FEATURE ARTICLE

Real-World Screening for Retinopathy in Youth With Type 1 Diabetes Using a Nonmydriatic Fundus Camera

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OBJECTIVE | To assess the use of a portable retinal camera in diabetic retinopathy (DR) screening in multiple settings and the presence of associated risk factors among children, adolescents, and young adults with type 1 diabetes.

DESIGN AND METHODS | Five hundred youth with type 1 diabetes of at least 1 year's duration were recruited from clinics, diabetes camp, and a diabetes conference and underwent retinal imaging using a nonmydriatic fundus camera. Retinal characterization was performed remotely by a licensed ophthalmologist. Risk factors for DR development were evaluated by a patient-reported questionnaire and medical chart review.

RESULTS | Of the 500 recruited subjects aged 9–26 years (mean 14.9, SD 3.8), 10 cases of DR were identified (nine mild and one moderate nonproliferative DR) with 100% of images of gradable quality. The prevalence of DR was 2.04% (95% CI 0.78–3.29), at an average age of 20.2 years, with the youngest affected subject being 17.1 years of age. The rate of DR was higher, at 6.5%, with diabetes duration >10 years (95% CI 0.86–12.12, $P = 0.0002$). In subjects with DR, the average duration of diabetes was 12.1 years (SD 4.6, range 6.2–20.0), and in a subgroup of clinic-only subjects ($n = 114$), elevated blood pressure in the year before screening was associated with DR ($P = 0.0068$).

CONCLUSION | This study in a large cohort of subjects with type 1 diabetes demonstrates that older adolescents and young adults (>17 years) with longer disease duration (>6 years) are at risk for DR development, and screening using a portable retinal camera is feasible in clinics and other locations. Recent elevated blood pressure was a risk factor in an analyzed subgroup.

Diabetic retinopathy (DR) is the leading cause of blindness among young adults and a common microvascular complication of diabetes. More than 90% of individuals with type 1 diabetes will develop DR within 20 years after diagnosis, but most cases are not diagnosed until >5 years after diabetes onset (1).

DR is associated with long-term hyperglycemia, which may contribute to vascular endothelial dysfunction and, ultimately, widespread neovascularization of the retina and optic disk. When these fragile vessels bleed, they can cause vitreous hemorrhage, eventual vessel fibrosis, retinal ischemia, and loss of vision. DR is often asymptomatic until vision loss occurs, but treatment with laser photocoagulation therapy or intravitreal injections of anti–vascular endothelial growth factor is available for those with more advanced disease and can prevent progression and loss of vision (1). Thus, early detection of this disease is paramount because effective therapies can be instituted to prevent vision loss.

Adherence to DR screening guidelines is poor, with first and subsequent screenings occurring on time in only two-thirds of youth with type 1 diabetes, with even lower odds of screening in those from low-income households or minority racial and ethnic groups (2–4).

To identify patients at risk for DR, current American Diabetes Association (ADA) guidelines advise that patients with type 1 diabetes have dilated eye exams every 2 years

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starting 3–5 years after diagnosis once they are 11 years of age or puberty has started, whichever is earlier (5). Major risk factors for DR include time since diabetes diagnosis, age at diagnosis, and severity of prolonged hyperglycemia (6). Previous studies in pediatric patients with type 1 diabetes have reported conflicting results, with some studies showing minimal risk in patients <15 years of age (7–9) and duration of type 1 diabetes <6 years (10,11), whereas others report DR within 3 years of diagnosis and at ages as young as 6 years (12,13).

Overall, the incidence of DR has been declining since the landmark Diabetes Control and Complications Trial (DCCT), with initiation of intensive insulin therapy as a standard of care (14–16). Therefore, although the rate of DR is high after 20 years of type 1 diabetes, the rate in the pediatric population is unclear, and questions have arisen regarding the cost-effectiveness of current recommendations (17).

Digital fundus photography is a valuable new tool in the detection of retinopathy. In 2004, the American Academy of Ophthalmology reported level 1 evidence that fundus photography can be used to screen adult patients for DR (18). Reports of its feasibility in pediatric populations with type 1 diabetes have varied, with one study obtaining gradable images for both eyes in only 46% of participants (19) and others obtaining high-quality images in 86 and 97.5% of patients, respectively (12,20). However, a recent study demonstrated improved evaluation of the peripheral retina with digital ultra-widefield photography in pediatric patients compared with indirect ophthalmoscopy, although pupillary dilation was required for this evaluation (21).

Here, we aimed to assess the use of nonmydriatic digital fundal photography in varied settings to determine DR prevalence and associated risk factors among a large population of diverse children, adolescents, and young adults with established type 1 diabetes.

Research Design and Methods

This cross-sectional study recruited subjects aged 9–26 years with type 1 diabetes of at least 1 year's duration from the pediatric diabetes clinic, diabetes camp, and a large patient-run diabetes conference from June 2016 through January 2018. Subjects were screened for DR using a CenterVue Digital Retinography System (DRS). The DRS, a nonmydriatic fundus camera, was operated by study personnel. It provides a field of view of 45° × 40°, color and red-free images for each eye, and an image resolution of 48 pixels/degree. One image of each retina is obtained in 1 minute. Images were evaluated by a single licensed ophthalmologist and retinal specialist who was blinded to subjects' identity and medical history. Image quality was assessed and DR was classified using the Early Treatment Diabetic Retinopathy Study scoring system (22).

All subjects completed a study questionnaire assessing demographics, diabetes management, comorbidities, and episodes of diabetic ketoacidosis (DKA). When available, subjects' medical records were reviewed for date of diagnosis, A1C level, urine microalbumin-to-creatinine ratio, and presence or absence of elevated systolic and diastolic blood pressure readings (based on age, sex, and height percentiles as defined by the American Academy of Pediatrics [23]) during the 12 months before screening. BMI, Tanner staging, insulin regimen, continuous glucose monitoring (CGM) use, and previous diagnoses of microalbuminuria, hyperlipidemia/hypercholesterolemia, or hypertension documented in the medical record were also queried. Point-of-care A1C (Siemens DCA Vantage Analyzer) on the day of eye screening was obtained for 78% of subjects.

The large sample size was determined to allow for precise estimates of the prevalence of DR. The two-sided Fisher exact test was used to compare the presence of DR across binary age categories, as well as the presence of other risk factors (e.g., hyperlipidemia, hypertension, and microalbuminuria). The Cochran-Mantel-Haenszel test was used to evaluate the presence of DR across diabetes duration and BMI categories. Subgroup analysis for DR risk factors was conducted among the group of subjects followed in clinics (n = 114), with available electronic medical records including a measurement of blood pressure and BMI within the past 6 months.

Results

In this study, 500 subjects aged 9–26 years with a duration of type 1 diabetes of at least 1 year were screened for DR using fundal photography. Nine subjects were excluded because of incomplete data regarding their duration of diabetes, age of onset, or recent A1C levels. All nine were negative for DR.

Characteristics of the 491 eligible subjects are described in Table 1. The mean age was 14.9 years, and the mean duration of type 1 diabetes was 6.6 years. The mean A1C was 8.8%, and 44% had DKA at the time of diabetes diagnosis. One-fourth of subjects had an A1C value <7.5%, the recommended goal set by the ADA for pediatric patients (2). Thirty-seven percent of subjects were on a multiple daily injection insulin regimen, 53% used an insulin pump, 7%

TABLE 1 Demographics of Subjects With and Without DR

	All Subjects	Subjects Without DR	Subjects With DR
Total subjects	491 (100)	481 (98.0)	10 (2.0)
Sex			
Male	216 (44.0)	212 (44.1)	4 (40.0)
Female	275 (56.0)	269 (55.9)	6 (60.0)
Race			
American Indian	2 (0.4)	2 (0.4)	0 (0.0)
Alaskan Native	1 (0.2)	1 (0.2)	0 (0.0)
Asian	3 (0.6)	2 (0.4)	1 (10%)
Black or African American	31 (6.3)	30 (6.2)	1 (10.0%)
Native Hawaiian or Pacific Islander	1 (0.2)	1 (0.2)	0 (0.0)
White	396 (80.7)	388 (80.7)	8 (80.0%)
Multiple	35 (7.1)	35 (7.3)	0 (0.0)
Not reported	22 (4.5)	17 (4.6)	0 (0.0)
Ethnicity			
Non-Hispanic	352 (71.7)	342 (71.1)	10 (100)
Hispanic	73 (14.9)	73 (15.2)	0 (0.0)
Not reported	66 (13.4)	66 (13.7)	0 (0.0)
Age, years			
At screening	14.9 ± 3.7	14.8 ± 3.7	20.2 ± 2.3
At type 1 diabetes diagnosis	8.3 ± 3.9	8.3 ± 3.9	8.1 ± 3.1
Duration of diabetes, years	6.6 ± 4.4	6.5 ± 4.3	12.1 ± 4.6
A1C, %	8.8 ± 1.7	8.7 ± 1.7	9.3 ± 2.2
Pubertal status*			
Prepubertal	69 (14.1)	69 (14.3)	0 (0.0)
Pubertal	358 (72.9)	352 (73.2)	6 (60.0)
Unknown/not reported	64 (13.0)	60 (12.5)	4 (40.0)
DKA present at diagnosis			
Yes	215 (43.8)	209 (43.5)	6 (60.0)
No	248 (50.5)	245 (50.9)	3 (30.0)
Unknown	28 (5.7)	27 (5.6)	1 (10.0)
Insulin regimen			
Insulin pump	259 (52.7)	255 (53.0)	4 (40.0)
Multiple-dose injection	183 (37.3)	181 (37.6)	2 (20.0)
NPH/premixed	33 (6.7)	31 (6.5)	2 (20.0)
Unknown	16 (3.3)	14 (2.9)	2 (20.0)
CGM use†			
Yes	140 (28.5)	139 (28.9)	1 (10.0)
No	275 (56.0)	269 (55.9)	6 (60.0)
Unknown	76 (15.5)	73 (15.2)	3 (30.0)
Recruitment location			
Camp	274 (55.8)	271 (56.3)	3 (30.0)
Clinic	158 (32.2)	152 (31.6)	6 (60.0)
Youth conference	59 (12.0)	58 (12.1)	1 (10.0)

Data are *n* (%) or mean ± SD. *Pubertal status identified through Tanner staging if available or patient-reported survey for the presence or absence of breast development, menarche, pubic hair, or facial hair. †At time of screening.

were using NPH or premixed insulin, and 3% did not have the type of insulin regimen reported.

All subjects had gradable retinal images of both eyes. Image capture was performed by pediatric endocrinology fellows, medical students, and undergraduate students. Images covered a 45° × 40° retinal field of view without the need for any mydriatic agents (Figure 1).

Ten subjects had DR, whereas 481 did not have DR (Tables 1 and 2). Of the 10 who did have DR, 1 had moderate nonproliferative and 9 had mild nonproliferative DR. There

were no cases of proliferative DR. The overall DR prevalence was 2.04% (95% CI 0.78–3.29). In subjects with DR, the average duration of type 1 diabetes was 12.1 years, with the shortest duration being 6.1 years, compared with an average duration of 6.5 years in subjects without DR. The average age at the study visit was 20.2 years in those with DR, with the youngest subject with DR being 17.1 years of age, compared with an average age of 14.8 years in those without DR. DR was associated with an increased duration of type 1 diabetes of ≥6 years ($P = 0.0002$) (Table 2). There was no statistical difference in mean age at diagnosis or screening. The average A1C was higher in those with DR compared with those without DR (9.3 vs. 8.7%, respectively); however, this finding was not statistically significant. Of subjects with DR, 60.0% had DKA at the time of diagnosis compared with 43.5% of subjects without DR. Twenty percent of subjects with DR were on NPH or premixed insulin regimens compared with 6.5% of those without DR.

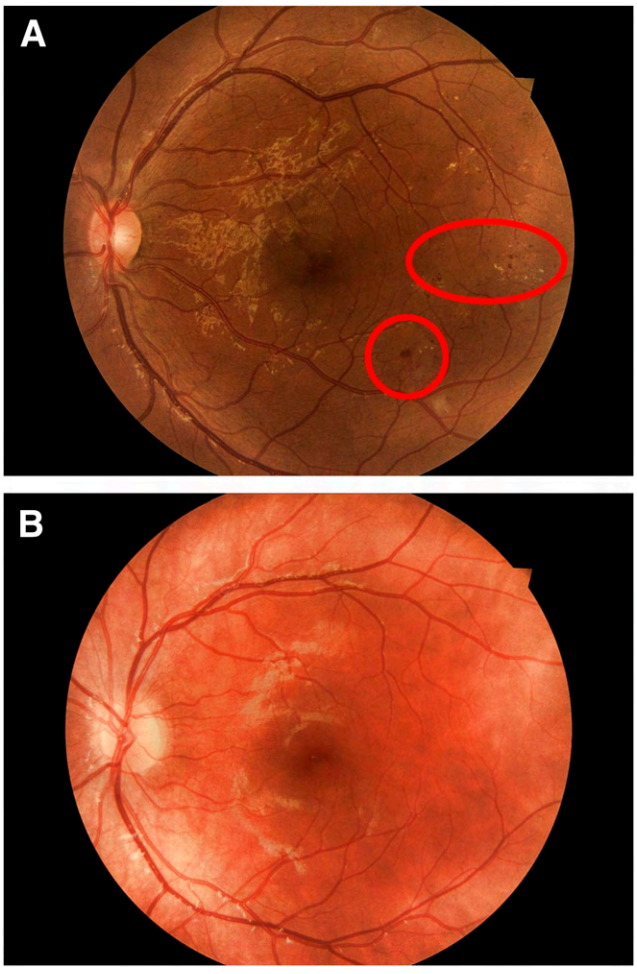

FIGURE 1 Retinal camera fields of view in a subject with DR (*A*) (areas of hemorrhage circled) and without DR (*B*).

Subgroup analysis of subjects from clinics with risk factor data available ($n = 114$) is presented in Table 3. Although 50% of those with DR were overweight or obese compared with 41% of those without DR, only the presence of at least one elevated systolic or diastolic blood pressure reading (during a diabetes clinic visit) within the past year was statistically significant in this subgroup analysis. Thirty-three percent of subjects with DR had a diagnosis of microalbuminuria compared with 2.6% of subjects without DR. Laboratory measurement of the urine microalbumin-to-creatinine ratio was not documented within the previous year for 42% of clinic subjects, so these data were not available for analysis.

Discussion

Although adherence to DR screening guidelines in children remains poor (2–4), additional clinic visits to perform such screening can prove burdensome for patients who have transportation or cost issues or problems with missing school and work. Our study shows that nonmydriatic fundal photography is fast and easy to perform and can be completed in children as young as 9 years of age during their clinic visit or at a location outside of the clinic.

All study subjects who were screened had adequate images for evaluation, and staff required minimal training to operate the camera. The auto-focus and auto-alignment features of the device likely aided the ability to collect adequate images. Because cases have been reported in the literature of young children developing DR, we included subjects as young as 9 years of age and experienced no difficulties using the camera in this age-group. The camera was easy to use, did not require pupil dilation, and was portable, making it an attractive option for primary care or endocrinology clinics. This one-stop-shopping option could potentially improve adherence to screening guidelines, in addition to facilitating screening at diabetes camps or other events.

Many studies in adults have demonstrated the clinical efficacy of fundal photography for detection of DR (24–26). This technology is commonly used in screening adults for DR, with a sensitivity of 98% and a specificity of 100% (24). A 2002 study by Lin et al. (25) demonstrated increased sensitivity for the detection of DR with a single nonmydriatic digital photograph of the disk and macula compared with a dilated eye exam. As of 2020, ADA guidelines have adopted retinal photography as a potential screening strategy for DR in adults with diabetes and youth with type 2 diabetes (5,27).

The application of artificial intelligence in grading fundal photographs for DR is another interesting area of research,

TABLE 2 Prevalence of DR by Age and Duration of Diabetes

	n	Prevalence of DR, *n* (%)	95% CI	*P*
Overall	491	10 (2.04)	0.78–3.29	–
Age, years				0.1280*
9–11	119	0 (0.00)	–	
12–26	372	10 (2.69)	1.04–4.34	
Diabetes duration, years				0.0002†
0–5	252	0 (0.00)	–	
6–10	162	5 (3.09)	0.39–5.78	
11–26	77	5 (6.49)	0.86–12.12	
ADA screening eligible‡	255	10 (3.92)	1.52–6.32	

*Fisher exact test, two-sided probability. †Cochran-Mantel-Haenszel test used to account for small outcome rates. ‡Subjects with diabetes duration ≥5 years and age ≥11 years.

with more than 80 articles published from 2007 to 2018 (28). More widespread use of this technology may make screening for referable DR in primary care or endocrinology clinics more practicable.

We found a 2% prevalence of DR in children and young adults with type 1 diabetes. The youngest subject with DR was 17 years of age, and the shortest duration of type 1 diabetes was 6 years. ADA currently recommends screening in children starting at 11 years of age (or sooner if pubertal) starting 3–5 years after diabetes onset (5). In addition, we found no cases of proliferative DR in any of the 500 study subjects and therefore had no subjects requiring any DR intervention. This finding is similar to that of a recent study in which 12,535 pediatric patients or their parents were surveyed, with only 45 self-reporting having been diagnosed with DR and none requiring intervention (29).

It has been proposed that the prevalence of DR has decreased in recent years as a result of more widespread use of intensive insulin therapy regimens after the DCCT (14,15,30). Although mean A1C has largely remained unchanged over time or, as recently demonstrated, has actually worsened in adolescents and young adults, intensive insulin regimens have demonstrated decreased microvascular complication rates (30,31).

Because strict blood glucose control and medical interventions can prevent or attenuate progression of DR, it will be beneficial to determine which factors confer higher risk for developing DR and potentially include these risk factors in future screening guidelines. In our study, elevated blood pressure in the year before screening was associated with DR, as was longer duration of diabetes.

Despite a large sample size, our study only found 10 subjects with DR, which prevented us from performing multivariable analyses addressing potential confounding or commenting on the significance of other previously reported risk factors, including A1C, microalbuminuria, hyperlipidemia, obesity, and type of insulin regimen (32,33). Because this was a mainly pediatric population, pregnancy, a known risk factor for DR, was not assessed.

TABLE 3 DR Risk Factors in Clinic Subjects

	Subjects Without DR (*n* = 108)	Subjects With DR (*n* = 6)	*P*
BMI*			
Normal weight	76 (59.4)	3 (50.0)	0.6039†
Overweight	9 (22.7)	1 (16.7)	
Obese	23 (18.0)	2 (33.3)	
Elevated blood pressure in the year before screening‡	18 (14.1)	4 (66.7)	0.0068§
Diagnoses documented in medical record			
Microalbuminuria	4 (2.6)	2 (33.3)	
Hyperlipidemia	48 (37.5)	3 (50.0)	
Hypertension	3 (2.0)	0 (0.0)	

Data are *n* (%). *Overweight was defined as a BMI in the 85th to <95th percentile in subjects aged 9–17 years or a BMI of 25.0 to <30.0 kg/m^2 in those aged 18–26 years. Obesity was defined as a BMI in the ≥95th percentile range in subjects aged 9–17 years or a BMI ≥30.0 kg/m^2 in those aged 18–26 years. †Using the Cochran-Mantel-Haenszel test. ‡Elevated blood pressure was defined as one or more readings with either a systolic blood pressure of ≥130 or a diastolic blood pressure of ≥80 mmHg in subjects aged ≥13 years of age or a systolic or diastolic blood pressure in the ≥95th percentile range in subjects aged 9–12 years. §Using a Fisher exact test with two-sided probability.

A potential limitation of our study was the use of retrospective blood pressure measurements from clinical encounters; also, the DRS did not visualize the peripheral retina. Our study was also limited by a lack of comparison with dilated ophthalmoscopy, the gold standard for DR diagnosis. Despite these limitations, the focus of this study on the ease of use of this new technology in a large number of pediatric patients provided valuable insight about the rate of DR in this population.

Advantages of digital fundus photography include its ease of use, decreased patient burden, and the ability to perform the screening in any health care space and via telemedicine. The cost-effectiveness of current pediatric DR screening guidelines has been called into question in the literature (17), and our study showed a low prevalence of DR occurring at an older age and longer duration of diabetes than current recommendations for screening. Focusing resources on those most at risk for DR, given the low prevalence in pediatric and young adult patients, has the potential to yield greater benefit to patients and provide more cost-effective care.

Prospective studies that include larger numbers of children with DR are needed for risk factor deduction because the current study, while large, was cross-sectional in design. Our results support the feasibility of fundal photography in the pediatric setting. Improved use of DR screening services is key, and technologies such as this may allow for increased adherence to screening guidelines.

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DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

C.Z., B.B., and L.M.J. analyzed the data and wrote the manuscript. A.L., S.K., M.S., G.B., K.D., P.H., and J.H.S. reviewed the data and contributed to discussion and the manuscript. M.S. and J.H.S. conceptualized the study. S.L.F. and M.J.G. analyzed the data, contributed to discussion, and provided statistical guidance. L.M.J. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

PRIOR PRESENTATION

Parts of this study were presented in poster form at the 77th Scientific Sessions of the American Diabetes Association, 9–13 June 2017, San Diego, CA.

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