



Twenty-Year Trends in Prevalence and Incidence of Diabetic Retinal Disease

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Purpose: To determine how the rates of diabetic retinal disease (DRD) and its vision-threatening components (VTDR), diabetic macular edema (DME), and proliferative diabetic retinopathy (PDR) among patients with diabetes mellitus (DM) have changed over the past 20 years.

Design: Retrospective cohort study.

Participants: All DM patients insured by commercial and Medicare Advantage insurance plans in a claims database from 2000 through 2022 and at least 1 full calendar year of data. Cohorts were created using International Classification of Diseases codes to determine the yearly prevalence and incidence of DRD, VTDR, DME, and PDR.

Methods: Logistic and Poisson regression models created prevalence and incidence estimates, respectively.

Main Outcome Measures: DRD, DME, and PDR prevalence and incidence.

Results: The prevalence of DRD initially decreased from 2001 (13.6%) to 2007 (10.9%), but then increased every year through 2021 (20.8%; $P < 0.001$, adjusted test for trend [aTT]). Incidence of DRD varied considerably, ranging from 16.9 cases per 1000 patient-years in 2013 to its highest of 32.2 cases per 1000 patient-years in 2021 ($P < 0.001$, aTT). The prevalence of VTDR and DME trended similarly, with increases from 2007 (VTDR, 5.2%; DME, 3.2%) through 2016 (VTDR, 7.5%; DME, 5.4%), followed by decreases each year through 2021 (VTDR, 6.9%; DME, 4.9%; $P < 0.001$, aTT). The VTDR and DME incidence rates peaked in 2009 (VTDR, 12.4 cases per 1000 patient-years; DME, 8.6 cases per 1000 patient-years) and decreased through 2022 (VTDR, 6.1 cases per 1000 patient-years; DME, 5.0 cases per 1000 patient-years; $P < 0.001$, aTT, for both VTDR and DME). Prevalence of PDR varied between 3.2% and 4.0% throughout the 20-year observation period ($P < 0.001$, aTT). Incidence of PDR decreased over time to 2.6 cases per 1000 patient-years in 2022 ($P < 0.001$, aTT).

Conclusions: DRD prevalence (through 2007) and incidence (through 2014) initially decreased, but the rate of each has doubled since. Despite increases in DRD, incidence rates of VTDR, DME, and PDR have improved dramatically over the past 20 years.

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According to diabetic focus groups, blindness resulting from diabetic retinal disease (DRD) is one of the most feared complications of diabetes mellitus (DM).¹ Diabetic retinal disease is the leading cause of blindness in working-age adults.² As with any pressing public health concern, tracking the disease is paramount to understanding its impact on society and creating effective policies to combat its effects.

Initiated in 1979, the Wisconsin Epidemiologic Study of Diabetic Retinopathy was the sentinel study to assess DRD rates and is still cited as a primary source for prevalence data 45 years later.^{3,4} Historically, the United States has used population-based studies to determine DRD rates^{5–7}; however, the most recent of these studies is more than 15 years old.⁸ Since then, other avenues of estimating disease rates have been used.^{9–12} However, most of these analyses have been fragmented, focusing only on specific forms of DRD in specified age groups. Further, they do not address the other important factor in understanding the future of DRD: incidence.

The limited data on DRD trends also do not capture the fact that numerous advances have improved the systemic care of patients with DM, including 4 new classes of antidiabetic medications, more physiologic insulin analogs, and advanced technology in insulin delivery and glucose monitoring over the past 20 years.¹³ Also impacting DM care in the United States is the Affordable Care Act, which has been responsible for an increase in the proportion of patients with DM who have insurance coverage and access to health care resources.^{14,15} From 1999 through 2010 in the United States, significant gains in glycemic control were made; however since then, control has worsened.¹⁶ Also counteracting the advances in care is the increasing incidence of patients with DM, leading to an ever-expanding population at risk of DRD and vision problems.¹⁷ How these conflicting effects have impacted the prevalence and incidence of DRD and vision-threatening diabetic retinopathy (VTDR) in the United States has yet to be assessed fully. This study aimed to understand better the

current trends in prevalence and incidence of DRD and its vision-threatening forms in the United States using a longitudinal dataset with more than 20 years of data.

Methods

Study Dataset

Data were abstracted from Optum's de-identified Clinformatics Data Mart Database. This database is derived from administrative health claims for members of large commercial and Medicare Advantage health plans. Clinformatics uses medical and pharmacy claims to derive patient-level enrollment information and health care resource use information. The population is geographically diverse, spanning all 50 states. The subset of data available for this study included all patients in the database from April 1, 2000, through June 30, 2022. The longitudinal nature and large size of the dataset allow it to offer a unique view into trends the prevalence and incidence of DRD in the United States. This study adhered to the tenets of the Declaration of Helsinki. Because of the de-identified nature of the data, the University of Pennsylvania's institutional review board deemed this study exempt from review and informed consent was waived. The STROBE checklist for observational studies was followed throughout this study.

Cohorts

All patients with DM, defined as having 1 or more International Classification of Diseases (ICD), Ninth or Tenth Revision, codes corresponding to DM, were used to create the prevalence cohort (See [Table S1](#) [available at www.aaojournal.org] for codes used in this study). The first date that a DM diagnosis code appeared was considered the index date. Patients coded with only prediabetes or who did not have a full calendar year of data in the dataset were excluded. A secondary cohort was created from all patients within the database regardless of DM status to estimate unadjusted population-level DRD prevalence. The index date for this cohort was defined as the date of enrollment. Patients who disenrolled were allowed to re-enter the analysis on re-enrollment.

An incidence cohort was created from all patients with DM and at risk of the DRD outcome of interest developing. The index date was considered either the first instance of a DM diagnosis code or the date 2 years after entry into the dataset, based on whichever date occurred later. Patients were excluded if they had any history of the DRD outcome of interest (outcomes outlined below). A 2-year look-back window was used to exclude patients with prevalent DRD. This length of look-back period has been shown to improve incident ocular disease identification greatly.¹⁸

Outcomes

The primary outcome was the yearly prevalence and incidence of DRD (any code for any level or form of DRD) among patients with DM. Secondary outcomes were the yearly prevalence and incidence of VTDR and its component disease states: diabetic macular edema (DME) and proliferative diabetic retinopathy (PDR). Previous studies have shown ICD coding for DRD, DME, and PDR to be highly reliable.^{19–21}

Statistical Analysis and Covariates

Prevalence and incidence of DRD, VTDR, DME, and PDR were calculated for each year among all patients with DM. Yearly prevalence estimates also were calculated among the entire dataset. Those with a diagnosis of an outcome in any specific year were counted toward the prevalence and incidence estimates in that year

and toward the prevalence for each subsequent year until disenrollment from the database. Any DRD outcome within the first 2 years of entry into the dataset was counted as a prevalent, but not incident, diagnosis. To reduce the possibility that an increase in prevalence rates was the result of patients simply accruing more time in the dataset as the years progressed, a sensitivity analysis was performed that limited ongoing prevalence to 3 years after the last date of the most recent diagnosis. Confidence intervals for estimates were based on the binomial distribution.

Logistic regression models were used to analyze the trends in prevalence.²² Because of the large sample size, it was infeasible computationally to account for within-person correlation across multiple years in these models, suggesting that *P* values may be underestimated. Poisson regression was used in incidence models. Initial analysis treated a calendar year as a continuous variable, but additional analyses divided calendar time into a categorical variable with delineations based on important landmarks in the treatment of DRD: 2002 through 2006 (representing the time of increasing use of OCT in ophthalmic practice), 2007 through 2011 (Food and Drug Administration approval of anti-vascular endothelial growth factor [VEGF] agents), 2012 through 2016 (anti-VEGF becomes first-line treatment of DME^{23–25}), and 2017 through 2022 (expansion of the use of anti-VEGF agents for PDR²⁶). In addition, an analysis that divides calendar time into 2 categories, up to and including 2010 and beyond 2010, was performed to coincide with the report finding hemoglobin A1c control in the United States improved, then worsened after 2010.¹⁶ All multivariable models evaluating changes in incidence and prevalence over time included the following covariates: age, interaction between age and year, race, sex, geographic location, insurance type, and yearly income.

Results

Prevalence

Of the 6 155 025 patients who had DM during their time in the plan, 1 041 613 patients received a diagnosis of DRD, with an overall prevalence of 16.9%. These diagnoses included 417 155 instances of VTDR, 286 215 instances of DME, and 225 137 instances of PDR, for longitudinal prevalence estimates of 6.8%, 4.7%, and 3.7%, respectively, among patients with DM. Among all 58 758 746 patients with a full calendar year in the dataset, the longitudinal prevalence was 2.1% for DRD. [Table S2](#) (available at www.aaojournal.org) shows the characteristics of the population of patients with DM in each year of evaluation.

The yearly prevalence of DRD among patients with DM decreased every year from 2001 (13.6%) through 2007 (10.9%), followed by an increase each year through 2021 (20.8%). See [Figure 1](#) for the graph of yearly DRD prevalence rates. The VTDR prevalence was lowest in 2007 (5.2%), increased through 2016 (7.5%), and then decreased through 2021 (6.9%). Prevalence of DME increased every year from 2001 (2.8%) through 2016 (5.4%), but then decreased through 2021 (4.9%). The prevalence of PDR varied from its low in 2007 (3.2%) to its high in 2015 (4.0%), but then decreased yearly through 2021 (3.5%). See [Figure 2](#) for graphs of prevalence and [Table S3](#) (available at www.aaojournal.org) for specific yearly prevalence estimates.

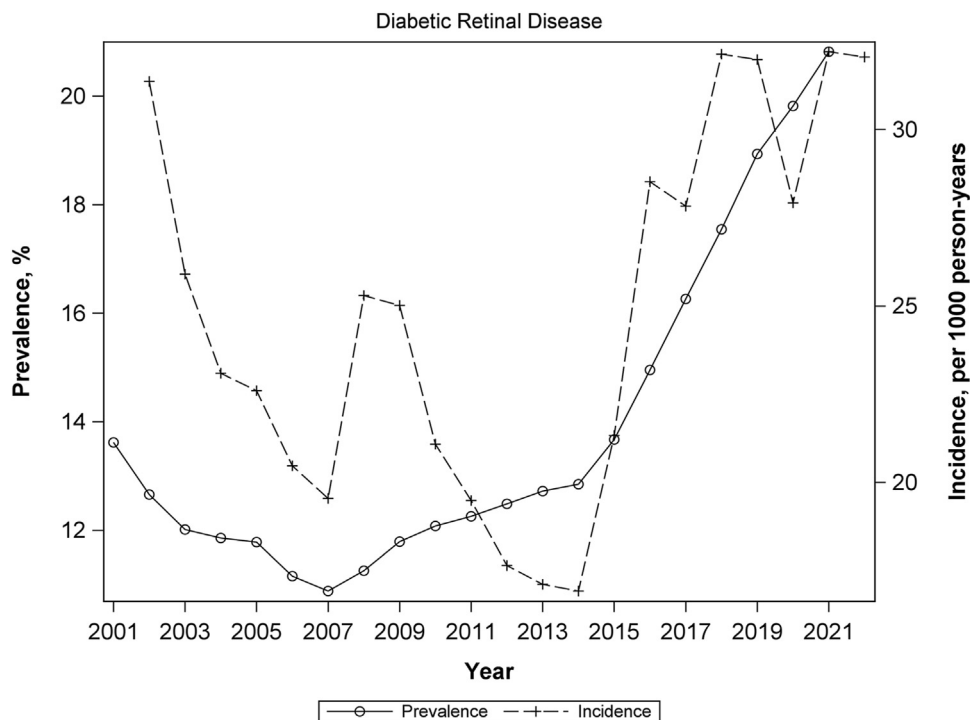


Figure 1. Graph showing the yearly prevalence and incidence of diabetic retinal disease among patients with diabetes mellitus.

Similar patterns emerged when categorical years were analyzed, with the prevalence of DRD being highest in the most recent years (2017 and earlier, 18.9%; 2011 and earlier, 16.5%). Both VTDR and DME showed similar trajectories that increased across each period (2006 and earlier, 2007 through 2011, and 2012 through 2016), but then decreased in the final period (2017 and beyond). Prevalence of PDR also peaked from 2012 through 2016 (3.9%), then decreased from 2017 and beyond (3.5%). Dichotomizing calendar years into 2010 and earlier versus 2011 and beyond showed that VTDR, DME, and PDR were all higher after 2010. All adjusted test for trend analyses showed significant trends as described above ($P < 0.001$ for all comparisons).

When considering the full dataset cohort (vs. the DM only cohort), the overall prevalence of DRD increased from 0.6% in 2001 to 4.1% in 2021. (See Table S4 [available at www.aaojournal.org] for study population-level prevalence estimates.) Results of the sensitivity analysis in which patients were counted as prevalent only for 3 years after the most recent diagnosis were the same qualitatively as in the primary analysis (see Table S5 [available at www.aaojournal.org] for sensitivity analysis results).

Incidence

Overall, 477 014, 172 885, 134 861, and 87 334 incident cases of DRD, VTDR, DME, and PDR occurred, respectively. Among patients with DM, longitudinal incidence rates were 25.8 cases per 1000 person-years, 8.5 cases per 1000 person-years, 6.5 cases per 1000 person-years, and 4.2 cases per 1000 person-years for DRD, VTDR, DME, and PDR, respectively.

The yearly DRD incidence rate among patients with DM varied until it reached its lowest level in 2014 (16.9 cases per 1000 person-years). The rate then increased, reaching its highest level in 2022 (32.1 cases per 1000 person-years). (See Table S6 [available at www.aaojournal.org] for yearly incidence rates.) The VTDR incidence rate showed an initial decrease from 2002 (13.6 cases per 1000 person-years) through 2007 (9.5 cases per 1000 person-years) and a large increase in 2008/2009 (12.4 cases per 1000 person-years), followed by a general decline through 2022 (6.1 cases per 1000 person-years). The yearly incidence rate for DME varied between 2003 and 2015 (lowest estimate in 2006, 6.9 cases per 1000 person-years; highest estimate in 2009, 8.6 cases per 1000 person-years). Then, the rate decreased from 2016 (6.8 cases per 1000 person-years) through 2022 (5.0 cases per 1000 person-years). The incidence rate of PDR showed a decrease over time, with the highest rate in 2002 (8.3 cases per 1000 person-years) and the lowest rate in 2022 (2.6 cases per 1000 person-years). See Figure 3 for graphs of yearly incidence of VTDR, DME, and PDR. All adjusted test-for-trend analyses showed significant trends as described above ($P < 0.001$ for all comparisons).

When years were grouped, the DRD incidence rate was higher in the period at or after 2011 (26.5 cases per 1000 person-years vs. 2010 or earlier, 23.0 cases per 1000 person-years). When grouped in 5- to 6-year increments, the DRD incidence rate decreased from 2006 and beyond (23.2 cases per 1000 person-years) through 2012 through 2016 (20.6 cases per 1000 person-years), then increased to its highest rate in the period from 2017 and beyond (30.7 cases per 1000 person-years; $P < 0.001$). The incidence

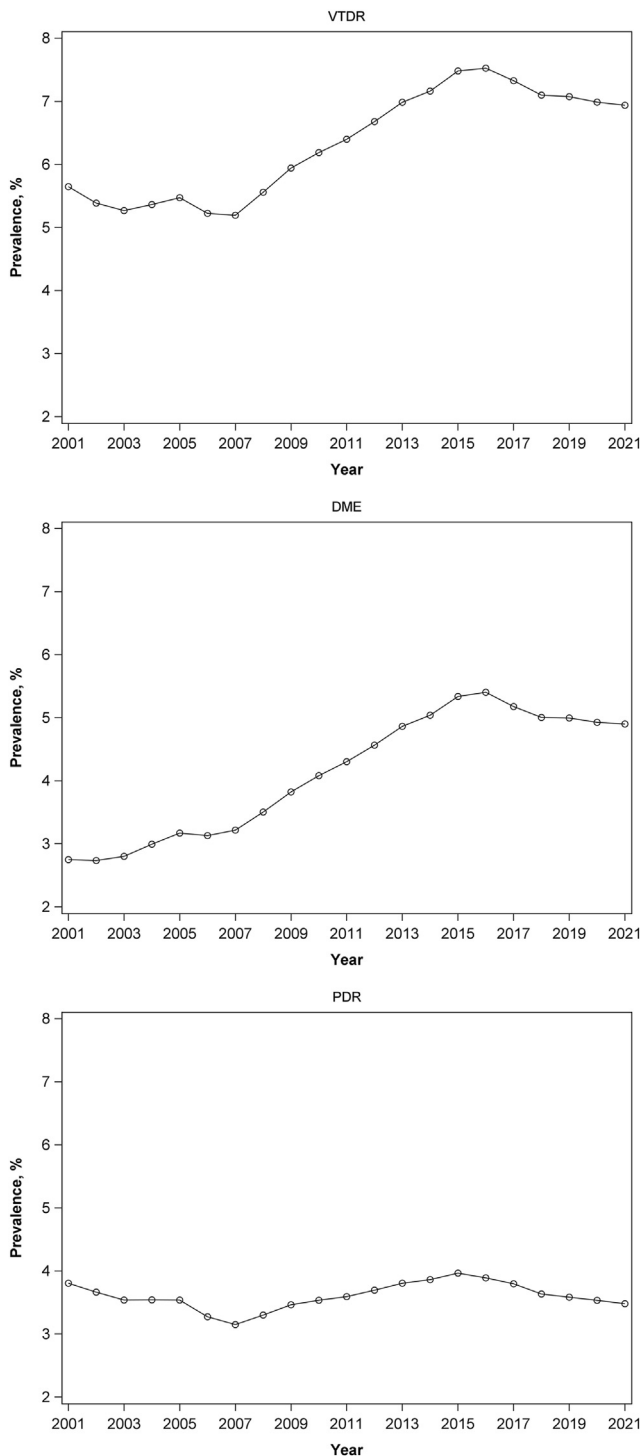


Figure 2. Graphs showing the yearly prevalence of (A) vision-threatening diabetic retinopathy (VTDR), (B) diabetic macular edema (DME), and (C) proliferative diabetic retinopathy (PDR) among patients with diabetes mellitus.

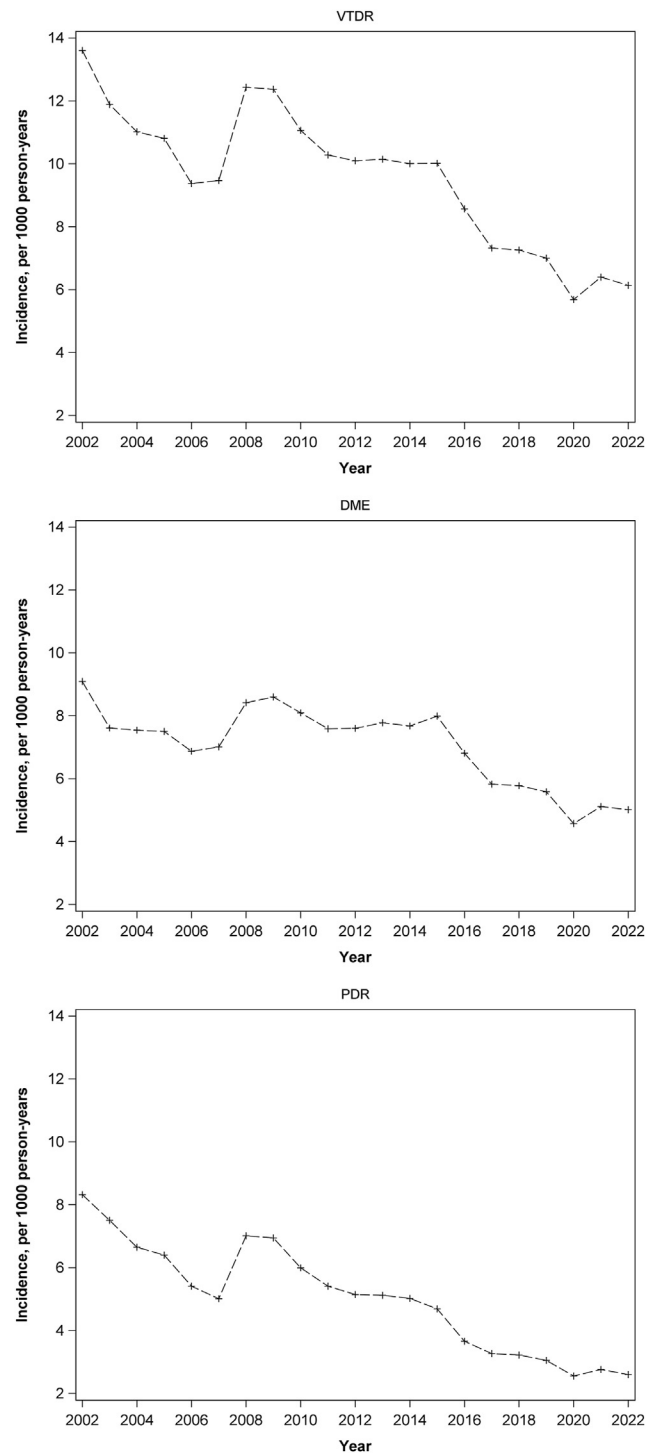


Figure 3. Graphs showing the yearly incidence of (A) vision-threatening diabetic retinopathy (VTDR), (B) diabetic macular edema (DME), and (C) proliferative diabetic retinopathy (PDR) among patients with diabetes mellitus.

rates for VTDR, DME, and PDR all decreased in the period from 2011 and beyond compared with 2010 and earlier ($P < 0.001$ for VTDR and PDR; $P = 0.04$ for DME). The VTDR and DME incidence rates increased

from 2006 and earlier (VTDR, 10.8 cases per 1000 person-years; DME, 7.4 cases per 1000 person-years) to 2007 through 2011 (VTDR, 11.2 cases per 1000 person-years; DME, 8.0 cases per 1000 person-years), then decreased

each of the last two year groupings (VTDR: 2012 through 2016, 9.7 cases per 1000 person-years; 2017 and beyond, 6.6 cases per 1000 person-years; DME: 2012 through 2016, 7.6 cases per 1000 person-years; 2017 and beyond, 5.3 cases per 1000 person-years); however, although the VTDR trend was significant ($P < 0.001$), the DME trend was not ($P = 0.30$). The incidence rate of PDR decreased in each of the 4 groupings (2006 and earlier, 6.5 cases per 1000 person-years; 2017 and beyond, 2.9 cases per 1000 person-years; $P < 0.001$).

Discussion

The percentage of patients affected by DRD has increased dramatically over the past 20 years, nearly doubling among patients with DM (from 10.8% in 2007 to 20.8% in 2021), but proportionately less than the 6.8-fold increase in the full population (0.6% in 2001 vs. 4.1% in 2021). The incidence rate of DRD among patients with DM varied considerably until stabilizing near its peak rate, 90% higher than its lowest rate, with 4 of the last 5 years having rates of more than 32 cases per 1000 patient-years.

Although the prevalence of VTDR and DME peaked in 2016, it has decreased since, each dropping by roughly 10% in the subsequent 5 years. These trends contrast with PDR, which has shown a stable prevalence among patients with DM throughout the observation period. Despite the increasing pool of individuals at risk of visually threatening DRD complications, the incidence rates for DME and PDR have fared much better. The incidence rate decreased 55% (2002, 13.6 cases per 1000 person-years to 2022, 6.1 cases per 1000 person-years) for VTDR, 40% for DME (2009, 8.6 cases per 1000 person-years to 2022, 5.0 cases per 1000 person-years), and 69% for PDR (2002, 8.3 cases per 1000 person-years to 2022, 2.6 cases per 1000 person-years).

Taking the prevalence and incidence rates together offers a nuanced view of the current state and direction of DRD. The 6.8-fold increase in the prevalence of DRD in the overall population compared with the doubling among those with DM shows that a major driver of DRD rates is the epidemic expansion of the population with DM. Second, the Affordable Care Act has increased health care access every year since its inception in 2014, expanding who was likely to be entered into this database, especially for those at lower income levels and members of disadvantaged minority groups, both populations at higher risk of DM.¹⁴ Also likely impacting the prevalence of DRD has been the concerted effort to promote screening diabetic eye examinations, including broadening the use of telemedicine screening.²⁷

Although the growing number of patients impacted by DRD is certainly concerning, it does not seem to have impacted the incidence of VTDR or its component diseases, which have decreased over the 20-year analysis. Historically, the conversion to DME or PDR has been thought to occur 5 to 9 years after the onset of DRD.²⁸ It is possible if the database were extended, additional years of data could capture an impending wave of VTDR. However, given the increased systemic DM treatment and monitoring options within a better-insured population (expanding access to those improved treatments), it is unclear if

the 5- to 9-year estimation is still relevant to today's patients. Supporting this idea is a report showing that newly insured Affordable Care Act patients with DM demonstrated a significant reduction in hemoglobin A1c levels that lasted up to 2 years after initiating insurance coverage.²⁹ Also, increased screening may be inducing a detection bias, whereby the disease is diagnosed in a much earlier state, thereby extending the time between diagnosis and when complications would be expected. Despite these possibilities, this study spanned 20 years with a near-constant increase in DRD prevalence, yet if anything, the trend showed decreases for both the prevalence and incidence of VTDR, DME, and PDR.

The decreases in DME and PDR also may correspond to the broadening use of glucagon-like peptide-1 receptor agonists. Glucagon-like peptide-1 receptor agonists have been shown in clinical trials to lower glycemic levels and reduce numerous diabetes-related complications effectively.^{30,31} An odd exception to this complication reduction has been DRD, which in some studies was shown to worsen with glucagon-like peptide-1 receptor agonist use.^{32,33} It is possible that any worsening in DRD resulting from glucagon-like peptide-1 receptor agonist use is related to "paradoxical worsening," a recognized phenomenon when a sudden rapid decrease in hemoglobin A1c is associated with a temporary worsening of DRD.³⁴ If this is the case, then what was found in the clinical trials was simply the temporary worsening before the long-term improvement in DRD progression.

Finally, the last decade of decreasing PDR incidence rates corresponded with and was likely influenced by the growing use of anti-VEGF agents for DME and other diseases. These agents have been shown to reduce, if not potentially reverse, DRD progression.^{35,36} Patients with macular edema receiving this near-ubiquitous first-line therapy would shrink the pool of potential progressors to PDR. Although exact causes for the decrease in DME and PDR rates cannot be determined, it is likely each of the above possibilities has made some contribution to this phenomenon.

Recent studies have focused on specific aspects of DRD prevalence. A study using many data sources found a higher overall DRD prevalence (26.4% vs. 20.8%), but a lower VTDR prevalence (5.1% vs. 6.9%) for the United States in 2021 compared with our study.⁹ In addition, a recent analysis of Medicare beneficiaries (older than 68 years) with DM found DRD and VTDR prevalence to be much lower than that found in our study.¹⁰ A different Medicare study focused on DME showed similar increases in prevalence, but had a lower estimate (3.3% vs. 5.5%) than our study.¹¹ The same study also found a generally decreasing rate of VTDR (versus the time frame when it increased in our study), but a similar prevalence (7.3% vs. 7.1%).¹¹ Another recent study among patients with DM 18 to 64 years of age found an increasing prevalence of VTDR (from 2.1% in 2009 to 3.4% in 2018) and DME (from 0.7% in 2009 to 2.6% in 2018), but at rates roughly of half those found in our study.¹² Although the exact causes for differences seen across these studies are unknown, many are likely the result of differences in underlying populations.

The database used in this analysis offers a wealth of information on a national population of patients; however, the

insurance claims nature of the database has limitations that should be noted. First, the dataset is not a statistical representation of the United States and has proportionally fewer members of racial and ethnic minority groups. Similarly, patients who are uninsured or those receiving insurance through other health systems (like the Veterans Health Administration) are not represented within this database. This may limit the generalizability of our findings. Also, because of the de-identified nature of the database, it is not possible to verify independently the accuracy of any specific ICD diagnosis codes with medical chart-level data. Although verification is not possible, the ICD codes used for DRD, DME, and PDR each have been validated previously.^{19–21,37} Next, recent analysis showed that the changeover from ICD, Ninth Revision, coding to ICD, Tenth Revision, coding did not impact the accuracy of coding for DRD, DME, or PDR, which was consistent with our results that showed no discernable change from 2015 through 2016 in our dataset.²¹ In addition to the ICD, Ninth to Tenth Revision, change in 2015, the ICD, Ninth Revision, coding for DME changed over time with the introduction of code 362.07 in 2010. Although both versions of ICD, Ninth Revision, coding have been validated,^{19,21} we cannot be sure these changes did not impact our rates.

Next, diagnoses themselves have changed over time. One such change is the criteria to diagnose diabetes.³⁸ Similarly,

previously clinically silent DME can now be diagnosed earlier through the use of OCT. Conversely, the reduced use of routine fluorescein angiography has made the detection of early PDR more difficult. Although the impacts of changing diagnostic criteria over time cannot be eliminated fully, most changes were limited to a few years, reducing the impact over the entire 20-year observation period. Another issue is that many patients with DM do not follow the recommendations for yearly eye examinations.^{39,40} This misclassification bias suggests that our estimates are likely to be an underestimate of the overall true rate of disease. Finally, because of the nature of the database, we are unable to assess duration of disease, limiting our ability to determine if some of the trends found in the analysis are the result of a case-mix difference in the underlying diabetes population.

Conclusions

The current prevalence of DRD in patients with DM is nearly twice as high compared with its low in 2007, with a corresponding rise in incidence that peaked but plateaued in the past 5 years. Despite these increases in DRD, incidence rates of VTDR, DME, and PDR all have improved dramatically.

Footnotes and Disclosures

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No animal subjects were included in this study.

Author Contributions:

Conception and design: VanderBeek, Cardillo, Hubbard

Analysis and interpretation: VanderBeek, Yu, Cardillo, Hubbard

Data collection: VanderBeek, Yu

Obtained funding: VanderBeek, Cardillo, Hubbard

Overall responsibility: VanderBeek, Yu, Cardillo, Hubbard

Abbreviations and Acronyms:

DM = diabetes mellitus; **DME** = diabetic macular edema; **DRD** = diabetic retinal disease; **ICD** = International Classification of Diseases; **PDR** = proliferative diabetic retinopathy; **VEGF** = vascular endothelial growth factor; **VTDR** = vision-threatening diabetic retinopathy.

Keywords:

Diabetic macular edema, Diabetic retinal disease, Incidence, Prevalence, Proliferative diabetic retinopathy.

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