

The Prevalence of Diabetic Retinopathy Among Adults in the United States

The Eye Diseases Prevalence Research Group*

Objective: To determine the prevalence of diabetic retinopathy among adults 40 years and older in the United States.

Methods: Pooled analysis of data from 8 population-based eye surveys was used to estimate the prevalence, among persons with diabetes mellitus (DM), of retinopathy and of vision-threatening retinopathy—defined as proliferative or severe nonproliferative retinopathy and/or macular edema. Within strata of age, race/ethnicity, and gender, US prevalence rates were estimated by multiplying these values by the prevalence of DM reported in the 1999 National Health Interview Survey and the 2000 US Census population.

Results: Among an estimated 10.2 million US adults 40 years and older known to have DM, the estimated crude

prevalence rates for retinopathy and vision-threatening retinopathy were 40.3% and 8.2%, respectively. The estimated US general population prevalence rates for retinopathy and vision-threatening retinopathy were 3.4% (4.1 million persons) and 0.75% (899 000 persons). Future projections suggest that diabetic retinopathy will increase as a public health problem, both with aging of the US population and increasing age-specific prevalence of DM over time.

Conclusion: Approximately 4.1 million US adults 40 years and older have diabetic retinopathy; 1 of every 12 persons with DM in this age group has advanced, vision-threatening retinopathy.

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DIABETIC RETINOPATHY, A retinal vascular disorder that occurs as a complication of diabetes mellitus (DM), is a leading cause of blindness in the United States, often affecting working-aged adults.¹ It is characterized by signs of retinal ischemia (microaneurysms, hemorrhages, cotton-wool spots, intraretinal microvascular abnormalities, venous caliber abnormalities, and neovascularization) and/or signs of increased retinal vascular permeability. Vision loss can result from several mechanisms, including neovascularization leading to vitreous hemorrhage and/or retinal detachment, macular edema, and retinal capillary nonperfusion.¹ Retinopathy occurs in most persons with longstanding DM,² but its incidence rate can be reduced by aggressive control of hyperglycemia^{3,4} and hypertension.³⁻⁶

The Eye Diseases Prevalence Research Group, a consortium of population-based eye studies and ophthalmic epidemiologists, was charged with generating the best possible estimates of the prevalence rates for major eye diseases and dis-

orders, including diabetic retinopathy. Since 1980, several population-based eye surveys have assessed the prevalence of diabetic retinopathy using the "gold standard" Early Treatment Diabetic Retinopathy Study (ETDRS) interim or final fundus photograph grading protocol for diabetic retinopathy.^{7,8} The National Health Interview Survey (NHIS) provides annual estimates of the self-reported prevalence of DM in the United States, and the 2000 US Census population data were recently made available for the populations of interest. In this article, we report prevalence estimates for diabetic retinopathy in persons 40 years and older, based on combined data from these sources.

METHODS

INCLUSION OF STUDIES OF THE PREVALENCE OF DIABETIC RETINOPATHY

To estimate the prevalence of diabetic retinopathy among persons with DM, data on participants 40 years and older were requested from population-based, cross-sectional eye dis-

Table 1. Studies Included in Estimates of the Prevalence of Diabetic Retinopathy*

Variable	Barbados Eye Study, Barbados, West Indies	BDES, Beaver Dam, Wis	BMES, Blue Mountain, Australia	Melbourne VIP, Melbourne, Australia	Proyecto VER, Nogales and Tucson, Ariz	SAHS, San Antonio, Tex†	SLVDS, San Luis Valley, Colo	WESDR, Southern Wis
Years study conducted	1988-1992	1988-1990	1992-1994	1991-1998	1999-2000	1985-1987	1984-1988	1980-1982
No. of participants with diabetes mellitus‡	615	410	252	233	899	351	360	1313
Photographic fields taken§	1 and 2	1-7	1-5	1 and 2	1, 2, and 4	1-7	1, 2, and 4	1-7
Age, y								
40-49	19.2	6.6	0.0	9.9	17.8	31.2	22.9	7.4
50-64	47.2	36.3	38.9	40.8	44.6	66.7	55.8	35.9
65-74	26.3	34.9	36.5	31.7	25.4	12.5	31.4	33.8
≥75	7.3	22.2	24.6	17.6	12.2	NA	NA	22.8
Gender								
Women	63.4	56.8	47.2	43.8	63.0	58.7	56.4	53.2
Men	36.6	43.2	52.8	56.2	37.0	41.3	33.6	46.8
Race/ethnicity								
Black	100.0	NA	NA	NA	NA	NA	NA	NA
Hispanic	NA	NA	NA	NA	100.0	80.6	64.7	NA
White	NA	100.0	100.0	100.0	NA	19.4	35.3	100.0
Crude prevalence								
Mild NPDR	19.8	22.9	21.0	16.3	36.6	18.2	20.6	36.6
Moderate NPDR	8.0	10.0	4.4	6.9	1.7	13.7	10.3	6.8
Severe NPDR and/or PDR	1.0	2.2	3.6	4.3	6.0	4.3	4.4	6.9
Macular edema	8.6	1.2	4.8	2.2	8.9	2.6	3.3	5.1
DR of any type	28.8	35.1	29.0	27.5	44.3	36.2	35.3	50.3
VTDR	9.1	3.2	6.4	4.3	8.9	5.3	6.4	10.0

Abbreviations: BDES, Beaver Dam Eye Study; BMES, Blue Mountains Eye Study; DR, diabetic retinopathy; NA, not applicable; NPDR, nonproliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy; SAHS, San Antonio Heart Study; SLVDS, San Luis Valley Diabetes Study; VER, Vision Evaluation Research; VIP, Visual Impairment Project; VTDR, vision-threatening diabetic research; WESDR, Wisconsin Epidemiologic Study of Diabetic Retinopathy.

*Data are given as percentage of persons unless otherwise indicated.

†Persons with adult-onset diabetes mellitus only.

‡The number of persons reported for each study in this table reflects the number contributing to our estimates in the current article and not necessarily the total number of participants in the original study as published.

§The photographic fields are described in reference 8.

eases prevalence studies⁹⁻¹⁶ that had ascertained diabetic retinopathy by grading color fundus photographs (**Table 1**).

STANDARDIZATION BETWEEN STUDIES

Severity of diabetic retinopathy was graded in all studies by a color fundus photograph reading center. The reading center also indicated whether macular edema was observed.

Grading was performed using the ETDRS interim or final scale,^{7,8} except in the Barbados Eye Study, Barbados, West Indies (see below). Use of the ETDRS final scale to evaluate the severity of diabetic retinopathy is summarized in **Table 2** and **Figure 1**. With the ETDRS interim scale, level 40/41 was approximately equivalent to level 43 of the final scale, and level 50/51 was approximately equivalent to level 53 of the final scale. For our evaluation of the prevalence of diabetic retinopathy, these severity scales were collapsed into the following categories, based on the consensus of the Eye Diseases Prevalence Research Group:

- Mild nonproliferative retinopathy (level 14 up to but not including level 40)
- Moderate nonproliferative retinopathy (level 40 up to but not including level 50)
- Severe retinopathy (level ≥50, including severe nonproliferative and proliferative retinopathy)

In natural history observations from the ETDRS, among eyes with level 35 retinopathy (at the highest end of our mild level), 1.2%, 6.5%, and 15.2% progressed to high-risk proliferative retinopathy (warranting panretinal photocoagula-

tion)¹⁷ within 1, 3, and 5 years' follow-up, respectively. Eyes with level 43 and 47 retinopathy (corresponding to our moderate level) progressed to high-risk proliferative retinopathy in 3.6% and 8.1%, 13.3% and 24.7%, and 21.0% and 27.1% of cases by 1, 3, and 5 years' follow-up, respectively. Eyes with level 53 retinopathy, at the low end of the spectrum of severe retinopathy as defined in our study, progressed to high-risk proliferative retinopathy in 17.1%, 44.4%, and 57.8% of cases by 1, 3, and 5 years' follow-up, respectively.⁷

The Barbados Eye Study used a valid, simplified grading scheme, in which fundus photographs were graded as no retinopathy, mild retinopathy (3 microaneurysms, hard or soft exudates, or retinal hemorrhages), moderate retinopathy (intraretinal microvascular abnormalities or venous beading), or severe retinopathy (any neovascularization).¹⁸ For purposes of pooled analysis, severe retinopathy as defined in the Barbados Eye Study was used to correspond to the severe category (level ≥50) used for the remaining studies, recognizing that some cases of severe nonproliferative retinopathy may have been included in the Barbados Eye Study's moderate category. Mild retinopathy from the Barbados Eye Study was used to correspond to mild nonproliferative retinopathy as defined earlier. The extent to which the differences in outcome definitions in the Barbados Eye Study affected results was explored by sensitivity analysis.

We derived meaningful composite outcomes from these results as follows: (1) DR (any diabetic retinopathy [technically defined as level 14 or higher retinopathy and/or macular edema]), consisting of mild, moderate, or severe retinopathy, diabetic macular edema, or any combination thereof; and (2)

Table 2. The Eye Diseases Prevalence Research Group: Prevalence of Diabetic Retinopathy*

Level	Severity	Definition†
10	DR absent	Microaneurysms and other characteristics absent
14	DR questionable	HE, SE, or IRMA definite; microaneurysm absent
15	DR questionable	Hemorrhage(s) definite; microaneurysm absent
20	Microaneurysms only	Microaneurysms definite; other characteristics absent
35‡	Mild NPDR	One or more of the following: venous loops \geq D/1; SE, IRMA; or VB = Q; retinal hemorrhages present; HE \geq D/1; and SE \geq D/1
43	Moderate NPDR	H/Ma = M/4-5 -S/1 or IRMA = D/1-3 (not both)
47	Moderately severe NPDR	Both level 43 characteristics and/or 1 (only) of the following: IRMA = D4-5; H/Ma = S/2-3; or VB = D/1
53	Severe NPDR‡	One or more of the following: \geq 2 of the 3 level 47 characteristics; H/Ma \geq S/4-5; IRMA \geq M/1; VB \geq D/2-3
61	Mild PDR	FPD or FPE present with NVD and NVE absent; or NVE = D
65	Moderate PDR	Either of the following: NVE \geq M/1 or NVD = D; and VH and PRH = A or Q; or VH or PRH = D and NVE <M/1 and NVD absent
71	High-risk PDR	Any of the following: VH or PRH \geq M/1; NVE \geq M/1 and VH or PRH \geq D/1; NVD-2 and VH or PRH \geq D/1; or NVD \geq M
75	High-risk PDR	NVD \geq M and VH or PRH \geq D/1
81	Advanced PDR: fundus obscured, center of macula attached	NVD cannot be graded, or NVD <D and NVE cannot be graded in \geq 1 field and absent in all others; and retinal detachment at center of macula
85	Advanced PDR: posterior fundus obscured, or center of macula detached	VH = VS in fields 1 and 2; or retinal detachment at center of macula = D
90	Cannot grade, even sufficiently for level 81 or 85	

Abbreviations: A, absent; D, definitely present; DR, diabetic retinopathy; FPD, fibrous proliferations of optic disc; FPE, fibrous proliferations elsewhere; HE, hard exudates; H/Ma, hemorrhages/microaneurysms; IRM, intraretinal microvascular abnormalities; M, moderate; NPDR, nonproliferative DR; NVD, new vessels disc (within 1 DD or optic disc margin); NVE, new vessels elsewhere ($>$ 1 disc diameter [DD] from optic disc); PDR, proliferative DR; PRH, preretinal hemorrhage; Q, questionable; S, severe; SE, soft exudates; VB, venous beading; VH, vitreous hemorrhage; VS, very severe.

*Adapted from the Diabetic Retinopathy Study Research Group.⁷

†Severity categories for characteristics graded in multiple fields are of the form (maximum severity/extent), where maximum severity can be A, Q, D, M, S, or VS, and extent is the number of fields at that severity level. For example, M/2-3 means there are 2 or 3 fields from 3 to 7 with moderate severity, and none with higher severity.

‡Nonproliferative DR levels 35 and above all require the presence of microaneurysms.

vision-threatening diabetic retinopathy (VTDR), consisting of severe retinopathy, diabetic macular edema, or both. These composite outcomes serve as the primary outcomes for this article, respectively indicating (1) the presence of any diabetic retinopathy; and (2) a level of diabetic retinopathy likely to result in vision loss in the short run, absent treatment with laser photocoagulation.

The contributing studies also provided data on age, gender, and race/ethnicity. Diagnosis of DM included laboratory verification for persons with DM, except in the Melbourne Visual Impairment Project, Melbourne, Victoria, Australia. Unfortunately, data on the duration of DM, type of DM, and severity of hyperglycemia over time were not available from all studies in a manner that could be combined, so these factors could not be evaluated in the pooled analysis. For the southern Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR), and San Antonio Heart Study, San Antonio, Tex, we elected to use only data for subjects with type 2 DM, on the grounds that only a few persons 40 years and older would have type 1 DM, so that the persons with type 2 DM would be approximately representative of the US general population with DM in this age group. For the other studies, data for all persons 40 years and older identified as having DM were used.

AGE-SPECIFIC PREVALENCE ESTIMATES FOR DIABETIC RETINOPATHY AMONG PERSONS WITH DM

Data analysis was conducted by pooling the age-, gender-, and race/ethnicity-specific prevalence rates for DR and for VTDR among persons with DM from each of the participating studies. In accord with the established age groupings used for reporting the prevalence of DM from the NHIS,¹⁹ the following age categories were used: 40 through 49, 50 through 64, 65 through 74 years, and 75 years and older. Pooled prevalence estimates for each of these age groupings, by race/ethnicity and gender, were calculated using minimum variance linear estimation logarithm odds transformation, of the prevalence proportion. As in the other Eye Diseases Prevalence Research Group articles, racial/ethnic groups were defined as white, non-Hispanic; black, non-Hispanic; Hispanic; and other. Variances were computed assuming a binomial distribution. Prevalence rates were derived from the pooled data of all relevant studies to obtain estimates for retinopathy among white and Hispanic persons with DM. Prevalence rates for retinopathy among black persons with DM were taken directly as reported from the Barbados Eye Study. Prevalence rates for other American race/ethnicity groups that have not been studied were estimated using an unweighted average of the pooled prevalence estimates for white, black, and Hispanic persons, so that national prevalence estimates could be generated.

PREVALENCE ESTIMATES FOR DIABETIC RETINOPATHY IN THE US GENERAL POPULATION

To determine the number of individuals with diabetic retinopathy in the US general population 40 years and older, we first estimated the number of individuals with DM in strata of age, gender, and race/ethnicity. These estimates were based on self-reported answers to the question, "Have you ever been told by a physician that you have diabetes?" from the most recently available (1999) NHIS. The NHIS, conducted by the National Center for Health Statistics, gathers data from a nationally representative sample of civilian, noninstitutionalized persons residing in the United States.¹⁹ The stratum-specific 1999 prevalence rates for DM were applied to the stratum-specific 2000 US Census population results²⁰ to arrive at estimates of the number of persons with DM in each stratum in 2000. The pooled stratum-specific prevalence estimates for DR and VTDR among persons with DM then were applied to the estimates of the number of persons with DM in each stratum, resulting in stratum-specific estimates of the prevalence of DR and of VTDR for the US population in 2000. A similar approach was used to obtain prevalence estimates for mild, moderate, and severe diabetic retinopathy, and also for diabetic macular edema.

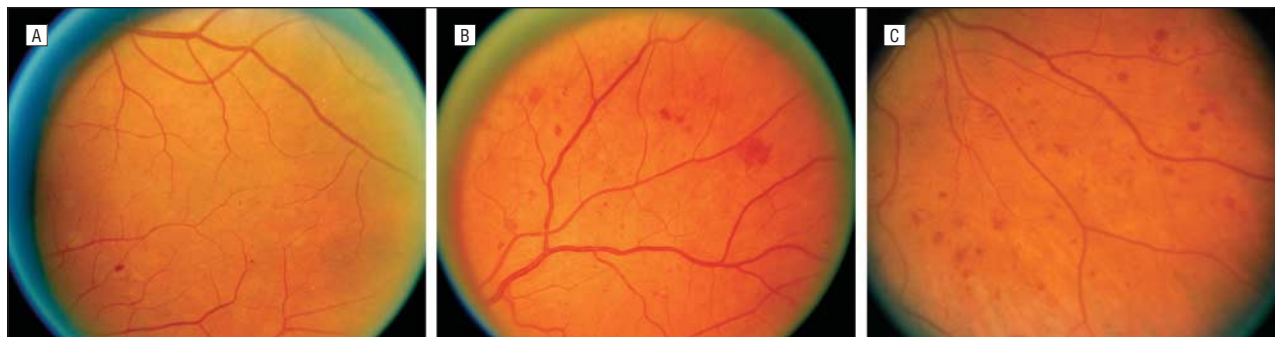


Figure 1. A, Standard photograph 1. Retinopathy equal to this level in 4 quadrants would constitute level 43 (or 40) diabetic retinopathy, the lower threshold for moderate diabetic retinopathy. Retinopathy less than this photograph in any field would constitute mild retinopathy. B, Standard photograph 2. Retinopathy equal to this level in 1 quadrant with lesser retinopathy in the remaining quadrants would constitute level 43 (or 40) moderate retinopathy. Retinopathy equal to this level in all 4 quadrants, venous beading in 2 quadrants, or intraretinal microvascular abnormalities in 1 quadrant would constitute level 53 (or 50) diabetic retinopathy, the lowest level of severe retinopathy. C, Severe diabetic retinopathy illustrating extensive blot hemorrhages, venous beading, and intraretinal microvascular abnormalities. Courtesy of the Early Treatment of Diabetic Retinopathy Study Research Group.

For confidence intervals based on the prevalence of DM in the general population, SUDAAN software (Research Triangle Institute, Research Triangle Park, NC) was used to apply the sampling weights from the complex multistage sampling design of the NHIS appropriately. Confidence intervals for prevalence rates and counts of persons with DR and VTDR in the general population were calculated from variance values derived using the delta method for the product of 2 dependent binomial proportions (proportion of persons with DM times the proportion of persons with DM having retinopathy [either DR or VTDR]).²¹

Projections for the prevalence rates for DR and for VTDR in 2020 were based on 2 scenarios, one assuming a constant stratum-specific prevalence of DM over time, and the other using projected increases in the prevalence of DM over the 20-year period. For both scenarios, a constant prevalence of DR and of VTDR among persons with DM was assumed. For the latter scenario, we used the projections of increasing DM prevalence reported by Boyle et al,²² based on NHIS results during the 1980s and 1990s. These projections were based on a linear model (J. P. Boyle, PhD, written communication, September 11, 2002), which allowed us to recalculate the anticipated prevalence of DM in strata of age group and gender in 2020 by applying the slope to the 2000 rates. The ratio of the stratum-specific prevalence of DM in 2020 to that in 2000 then was calculated for each age and gender stratum. These ratios were applied to our 2000 age-, gender-, and race/ethnicity-specific values for DM prevalence to obtain stratum-specific estimates of the anticipated prevalence of DM in 2020, used in our projections of diabetic retinopathy prevalence under the increasing DM prevalence scenario. The ratio derived from persons aged 45 through 64 years in the model of Boyle et al²² was applied to both our 40- through 49- and 50- through 64-year age strata.

STATISTICAL TESTS

Tests for age, gender, and race/ethnicity effects were conducted among persons with DM for DR and for VTDR, as well as for mild, moderate, and severe diabetic retinopathy and for diabetic macular edema. Tests for gender differences, based on the pooled data from all contributing studies, were done separately by race/ethnicity using the Mantel-Haenszel χ^2 test, controlling both for age and for the study effect. Wald χ^2 tests from logistic regression models of the pooled prevalence rates were used to evaluate race/ethnicity and age effects, adjusting for gender. Age, gender, and race/ethnicity effects on the prevalence of DR and of VTDR in the general population were evaluated with logistic regression models and Wald χ^2 tests. For age tests, comparisons were made using ordinal age categories (40-49, 50-64, 65-74, and ≥ 75

years), and odds ratios (ORs) were reported for the prevalence in 1 category with respect to the category below. Pooled data analysis was conducted following approval by the institutional review board of The Johns Hopkins School of Medicine, and followed the principles of the Declaration of Helsinki.

RESULTS

Eight studies contributed data on diabetic retinopathy for 4440 persons with DM, of whom 615 were black (all from the Barbados Eye Study) and 1415 were Hispanic (100%, 80%, and 65%, respectively, of participants in the Proyecto VER, Nogales and Tucson, Ariz; San Antonio Heart Study, San Antonio, Tex; and San Luis Valley Study, San Luis Valley, Colo). Of 2410 white subjects, 1313 (54%) were from the WESDR. Characteristics of the subjects with DM from participating studies are given in Table 1. For DR (**Figure 2**) and VTDR (**Figure 3**), age-, gender-, and race/ethnicity-specific prevalence rates were overlapping between studies, except that the WESDR, conducted from 1980 through 1982, tended to have higher prevalence rates than did the other studies. Tests for homogeneity for each of the stratum-specific pooled rates showed no statistically significant differences in rates across studies when WESDR data were excluded.

Stratum-specific pooled prevalence estimate results for DR and for VTDR are presented below. For the sake of brevity, reporting of prevalence results for the underlying primary outcomes (mild, moderate, and severe diabetic retinopathy and diabetic macular edema) will be deferred to a supplemental Web site at: <http://www.nei.nih.gov/eyedata/>, at a future date.

PREVALENCE OF DIABETIC RETINOPATHY AMONG PERSONS WITH DM

Estimated prevalence rates for DR and for VTDR among persons with DM are given in **Table 3**. The estimated crude prevalence of DR among persons with DM was high, with an overall crude prevalence of 40.3% (95% confidence interval [CI], 38.8%-41.7%). The estimated overall crude prevalence of VTDR was 8.2% (95% CI, 7.4%-9.1%). Overall crude prevalence estimates would have been slightly lower had the WESDR results been

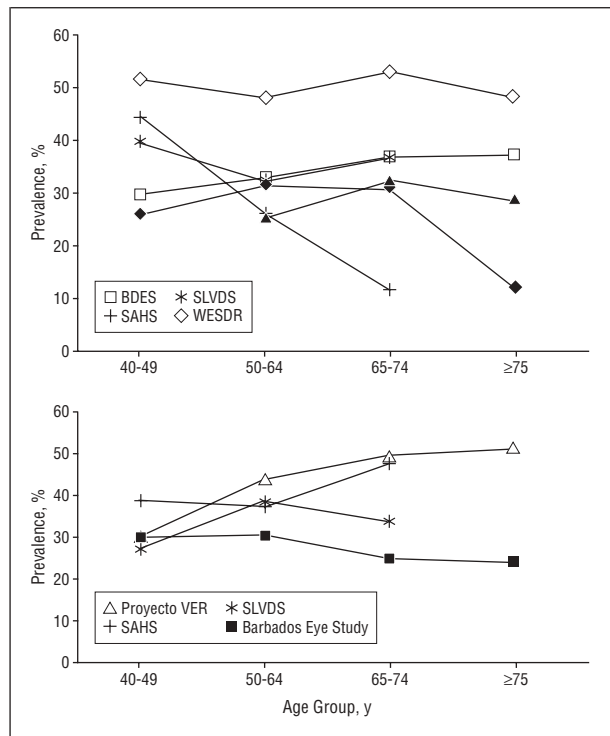


Figure 2. A, Prevalence of diabetic retinopathy among white subjects who have diabetes mellitus. B, Prevalence of diabetic retinopathy among Hispanic and black subjects who have diabetes mellitus. BDES indicates Beaver Dam Eye Study, Beaver Dam, Wis; SAHS, San Antonio Heart Study, San Antonio, Tex; SLVDS, San Luis Valley Diabetes Study, San Luis Valley, Colo; VER, Vision Evaluation Research, Nogales and Tucson, Ariz; and WESDR, Wisconsin Epidemiologic Study of Diabetic Retinopathy, southern Wisconsin. The Barbados Eye Study was conducted in Barbados, West Indies; all participants were black.

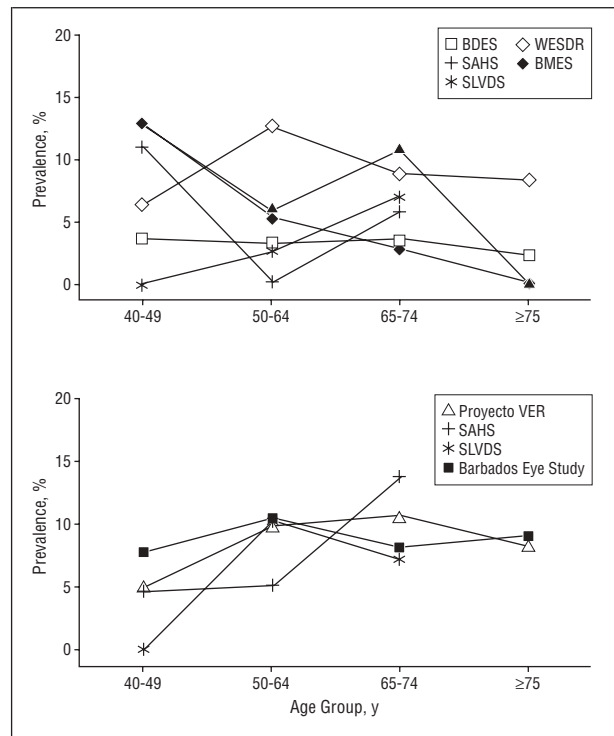


Figure 3. A, Prevalence of vision-threatening diabetic retinopathy among white subjects who have diabetes mellitus. B, Prevalence of vision-threatening diabetic retinopathy among Hispanic and black subjects who have diabetes mellitus. BDES indicates Beaver Dam Eye Study, Beaver Dam, Wis; BMES, Blue Mountains Eye Study, Sydney, New South Wales, Australia; SAHS, San Antonio Heart Study, San Antonio, Tex; SLVDS, San Luis Valley Diabetes Study, San Luis Valley, Colo; VER, Vision Evaluation Research, Nogales and Tucson, Ariz; and WESDR, Wisconsin Epidemiologic Study of Diabetic Retinopathy, southern Wisconsin. The Barbados Eye Study was conducted in Barbados, West Indies; all participants were black.

excluded (35.8% and 7.3%, respectively, for DR and VTDR).

Among persons with DM, little difference in the prevalence of retinopathy between age groups was observed. In logistic models, the odds of DR differed by no more than 6% between successive age groups (40-49, 50-64, 65-74, and ≥ 75 years) in any racial/ethnic group, although in some instances these differences were statistically significant. The strongest association with age was observed for increasing estimated prevalence of diabetic retinopathy among Hispanic persons with DM (OR per step in age category = 1.06, $P < .001$). Among black (OR = 0.97, $P = .02$) and white (OR = 1.00, $P = .88$) persons with DM, there was little change with age, whether or not WESDR data were included. For VTDR, no substantial differences in estimated prevalence between age groups were observed in any of the racial/ethnic groups (OR range, 0.99-1.01).

As with age, no consistent association between gender and the prevalence of diabetic retinopathy in persons with DM was observed. Although Hispanic women with DM had an estimated prevalence rate for DR (OR = 0.72, $P = .004$) and for VTDR (OR = 0.77, $P = .02$) approximately three fourths that among males, for black and white persons with DM, neither DR nor VTDR was associated with gender (OR range, 0.97-1.02).

In contrast, the prevalence of DR among persons with DM seemed to vary modestly among racial groups. The prevalence of DR in persons with DM was substantially higher among Hispanic subjects (OR = 1.17, $P < .001$) than among black persons. Comparisons of white persons with Hispanic or black persons differed according to whether data from the WESDR study (a study of white persons in which the rates of diabetic retinopathy were higher than in all of the other studies) were included, making inferences difficult. When WESDR data were included, the prevalence of DR was similar among white and Hispanic persons (OR = 0.99, $P = .61$), but the prevalence was significantly lower among white than Hispanic persons when WESDR data were excluded (OR = 0.944, $P < .001$). For the comparison of white with black persons, with data from WESDR excluded, the prevalence rates were less than 5% different (OR = 1.04, $P = .02$). For VTDR, the prevalence rates among persons with DM were similar in all 3 racial/ethnic groups, whether or not WESDR data were excluded (all ORs were between 0.98 and 1.02, all P values nonsignificant).

As mentioned previously, the definition of severe diabetic retinopathy used in the Barbados Eye Study did not include severe nonproliferative diabetic retinopathy (level 50-53), likely resulting in underestimation of the prevalence of VTDR among black persons in our analysis. To evaluate the extent of underestimation that may have occurred, the proportion of persons with level 50 or worse

Table 3. Estimates Prevalence of Diabetic Retinopathy in Persons with Diabetes Mellitus by Age, Gender, and Race/Ethnicity

Gender and Age Group, y	Prevalence per 100 Persons (95% Confidence Interval)		
	White Persons	Black Persons	Hispanic Persons
Any Retinopathy*			
Women			
40-49	33.8 (23.7-45.6)	27.9 (18.6-39.7)	28.6 (22.2-36.1)
50-64	40.4 (35.9-45.1)	28.6 (22.8-35.3)	37.3 (32.9-41.9)
65-74	45.3 (40.5-50.2)	29.2 (21.0-39.0)	45.4 (38.6-52.3)
≥75	45.7 (39.9-51.6)	25.9 (12.9-45.3)	52.5 (41.6-63.2)
Crude prevalence	42.8 (40.1-45.7)	28.5 (24.2-33.1)	38.9 (35.8-42.2)
Men			
40-49	51.6 (40.9-62.2)	34.0 (22.3-48.1)	38.5 (29.4-48.6)
50-64	39.7 (35.3-44.3)	35.2 (26.1-45.5)	48.3 (42.5-54.2)
65-74	44.4 (39.5-49.5)	19.7 (11.8-31.0)	48.9 (40.1-57.8)
≥75	38.1 (31.4-45.2)	22.2 (8.6-46.5)	50.0 (32.8-67.2)
Crude prevalence	41.5 (38.6-44.4)	29.3 (23.8-35.6)	46.6 (42.4-50.8)
Overall crude prevalence	42.2 (40.2-44.2)	28.8 (25.3-32.5)	41.8 (39.3-44.4)
Vision-Threatening Retinopathy†			
Women			
40-49	10.7 (5.0-21.4)	7.4 (3.1-16.5)	3.5 (1.5-7.9)
50-64	9.4 (7.0-12.6)	9.6 (6.2-14.5)	8.4 (6.1-11.4)
65-74	8.8 (6.3-12.1)	12.5 (7.2-20.7)	8.6 (5.4-13.4)
≥75	6.4 (4.0-10.2)	11.1 (3.6-29.3)	8.8 (4.2-17.2)
Crude prevalence	8.1 (6.6-9.8)	10.0 (7.4-13.4)	7.5 (5.9-9.4)
Men			
40-49	7.4 (3.4-15.1)	8.0 (3.1-19.5)	6.8 (3.2-13.9)
50-64	11.1 (8.2-14.8)	12.1 (6.8-20.5)	9.6 (6.7-13.8)
65-74	7.6 (5.3-11.0)	1.5 (0.2-10.0)	13.0 (8.1-20.2)
≥75	7.3 (4.2-12.6)	5.6 (0.8-30.7)	6.7 (1.7-23.1)
Crude prevalence	7.9 (6.4-9.8)	7.6 (4.7-11.8)	9.4 (7.2-12.2)
Overall crude prevalence	8.0 (6.9-9.2)	9.1 (7.1-11.6)	8.2 (6.9-9.7)

*Any retinopathy is defined as retinopathy severity level of 14 or greater (see "Standardization Between Studies" subsection of "Methods" section and Table 2), macular edema, or both. Vision-threatening retinopathy is defined as retinopathy severity level of 50 or greater, macular edema, or both. Additional results regarding the prevalence of retinopathy by severity level and the prevalence of macular edema are available at: <http://www.nei.nih.gov/eyedata>.

retinopathy who had level 50 (severe nonproliferative) retinopathy in the study with highest DR prevalence (WESDR), 40 years or older and diagnosed as having DM at 30 years or older, was calculated, and found to be 14.6% (B. E. K. Klein, MD, MPH, and R. K. and S. E. M., unpublished data, 2003). Thus, our estimates of the prevalence of severe retinopathy among black persons are probably underestimated by about 15%. The Barbados Eye Study definition of mild retinopathy also differed slightly from that used in the other studies, in that patients with 1 or 2 microaneurysms may not have been counted as having DR. However, based on clinical experience, the effect of this discrepancy on prevalence estimates was likely trivial.

PREVALENCE OF DIABETIC RETINOPATHY IN THE UNITED STATES

The prevalence of diabetic retinopathy in the general population is strongly dependent on the prevalence of DM itself, because only persons with DM can have diabetic retinopathy. Our estimates of the age-, gender-, and race/ethnicity-specific prevalence rates for DM in persons 40 years and older, derived from the 1999 NHIS data set,¹⁹ are given in **Table 4**, and the estimates of the prevalence rates for DR and VTDR are given in **Table 5**. The estimated crude prevalence of DR in the US population

40 years and older was 3.4% (95% CI, 3.2%-3.6%) or 4.1 million persons. The estimated crude prevalence of VTDR in the same population was 0.75% (95% CI, 0.66%-0.85%) or 899 000 persons. Excluding WESDR data, the crude prevalence estimate for DR would be 2.81% or 3.4 million persons, and the crude prevalence estimate for VTDR would be 0.57% or 680 000 persons.

Reflecting the increasing prevalence of DM with age, DR and VTDR among the US general population 40 years and older tended to increase in prevalence with age. The prevalence of DR increased on average across successive age groups among white (OR per step in age category = 1.47, $P < .001$; OR = 1.48, $P < .001$ without the WESDR data), black (OR = 1.30, $P < .001$), and Hispanic (OR = 1.58, $P < .001$) persons. For VTDR, the US general population prevalence also increased on average across successive age groups among white (OR = 1.34, $P = .008$; OR = 1.15, $P = .39$ without the WESDR data), Hispanic (OR = 1.56, $P < .001$), and black persons (OR = 1.31, $P = .06$), but not all increases were statistically significant. However, lower prevalence rates of DR and of VTDR generally were observed in the oldest (≥ 75 years) age group with respect to those aged 65 through 74 years.

A significant gender difference in the estimated US general population prevalence rates for DR and VTDR was observed in only 1 of 6 tests for gender effects, that for the prevalence of VTDR among black persons, wherein

Table 4. Estimated Prevalence of Diabetes Mellitus in the United States by Age, Gender, and Race/ethnicity*

Gender and Age Group, y	Prevalence per 100 Persons (95% CI)		
	White Persons	Black Persons	Hispanic Persons
Women			
40-49	3.1 (2.3-4.0)	7.2 (4.6-9.7)	6.3 (3.7-8.9)
50-64	7.1 (6.0-8.2)	21.3 (16.6-25.9)	24.1 (17.9-30.3)
65-74	10.6 (9.0-12.2)	23.3 (17.4-29.2)	16.3 (10.3-22.3)
≥75	10.5 (8.7-12.2)	22.4 (14.2-30.7)	18.4 (9.3-27.5)
Subtotal	7.0 (6.4-7.7)	16.1 (13.8-18.4)	14.8 (12.1-17.5)
Men			
40-49	2.5 (1.8-3.2)	5.5 (2.8-8.2)	6.2 (3.2-9.3)
50-64	9.0 (7.6-10.4)	12.4 (8.4-16.3)	15.4 (10.6-20.2)
65-74	15.3 (12.7-17.8)	21.4 (14.6-28.3)	16.5 (9.0-24.1)
≥75	11.6 (9.2-13.9)	22.1 (12.0-32.2)	27.1 (16.3-37.8)
Subtotal	8.0 (7.2-8.7)	11.3 (9.1-13.4)	11.7 (9.3-14.2)
Total	7.5 (7.0-8.0)	14.0 (12.4-15.6)	13.3 (11.5-15.2)
No. of Persons With Diabetes Mellitus (Expressed in Thousands) (95% CI)			
Women			
40-49	489 (351-627)	188 (121-254)	127 (74-179)
50-64	1174 (990-1357)	480 (375-585)	386 (286-486)
65-74	862 (729-995)	218 (163-273)	98 (62-134)
≥75	943 (786-1101)	178 (112-243)	74 (38-111)
Subtotal	3468 (3159-3777)	1064 (913-1215)	685 (561-809)
Men			
40-49	383 (270-495)	126 (63-188)	128 (65-192)
50-64	1427 (1206-1647)	230 (157-303)	226 (156-297)
65-74	1044 (870-1218)	141 (96-186)	78 (43-114)
≥75	607 (483-732)	89 (48-130)	68 (41-96)
Subtotal	3461 (3133-3789)	586 (473-699)	500 (395-605)
Total	6929 (6479-7379)	1650 (1461-1839)	1185 (1023-1347)

Abbreviation: CI, confidence interval.

*Estimates for the number of persons with diabetes mellitus are based on an adaption from the 1999 National Health Interview Survey Public Use Data Release¹⁹ and 2000 US Census Population Estimates.²⁰

female persons had higher rates than male persons (OR=2.53, $P=.03$). No statistically significant differences were observed between gender in any racial/ethnic group for DR, nor were substantial gender differences in the prevalence of VTDR observed in white and Hispanic persons.

Differences in the prevalence of DR between racial/ethnic groups in the US general population were larger than the differences among persons with DM, because of statistically significant differences between racial/ethnic groups in the prevalence of DM. Higher rates of DR in the general population were observed for Hispanic compared with white persons (OR=1.42, $P<.001$; OR=1.63, $P<.001$ excluding the WESDR data), and for Hispanic compared with black persons (OR=1.52, $P=.01$). Black persons also tended to have higher rates of DR than white persons (OR=1.32, $P=.10$; OR=1.75, $P<.001$ excluding the WESDR data). For VTDR in the general population, higher rates were observed in Hispanic compared with white persons (OR=1.75, $P=.04$; OR=2.47, $P=.004$ excluding the WESDR data), and for black compared with white persons (OR=1.32, $P=.02$; OR=1.51, $P=.003$ excluding the WESDR data). Rates of VTDR for Hispanic and black persons were similar (OR=1.00, $P=.98$).

Applying age-, gender-, and race/ethnicity-specific rates of DR among persons with DM 40 years and older to projected changes in the US population in the future,

assuming the prevalence of DM remains constant in the interval, the projected prevalence rates of DR and of VTDR are approximately 3.95% (6.1 million persons) and 0.88% (1.4 million persons), respectively, for 2020. If the expected increase in the prevalence of DM during the interval is considered, approximately 4.64% (7.2 million persons) and 1.02% (1.6 million persons) of the US general population 40 years and older, respectively, can be expected to have DR and VTDR in 2020.

COMMENT

The results of our pooled analysis indicate that diabetic retinopathy affects approximately two fifths of persons 40 years and older who identify themselves as having DM. An estimated one twelfth of persons with DM in this age group have reached the stage of vision-threatening disease. Even though diabetic retinopathy is a disease occurring only among persons with DM, the prevalence of DM in the general population is high enough that diabetic retinopathy is highly prevalent in the general US adult population. Approximately 1 in 29 Americans 40 years and older (4.1 million persons) has diabetic retinopathy of any level of severity, and approximately 1 in 132 persons (899 000 persons) has VTDR. To the extent that the eyes randomized to deferral of therapy in the Diabetic Retinopathy Study reflect the extent of disease present in eyes of persons with VTDR in the current general

Table 5. Estimated Prevalence of Diabetic Retinopathy in the United States, by Age, Gender, and Race/Ethnicity*

Gender and Age Group, y	No. of Persons (Expressed in Thousands)			Total US Population†	
	White Persons	Black Persons	Hispanic Persons	Persons With DR (95% CI)	Prevalence per 100 Persons (95% CI)
Any Retinopathy					
Women					
40-49	165	52	36	265 (185-344)	1.23 (0.86-1.60)
50-64	474	138	118	767 (656-879)	3.55 (3.04-4.07)
54-74	390	64	44	513 (432-594)	5.08 (4.28-5.89)
≥75	431	46	39	533 (432-633)	5.08 (4.12-6.04)
Subtotal	1460	300	237	2078 (1890-2266)	3.26 (2.97-3.56)
Men					
40-49	198	43	49	324 (239-410)	1.54 (1.13-1.95)
50-64	567	81	109	815 (689-941)	4.02 (3.40-4.65)
65-74	464	28	38	555 (457-653)	6.69 (5.50-7.87)
≥75	231	20	34	291 (222-360)	4.77 (3.63-5.90)
Subtotal	1460	172	230	1985 (1791-2180)	3.57 (3.22-3.92)
Both women and men					
40-49	363	95	85	589 (472-706)	1.38 (1.11-1.66)
50-64	1041	219	227	1582 (1414-1751)	3.78 (3.38-4.18)
65-74	854	92	82	1068 (940-1195)	5.81 (5.11-6.50)
≥75	662	66	73	824 (7.02-946)	4.96 (4.23-5.70)
Total	2920	472	467	4063 (3793-4334)	3.40 (3.18-3.63)
Vision-Threatening Retinopathy					
Women					
40-49	85	14	4	73 (30-117)	0.34 (0.14-0.54)
50-64	111	46	26	193 (147-238)	0.89 (0.68-1.10)
65-74	76	27	8	115 (83-147)	1.14 (0.82-1.46)
≥75	60	20	6	90 (52-128)	0.86 (0.49-1.22)
Subtotal	299	107	44	471 (391-551)	0.74 (0.61-0.87)
Men					
40-49	28	10	9	53 (26-80)	0.25 (0.13-0.38)
50-64	158	28	22	223 (165-281)	1.10 (0.82-1.39)
65-74	80	2	10	97 (64-131)	1.17 (0.77-1.57)
≥75	45	5	5	55 (26-84)	0.90 (0.43-1.38)
Subtotal	311	45	46	428 (351-506)	0.77 (0.63-0.91)
Both women and men					
40-49	80	24	13	126 (75-177)	0.30 (0.18-0.42)
50-64	269	74	48	416 (342-489)	0.99 (0.82-1.17)
65-74	156	29	18	212 (166-259)	1.15 (0.90-1.41)
≥75	105	25	11	145 (97-193)	0.86 (0.59-1.16)
Total	610	152	90	899 (788-1011)	0.75 (0.66-0.85)

Abbreviation: CI, confidence interval.

*All estimates are based on the 2000 US Census population.²⁰ Estimates for the prevalence of diabetic retinopathy in the total US population include estimates for other races (Asian, Native American, Alaska Native, Native Hawaiian, and other Pacific Islander, and any other race/ethnicity) and those designating more than 1 race on the 2000 US Census form. These estimates were derived from models using an unweighted average of the pooled age- and gender-specific rates for white, black, and Hispanic persons. Additional tables are available at Web site: <http://www.nei.nih.gov/eyedata>.

population, one third of the persons with VTDR (approximately 1 in 400, or 300 000 persons) would be expected to reach the legal blindness level (visual acuity of 20/200 or worse) in the affected eye(s) within 3 years absent appropriate application of photocoagulation, but only half to one tenth that many (1 in 800 to 1 in 4000 persons) if appropriate photocoagulation treatment is applied.^{17,23} The current proportions of visual impairment and blindness in the general population attributable to diabetic retinopathy are reviewed in our accompanying article on visual impairment and blindness.²⁴

While the general population prevalence rates for DR and VTDR are likely to be lower in younger persons, owing to the lower prevalence of DM in younger age groups,¹⁹ prevalence of type 2 DM is increasing in younger persons,²⁵ so this difference may narrow in the future.

The prevalence of diabetic retinopathy specifically among persons with type 1 DM is described in an accompanying article by Roy et al²⁶ in this issue. Because the prevalence of DR was higher in that group than in the current pooled analysis, our assumption that the prevalence of DR among persons with type 2 DM in the WESDR and San Antonio Heart studies was approximately representative of the prevalence of DR in the general adult population aged 40 years and older probably led to some degree of underestimation of prevalence values.

Among persons with DM, the prevalence of DR did not vary substantially by age group or gender—only small differences were observed, and their pattern was inconsistent. However, the general population prevalence of DR clearly increased with age, driven by the increasing prevalence of DM with age, but then declined beginning

at the age of 75 years. A similar pattern of reduced diabetic retinopathy prevalence in the oldest age groups was observed in Model Reporting Area data in 1970²⁷ and in the WESDR.²⁸ It seems likely that the apparently reduced prevalence of DR in the elderly could be explained on the basis of reduced survival among elderly persons with DR (possibly a marker for more severe DM and its life-threatening consequences). Although this theory cannot be tested directly in our pooled analysis, evidence supporting it has been observed in the WESDR.²⁹

Although the prevalence of retinopathy among persons with DM appeared to vary by racial/ethnic group, comparison of prevalence rates in white persons with DM with respect to Hispanic and black persons with DM was difficult to interpret, because conclusions differed depending on whether or not the WESDR results were included. Likewise, comparisons involving black persons were based on the results of a single study, which used slightly different retinopathy severity definitions that we could not perfectly adjust for. Considering these limitations, our data suggest that the prevalence of DR is higher among Hispanic than black persons with DM, and may be higher among Hispanic than white persons with DM. These interpretations are supported by concordant observations from the population-based Third National Health and Nutrition Examination Survey,³⁰ which was excluded from our pooled analysis because diabetic retinopathy was ascertained based on a single nonmydriatic image of the posterior pole. However, the prevalence of VTDR (not described in the Third National Health and Nutrition Examination Survey report) was similar between racial/ethnic groups. Further research using a nationally representative sample would be useful to clarify whether the risk of VTDR among persons with DM varies by race or ethnicity. Our study did not have appropriate data to evaluate the prevalence of diabetic retinopathy in other racial/ethnic groups, such as Asians, who represent a fast-growing segment of the US population.

From the general population perspective, however, large differences in the prevalence of diabetic retinopathy between racial/ethnic groups exist, driven by racial/ethnic differences in the underlying prevalence of DM. Hispanic persons had the highest prevalence of DR—1.4- to 1.6-fold higher odds than in white persons, and about 1.5-fold higher than in black persons—and also had higher rates of VTDR than did white persons. No significant difference in the general population prevalence of VTDR between Hispanic and black persons was observed. The odds of diabetic retinopathy among black persons, both DR and VTDR, was about 1.3-fold higher than among white persons, but this difference was only statistically significant for VTDR.

Although these results are based on the best available data, our estimates must be interpreted with caution for several reasons. Our results attempt to estimate the situation based on the status of a limited number of persons with DM who were identified in population-based samples from specific regions, 4440 people in all (including only 615 black subjects from a single Caribbean location). Because differences between geographic locations in diet, use of medical care, and socioeconomic factors might affect the prevalence of diabetic reti-

nopathy, a more robust approach would have been to use a larger, nationally representative sample; but appropriate data from such a group are unavailable. Hispanic rates are based on results from predominantly Mexican American populations in Arizona, Colorado, and Texas, whereas other Hispanic subgroups might differ in their prevalence rates. Because the estimates of the prevalence of DR are based on a smaller sample than that for the other diseases the Eye Diseases Prevalence Research Group addressed, confidence intervals are correspondingly wider.

It is known that a substantial number of persons with DM are unaware that they have DM, and that such persons may have diabetic retinopathy.¹⁰ Our pooled analysis was constrained to use self-reported DM to obtain DM prevalence values because evidence suggests that the prevalence of DM is rising over time,²² and no current, nationally representative examination survey results will be available until the next National Health and Nutrition Examination Survey report. Because of this limitation, it is best to interpret our general population-level results as reflecting the prevalence of diabetic retinopathy among persons 40 years and older who think they have DM. It is likely that additional persons, unaware of that they have DM, have diabetic retinopathy as well. In the Beaver Dam Eye Study, Beaver Dam, Wis.,¹⁰ The Rancho Bernardo Study, Rancho Bernardo, Calif.,³¹ and Proyecto VER study,¹³ the proportion of persons with previously undiagnosed DM who had diabetic retinopathy was 10.2%, 0.6%, and about 20%, respectively. Retinopathy meeting our VTDR definition was present in 2%⁹ and 0%,³¹ respectively, of the Beaver Dam and Rancho Bernardo subjects, while in Proyecto VER, about 2%¹³ had proliferative diabetic retinopathy or macular edema. These results suggest that persons not known to have DM have a low frequency of advanced, vision-threatening retinopathy.³² Therefore, our results may underestimate the overall prevalence of diabetic retinopathy in the general US population in this age group to an appreciable degree, but probably only slightly underestimate the prevalence of VTDR.

Another limitation of our study is the absence of data on the type of DM, the duration of DM, and on the degree of hyperglycemia and hypertension each subject experienced. We were unable to include these aspects in the pooled analysis because this information was not uniformly collected by all the participating studies in a way that could be combined. Therefore, we were unable to estimate the prevalence of diabetic retinopathy conditional on values of these critical variables, information that would be useful in clinical practice. However, such information is available from the primary WESDR reports,^{2,9,28,33,34} the San Luis Valley Diabetes Study,¹⁵ the San Antonio Heart Study,³⁵ the Third National Health and Nutrition Examination Survey,^{30,36} and other sources.

The lack of such information also makes it difficult to interpret the higher prevalence rates for diabetic retinopathy reported by the WESDR with respect to the other contributing studies. It seems likely, but cannot be proven, that the differences arise from poorer glycemic control, longer duration of DM, differences in blood pressure status, and/or an excess of other risk factors for diabetic retinopathy among WESDR subjects with respect to sub-

jects in more recent studies, resulting in higher prevalence values. Supporting this theory is clinical experience suggesting that the primary care of persons with DM has improved over time since the early 1980s, when the WESDR was conducted, with the incorporation of recommendations based on the observations of the Diabetes Control and Complications Trial,^{3,37} the United Kingdom Prospective Diabetes Study,^{4,5} and other studies. Improved control of blood glucose levels, blood pressure, and serum lipid levels is likely to reduce the incidence, rate of progression, and/or severity of diabetic retinopathy. On these grounds, an argument can be made that the WESDR results may be less generalizable to the US population in 2000 than the results of more recent studies. However, it seems surprising that a large change in the population risk of diabetic retinopathy would have occurred in the span of the few years that elapsed between the WESDR (1980-1982) and the Beaver Dam Eye Study (1988-1990), conducted in the same region. Because the WESDR was the most comprehensive study of diabetic retinopathy conducted to date, we have elected to include its data in developing the prevalence estimates reported herein. However, we also have provided the overall values for the estimated prevalence of DR and of VTDR that would have been obtained had the WESDR data been excluded, which are lower. Under either scenario, the estimated prevalence rates for DR and VTDR are high from a population perspective.

Unknown future secular trends in the risk of diabetic retinopathy limit our ability to make future diabetic retinopathy prevalence projections. For instance, improvements in the effectiveness of primary DM care over time could reduce the incidence of diabetic retinopathy and its rate of progression (as the preceding sentence states). However, improved DM care also could result in improved survival. More time at risk of diabetic retinopathy could potentially balance the effects of a lower risk per unit time on prevalence rates. It is impossible to predict reliably what effects secular trends occurring between now and 2020 will have on the prevalence of DR and VTDR. Therefore, our projections should be interpreted with an especially high degree of caution.

A strength of our study is that determinations of the outcomes for all studies were made using gold standard, highly reproducible techniques anchored by standard photograph reference points. The outcomes can be compared using the ETDRS scale,^{7,8} except for the Barbados Eye Study, which had slightly different definitions as described earlier. However, the number of standard fields photographed was not identical between studies, which could have contributed to slightly lower prevalence estimates from the studies imaging fewer fields. It has been demonstrated that 2-, 3-, and 4-field protocols have reasonable agreement with standard 7-field imaging using the Diabetic Retinopathy Study protocol,³⁸ particularly when the categorization of retinopathy was collapsed into fewer categories (85%, 93%, and 95% agreement with 7-field results, respectively)³⁹ in a manner similar to that used in our analysis. Therefore, underascertainment of diabetic retinopathy in studies using fewer than 7 fields is likely to have been on the order of 5% to 15%. Inspection of the crude prevalence rates for the various studies

(Table 2) demonstrates that the studies using larger numbers of photographic fields did not consistently have higher prevalence rates, suggesting that the degree of underascertainment of DR resulting from imaging fewer fields was probably small compared with other factors influencing prevalence rates. Nevertheless, underascertainment of diabetic retinopathy because of a small number of photographic fields is another factor that may have made our estimates of the prevalence of diabetic retinopathy among persons with DM artificially low.

In this study, we have opted to report actual results of the pooled analysis, rather than attempting to impute the effects of the various study limitations on prevalence rates. Although these problems impose limitations on the reliability of our estimates, no better methods for estimation of the burden of diabetic retinopathy in the US population are available. Our results provide an estimate as to what that burden of diabetic retinopathy may be, which should be useful for decisions regarding health policy and research priorities. Even if the true burden of diabetic retinopathy were considerably lower than we have estimated, diabetic retinopathy still would be a major public health problem in the United States. Because most of the study limitations would be expected to lead to underestimation of the prevalence of DR, it is more likely that our estimates are too low rather than too high.

Unlike other age-related eye diseases, diabetic retinopathy often causes blindness during the working-age years, resulting in a larger number of person-years of vision lost per case, more disability during the working years per case, and correspondingly large economic costs.^{32,40,41} In addition, most vision loss due to diabetic retinopathy is avoidable, through primary prevention (intensive control of hyperglycemia,^{3,37,42} hypertension,⁵ and of other risk factors for diabetic retinopathy), and secondary prevention (detecting high-risk diabetic retinopathy in time to apply palliative laser therapy^{17,43,44}). Because diabetic retinopathy is often asymptomatic during the period in which laser photocoagulation should be applied, screening of asymptomatic persons is needed to minimize the risk of vision loss.¹ Although it is recognized that the benefits of screening and treatment outweigh the costs, even from a purely financial perspective,^{40,41,45} many persons with DM do not presently receive such management.⁴⁶ It is our hope that this description of the extent of the problem of diabetic retinopathy in the United States will stimulate further efforts to prevent blindness from this disease.

CONCLUSIONS

The prevalence of diabetic retinopathy in the United States is high. An estimated 4.1 million persons age 40 and older in the US general population have diabetic retinopathy, 1 in 29 persons. An estimated 899 000 persons in this age range have vision-threatening diabetic retinopathy, 1 in 132 persons. The prevalence of diabetic retinopathy is expected to increase substantially by 2020, driven by an increasing prevalence of DM over time with the aging of the US population, in combination with anticipated increases in the age-specific prevalence of DM. Because diabetic reti-

The members of the Eye Diseases Prevalence Research Group, Diabetic Retinopathy subsection are as follows:

Participating Studies

The Barbados Eye Studies, Barbados, West Indies: M. Cristina Leske; Suh-Yuh Wu; Barbara Nemesure; Anselm Hennis; Leslie Hyman; Andrew Schachat. *Beaver Dam Eye Study, Beaver Dam, Wis:* Barbara E. K. Klein; Ronald Klein; Scot E. Moss. *Blue Mountains Eye Study, Sydney, New South Wales, Australia:* Paul Mitchell; Jie Jin Wang; Elena Rojchchina; Wayne Smith; Robert G. Cumming; Karin Attebo; Jai Panchapakesan; Suriya Foran. *Melbourne Visual Impairment Project, Melbourne, Australia:* Hugh R. Taylor; Cathy McCarty; Bickol Mukesh; LeAnn M. Weih; Patricia M. Livingston; Mylan Van Newkirk; Cara L. Fu; Peter Dimitrov; Matthew Wensor; Yuri Stanislavsky. *Proyecto Vision Evaluation Research, Ariz:* Sheila K. West; Ronald Klein; Jorge Rodriguez (deceased); Beatriz Muñoz; Aimee T. Broman; Robert Snyder; Harry A. Quigley. *San Antonio Heart Study, San Antonio, Tex:* Steven M. Haffner; Donald Fong; Michael P. Stern; Jacqueline A. Pugh; Helen P. Hazuda; Judith K. Patterson; Wichard A. van Heuven; Ronald Klein. *San Luis Valley Diabetes Study, San Luis Valley, Colo:* Richard F. Hamman; Elizabeth Mayer-Davis; Julie A. Marshall; Judy Baxter. *Wisconsin Epidemiologic Study of Diabetic Retinopathy,* Ronald Klein; Barbara E. K. Klein; Scot E. Moss.

Resource Centers

Meta-analysis Coordinating Center, Baltimore, Md: John H. Kempen, Diabetic Retinopathy Subsection; David S. Friedman; Nathan G. Congdon; Benita J. O'Colmain.
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nopathy is a substantial public health problem, public and private policy efforts directed toward improving primary and secondary prevention programs are warranted.

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REFERENCES

1. American Academy of Ophthalmology. *Preferred Practice Pattern: Diabetic Retinopathy*. San Francisco, Calif: American Academy of Ophthalmology; 1998.
2. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. The Wisconsin Epidemiologic Study of Diabetic Retinopathy, II: prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years. *Arch Ophthalmol*. 1984;102:520-526.
3. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993;329:977-986.
4. Stratton IM, Kohner EM, Aldington SJ, et al. UKPDS 50: risk factors for incidence and progression of retinopathy in type II diabetes over 6 years from diagnosis. *Diabetologia*. 2001;44:156-163.
5. UK Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38 [published erratum appears in *BMJ*. 1999;318:29]. *BMJ*. 1998;317:703-713.
6. Schrier RW, Estacio RO, Esler A, Mehler P. Effects of aggressive blood pressure control in normotensive type 2 diabetic patients on albuminuria, retinopathy and strokes. *Kidney Int*. 2002;61:1086-1097.
7. Early Treatment Diabetic Retinopathy Study Research Group. Fundus photographic risk factors for progression of diabetic retinopathy: ETDRS report number 12. *Ophthalmology*. 1991;98(suppl):823-833.
8. Early Treatment Diabetic Retinopathy Study Research Group. Grading diabetic retinopathy from stereoscopic color fundus photographs: an extension of the modified Airlie House classification: ETDRS report number 10. *Ophthalmology*. 1991;98(suppl):786-806.
9. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. The Wisconsin Epidemiologic Study of Diabetic Retinopathy, III: prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years. *Arch Ophthalmol*. 1984;102:527-532.
10. Klein R, Klein BE, Moss SE, Linton KL. The Beaver Dam Eye Study: retinopathy in adults with newly discovered and previously diagnosed diabetes mellitus. *Ophthalmology*. 1992;99:58-62.
11. Leske MC, Wu SY, Hyman L, et al. Diabetic retinopathy in a black population: the Barbados Eye Study. *Ophthalmology*. 1999;106:1893-1899.
12. Mitchell P, Smith W, Wang JJ, Attebo K. Prevalence of diabetic retinopathy in an older community: the Blue Mountains Eye Study. *Ophthalmology*. 1998;105:406-411.
13. West SK, Klein R, Rodriguez J, et al. Diabetes and diabetic retinopathy in a Mexican-American population: Proyecto VER. *Diabetes Care*. 2001;24:1204-1209.
14. Haffner SM, Hazuda HP, Stern MP, Patterson JK, Van Heuven WA, Fong D. Ef-

- fects of socioeconomic status on hyperglycemia and retinopathy levels in Mexican Americans with NIDDM. *Diabetes Care*. 1989;12:128-134.
15. Hamman RF, Mayer EJ, Moo-Young GA, Hildebrandt W, Marshall JA, Baxter J. Prevalence and risk factors of diabetic retinopathy in non-Hispanic whites and Hispanics with NIDDM: San Luis Valley Diabetes Study. *Diabetes*. 1989;38:1231-1237.
 16. McKay R, McCarty CA, Taylor HR. Diabetic retinopathy in Victoria, Australia: the Visual Impairment Project. *Br J Ophthalmol*. 2000;84:865-870.
 17. The Diabetic Retinopathy Study Research Group. Photocoagulation treatment of proliferative diabetic retinopathy: clinical application of Diabetic Retinopathy Study (DRS) findings: DRS report number 8. *Ophthalmology*. 1981;88:583-600.
 18. Schachat AP, Hyman L, Leske MC, et al, for the Barbados (West Indies) Eye Study Group. Comparison of diabetic retinopathy detection by clinical examinations and photograph gradings. *Arch Ophthalmol*. 1993;111:1064-1070.
 19. 1999 National Health Interview Survey (NHIS) Public Use Data Release. NHIS Survey Description. Division of Health Interview Statistics NCHS. Available at: ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/1999/srvydesc.pdf. Accessed September 30, 2002.
 20. US Census 2000 Population Tables were obtained from: US Census 2000 Summary File 1 (SF 1) 100-Percent Data. Available at: http://factfinder.census.gov/servlet/DatasetMainPageServlet?_lang=en. Accessed January 1, 2003.
 21. Lachin JM. *Biostatistical Methods*. New York, NY: John Wiley & Sons Inc; 2000.
 22. Boyle JP, Honeycutt AA, Narayan KM, et al. Projection of diabetes burden through 2050: impact of changing demography and disease prevalence in the US. *Diabetes Care*. 2001;24:1936-1940.
 23. Ferris FL III. How effective are treatments for diabetic retinopathy? *JAMA*. 1993;269:1290-1291.
 24. The Eye Diseases Prevalence Research Group. Causes and prevalence of visual impairment among adults in the United States. *Arch Ophthalmol*. 2004;122:477-485.
 25. American Diabetes Association. Type 2 diabetes in children and adolescents. *Diabetes Care*. 2000;23:381-389.
 26. Roy MS, Klein R, O'Colmain BJ, et al. The prevalence of diabetic retinopathy among adult type 1 diabetic persons in the United States. *Arch Ophthalmol*. 2004;122:546-551.
 27. Kahn HA, Moorhead HB. *Statistics on Blindness in the Model Reporting Area, 1969-1970*. Washington, DC: National Eye Institute, Superintendent of Documents, US Government Printing Office; 1973. NIH publication 73-427.
 28. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. The Wisconsin Epidemiologic Study of Diabetic Retinopathy, X: four-year incidence and progression of diabetic retinopathy when age at diagnosis is 30 years or more. *Arch Ophthalmol*. 1989;107:244-249.
 29. Klein R, Klein BE, Moss SE, Cruickshanks KJ. Association of ocular disease and mortality in a diabetic population. *Arch Ophthalmol*. 1999;117:1487-1495.
 30. Harris MI, Klein R, Cowie CC, Rowland M, Byrd-Holt DD. Is the risk of diabetic retinopathy greater in non-Hispanic blacks and Mexican Americans than in non-Hispanic whites with type 2 diabetes? a US population study. *Diabetes Care*. 1998;21:1230-1235.
 31. Klein R, Barrett-Connor EL, Blunt BA, Wingard DL. Visual impairment and retinopathy in people with normal glucose tolerance, impaired glucose tolerance, and newly diagnosed NIDDM. *Diabetes Care*. 1991;14:914-918.
 32. Klein R, Klein BEK. Vision disorders in diabetes. In: National Diabetes Data Group, ed. *Diabetes in America*. Bethesda, Md: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; 1995:293-338. NIH publication 95-1468.
 33. Klein R, Klein BE, Moss SE, Davis MD, DeMets DL. The Wisconsin Epidemiologic Study of Diabetic Retinopathy, IX: four-year incidence and progression of diabetic retinopathy when age at diagnosis is less than 30 years. *Arch Ophthalmol*. 1989;107:237-243.
 34. Klein R, Klein BE, Moss SE, Cruickshanks KJ. The Wisconsin Epidemiologic Study of Diabetic Retinopathy, XIV: ten-year incidence and progression of diabetic retinopathy. *Arch Ophthalmol*. 1994;112:1217-1228.
 35. Haffner SM, Fong D, Stern MP, et al. Diabetic retinopathy in Mexican Americans and non-Hispanic whites. *Diabetes*. 1988;37:878-884.
 36. Harris MI, Robbins DC. Prevalence of adult-onset IDDM in the US population. *Diabetes Care*. 1994;17:1337-1340.
 37. The Diabetes Control and Complications Trial. The effect of intensive diabetes treatment on the progression of diabetic retinopathy in insulin-dependent diabetes mellitus. *Arch Ophthalmol*. 1995;113:36-51.
 38. Diabetic retinopathy study. Report Number 7. A modification of the Airle House classification of diabetic retinopathy. Prepared by the Diabetic Retinopathy Study Group. *Invest Ophthalmol Vis Sci*. 1981;21(pt 2):210-226.
 39. Moss SE, Meuer SM, Klein R, Hubbard LD, Brothers RJ, Klein BE. Are seven standard photographic fields necessary for classification of diabetic retinopathy? *Invest Ophthalmol Vis Sci*. 1989;30:823-828.
 40. Chiang YP, Bassi LJ, Javitt JC. Federal budgetary costs of blindness. *Milbank Q*. 1992;70:319-340.
 41. Javitt JC, Aiello LP, Bassi LJ, Chiang YP, Canner JK, for American Academy of Ophthalmology. Detecting and treating retinopathy in patients with type I diabetes mellitus: savings associated with improved implementation of current guidelines. *Ophthalmology*. 1991;98:1565-1573.
 42. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet*. 1998;352:854-865.
 43. British Multicentre Study Group. Photocoagulation for diabetic maculopathy: a randomized controlled clinical trial using the xenon arc. *Diabetes*. 1983;32:1010-1016.
 44. Early Treatment Diabetic Retinopathy Study Research Group. Photocoagulation for diabetic macular edema: Early Treatment Diabetic Retinopathy Study Report Number 1. *Arch Ophthalmol*. 1985;103:1796-1806.
 45. Javitt JC, Aiello LP. Cost-effectiveness of detecting and treating diabetic retinopathy. *Ann Intern Med*. 1996;124(pt 2):164-169.
 46. Kraft SK, Marrero DG, Lazaridis EN, Fineberg N, Qiu C, Clark CM Jr. Primary care physicians' practice patterns and diabetic retinopathy: current levels of care. *Arch Fam Med*. 1997;6:29-37.