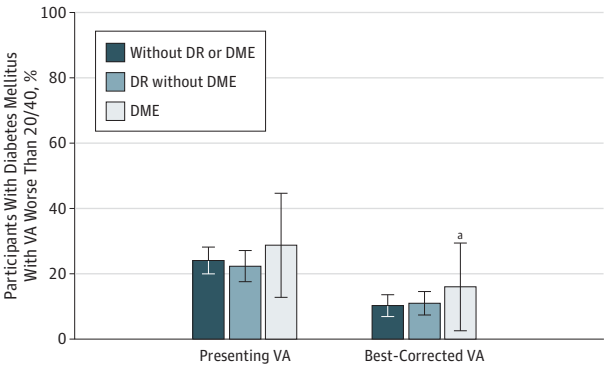


Participants 40 years or older were asked, "When was the last time you had an eye examination in which the pupils were dilated?" The total for each cohort equals 100%. If not, the difference represents participants who responded "don't know" to this question (not shown). Error bars represent 95% confidence intervals. DME indicates diabetic macular edema; DR, diabetic retinopathy.

examination within the past year at which the pupils were dilated (**Figure 3**) compared with 67.5% (95% CI, 59.6%-75.4%) with diabetic retinopathy but no macular edema and 61.8% (95% CI, 54.7%-68.9%) with diabetes mellitus but no retinopathy.

Among persons with DME, the presenting VA of the eye with disease was 20/40 or better in 69.4% (95% CI, 52.9%-86.0%) compared with 76.6% (95% CI, 71.4%-81.8%) with diabetic retinopathy but no macular edema and 75.1% (95% CI, 70.8%-79.4%) with diabetes mellitus but no retinopathy, whereas the best-corrected VA was 20/40 or better in 81.4% (95% CI, 66.6%-96.1%) compared with 87.3% (95% CI, 83.2%-91.5%) and 88.0% (95% CI, 84.5%- 91.5%), respectively. **Figure 4** displays the percentage of persons with DME with presenting or best-corrected VA worse than 20/40 (ie, visual impairment; 28.7% vs 16.0%, respectively).

Figure 4. Percentage of Study Participants With Presenting or Best-Corrected Visual Acuity (VA) Worse Than 20/40



Participants 40 years or older included those with diabetes mellitus, diabetes mellitus and diabetic retinopathy (DR) but no diabetic macular edema (DME), and diabetes mellitus with DME. Responses of "unknown" were not reported. Error bars represent 95% confidence intervals.
[a]Standard error is more than 30% of the estimate; estimate may be unreliable.

Discussion

Diabetic macular edema is a major cause of visual impairment among US adults 40 years or older with diabetes mellitus.[1,20,21] A recent report suggests that approximately 745 000 persons with diabetes mellitus in the US population have swelling of the center of the retina (ie, DME).[22] Treatment of DME has improved dramatically during the past few years so that prompt diagnosis and referral of patients with these complications has become more critical. Because, to our knowledge, the awareness and care of DME in the US population is uncharacterized, this study aimed to characterize eye care and awareness of eye disease among persons with DME in the general US population. Our results suggest that many individuals with DME report not receiving prompt diabetes-related or eye-related care, although many of these individuals are at risk of substantial visual loss that could be lessened or eliminated with appropriate care. Furthermore, many people 40 years or older in the United States have DME with best-corrected VA of 20/40 or better when they may not be seeking visual correction services, including many who are unaware that diabetes mellitus has affected their eyes. This study indicates that, even though DME is a major cause of visual impairment among people with diabetes mellitus, many individuals with DME report not receiving diabetes-related or eye-related care for at least 1 year.

Limitations of this study include the relatively small number of NHANES participants with DME, fundus photographs were not stereoscopic pairs, and the lack of optical coherence tomography measurements to determine the proportion of cases with central macular thickening among those in whom

DME was or was not suggested by retinal photographs. Furthermore, the answers to the eye care questions were based on self-report (as opposed to actual recorded use of health care resources), precluding the ability to eliminate recall bias. The possibility of underreporting cannot be excluded, and its magnitude, if present, cannot be determined. However, with respect to pupil dilation, self-reported use of eye examinations with dilation within the past year was comparable to that of the National Committee for Quality Assurance indicators report,[23] suggesting that the self-reported data, at least for this variable, is likely not affected substantially by recall bias. Also, persons who are severely ill may be less likely to participate in the NHANES. Although the NHANES design should account for this differential nonresponse by health status, severely ill people might still be underrepresented in this data set.

In summary, our results suggest that despite recent successes in the ability to treat visual loss due to diabetes mellitus, one of the most frequent and most feared complications of the disease, hundreds of thousands of people in the United States report that they are not getting care that can prevent visual impairment and blindness. These findings from the NHANES, which provide nationally representative estimates of the burden of diabetic eye disease and awareness of having the condition in the general US population, emphasize the need to strengthen our efforts in educating patients with diabetes mellitus concerning the eye complications of the disease. These efforts include getting patients to health care providers, including diabetes nurse educators, dieticians, nutritionists, primary care physicians, or endocrinologists, for treatment of their diabetes mellitus; getting appropriate eye examinations to detect and treat diabetic retinopathy, including DME; and identifying strategies that might result in greater awareness and appropriate eye care[24] to reduce the magnitude of visual impairment and blindness due to this common complication of diabetes mellitus.

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Study concept and design: Bressler, Varma, Doan, Danese, Selvin, Dolan, Fine, Colman, Turpcu.
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