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ORIGINAL ARTICLE

Direct Ophthalmoscopy versus Fundus Photography in Children with Type 1 Diabetes Mellitus

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ABSTRACT

Background: Clinical fundus examination in addition to fundus photography of Type 1 diabetes mellitus (T1DM) children patients to detect complications like diabetic retinopathy (DR). This study aimed to evaluate direct ophthalmoscopy accuracy compared to fundus photography in diagnosing diabetic retinopathy in children with T1DM at Zagazig University Hospital.

Methods: We carried out this cross-sectional study on 42 children diagnosed with T1DM for over five years who attended the Pediatrics Outpatient Clinic at Zagazig University Hospital. Routine laboratory investigations, such as complete blood count and blood glucose level, HbA1c, and albumin/creatinine ratio in urine, were done on all patients, in addition to direct ophthalmoscopy and fundus photography, for diagnosis of diabetic retinopathy.

Results: Direct ophthalmoscopy had a sensitivity of 25% and a specificity of 100%. On the other hand, fundus photography demonstrated a sensitivity of 80.69% and a specificity of 92.23%.Regarding positive predictive value (PPV) and negative predictive value (NPV), direct ophthalmoscopy showed a PPV of 100% and an NPV of 75%. In comparison, fundus photography in another study demonstrated a PPV of 62% and an NPV of 90%. Direct ophthalmoscopy and fundus photography identified one case of DR concordantly, while three cases initially identified as absence of DR by direct ophthalmoscopy were later confirmed as DR by fundus photography.

Conclusion: Direct ophthalmoscopy's sensitivity and specificity for detecting the presence and severity of DR were found to be lower than the recommended levels for a DR screening test. This suggests that fundus photography is more accurate than direct ophthalmoscopy for screening DR.

Keywords: Direct Ophthalmoscopy; Fundus Photography; Type 1 Diabetes Mellitus

INTRODUCTION

In type 1 diabetes mellitus (T1DM), an autoimmune disease, the pancreatic β-cells that produce insulin are damaged by auto-reactive immune cells, causing insulitis and, subsequently, an elevated hemoglobin A1C (HbA1c) level in the blood. The prevalence of type 1 diabetes has increased tremendously during the past three decades[1].

The most common complication of type 1 diabetes is diabetic retinopathy (DR). Some form of DR is present in nearly all patients with type 1 diabetes who develop the disease before the age of 30; after twenty years of diagnosis, it is important to screen the ocular fundi regularly to detect the onset and track the progression of DR. This is because DR can progress for a long time without symptoms[2].

Clinical ophthalmic examinations as a screening method for DR should be initiated 3-5 years after a diagnosis of type 1 diabetes mellitus (T1DM), with annual reviews for pediatric patients older than 9 years. However, another opinion suggests that all T1DM patients aged 12 years and up should undergo a clinical fundus examination and fundus photography each year [3].

Screening for DR is best accomplished with fundus photography, which is both sensitive and accurate. Typically, a 45-degree fundus camera is used [4].

Photographic screening of children with type 1 diabetes mellitus (T1DM) should start at 10 years, regardless of how long the disease has been present. This age was chosen as a middle ground between starting photography at the start of puberty, when disease remission (DR) typically begins, and prepubertal children, for whom DR has been reported as an exception. If no DR is detected, imaging should be done every 2 years, and then annually after DR is detected or if images show hardly gradable cases[5].

Therefore, the present study aimed to evaluate the accuracy of direct ophthalmoscopy in comparison to fundus photography in diagnosing diabetic retinopathy in children with T1DM at Zagazig University Hospital.

METHODS

We carried out this cross-sectional study on 42 children diagnosed with T1DM for over five years, the duration of 6 months from January 2024 to July 2024, who attended the Pediatrics and Ophthalmology outpatient clinics at Zagazig University Hospital. This study followed the guidelines [the World Medical Association's Code of Ethics (Declaration of Helsinki) for human studies]. All parents of participants provided informed and written consent. The Institutional Review Board has approved this research (IRB#10435)

Inclusion Criteria:Children of both sexes with type 1 diabetes mellitus for more than five years who have attended the pediatrics outpatient clinic at Zagazig University Hospital during the period of the study.

Exclusion Criteria: We excluded patients younger than 1 month and older than 18 years, patients with cardiac or blood disease, children with malignancy, CNS or congenital problems, children with any other non-diabetic eye diseases, and patients with previous eye surgeries.

All the included children were subjected to entire history taking including personal, complaint, present, past, family history, cause of admission, onset of the disease, duration, medical treatment in detail, and complication.General Clinical examination was done involving anthropometric measures,general dysmorphic features, whether the patient was cardiac or not, as well as assessment of the vital signs.

Investigation; Laboratory tests included: Routine laboratory investigations, including complete blood count (CBC), blood glucose level, HbA1c, and albumin/creatinine ratio in urine).

Direct ophthalmoscopy and fundus photography were performed on all patients. The following rules were taken to maximize the efficacy of direct ophthalmoscope examination: apply mydriatic eye drops if not contraindicated, dim the light of the room, ask the patients to take off their prescription glasses, and ask them to look straight ahead and examine right eye of the patient with right eye of the examiner while holding the direct ophthalmoscope(Riester, Germany)with right hand and vice versa. On the other hand, fundus photography (Topcon, Japan) involves photographing the fundus. It could detect the retina's macula, optic disc, and periphery. The examination was carried out with a 45-degree camera. Before the examination, mydriatic eye drops were applied to dilate the pupil of the patient. During examination, the patient sat in front of the camera and looked at a fixed point when the photographs were taken.

Statistical Analysis:

Microsoft Office Excel 2010 and SPSS 27.0 for Windows were used for data collection, tabulation, and statistical analysis. We displayed the median with range and the mean with standard deviation (SD) for continuous

quantitative data, and we indicated the frequencies and percentages for categorical qualitative variables. The Shapiro-Wilk test determined if the constant data was normally distributed. When dealing with data that did not follow a normal distribution, we used the Kruskal-Wallis H test for comparisons involving more than two groups and the Mann-Whitney U test for two groups. The chi-square test was used for categorical data. To ensure the best possible sensitivity and specificity in identifying diabetic retinopathy, the diagnostic accuracy of direct ophthalmoscopy was determined using receiver operating characteristic (ROC) curve analysis. The area under the curve (AUC) was also calculated, with the following criteria for AUC qualification: excellent (0.90 - 1), good (0.80 - 0.90), fair (0.70 - 0.80), poor (0.60 - 0.70), and fail (0.50 - 0.60). There was statistical significance when the p-value was less than 0.05.

RESULTS

The average age of the participants was 12.65 ±3.17.The median age was 13 years, ranging from 6 to 18 years. Regarding gender, the study cohort was evenly distributed, with 21 males (50%) and 21 females (50%). The mean weight of the participants was 46.86± 12.11 Kg. Similarly, the mean height was 151.43 ±15.84centimeters, and the participant's body mass index (BMI) had a mean of 19.93, ±1.83. The mean duration of diabetes was 7.05 ±2.11 years. For HbA1c levels, the mean was 9.26 ±1.63 years. The median HbA1c value was 9.5; regarding RBS, the mean was 245.71 ±92.13. The median RBS value was 200 mg/dl (Table 1).

The mean TLC was 7.77 ± 0.69. Hemoglobin (Hgb) had a mean of 10.89 ±0.94. Platelet levels showed a mean of 314.67 ±49.89. The albumin/creatinine ratio had a mean of 35.71 ±63.29 (Table 2).

The mean duration of diabetes was significantly higher in individuals with DR (9.25 ± 2.22 years) compared to those with no abnormality (6.82 ± 1.99 years), with a p-value of 0.026. Additionally, higher mean HgA1C levels were noted in individuals with DR (10.88 ± 1.65) compared to their counterparts with no DR (9.09 ± 1.55), with a p-value of 0.035. Moreover, the mean random blood sugar was markedly elevated in individuals with DR (353.00 ± 103.20) compared to those with no abnormality (229.00 ± 76.51), with a p-value of 0.005. Furthermore, the albumin/creatinine ratio was significantly higher in individuals with abnormalities (155.28 ± 182.80) compared to those with no abnormality (23.96 ± 7.34), with a p-value of < 0.0001 (Table 3).

In the diabetic retinopathy group, no cases exhibited abnormalities in the optic disc, while one showed diabetic retinopathy in the macula (macular edema). Forty-one cases (97.6%) showed no diabetic retinopathy in the macula (Table 4).

In the diabetic retinopathy group, 0% of cases exhibited abnormalities in the optic disc, 2.4% showed abnormalities in the macula (macular edema), and 9.5% showed irregularities in the periphery of the retina (3 cases showed microaneurysm, and one case showed neovessel formation). Conversely, in the group without diabetic retinopathy, all patients (100%) displayed normal findings in the optic disc and macula. Moreover, 90.5% of cases in this group exhibited a healthy periphery of the retina (Table 4).

One case with diabetic retinopathy was identified by both direct ophthalmoscopy and confirmed by fundus photography. No diabetic retinopathy identified by both direct ophthalmoscopy and confirmed by fundus photography represented 38 cases. No cases were identified as absence of diabetic retinopathy by direct ophthalmoscopy but confirmed as diabetic retinopathy by fundus photography. Three cases were initially identified as absence of diabetic retinopathy by direct ophthalmoscopy but later confirmed as diabetic retinopathy by fundus photography (Table 5).

The sensitivity of the direct ophthalmoscopy was reported as 25%, with a wide 95% CI ranging from 0.6% to 80.6%. In contrast, the specificity was reported as 100%, with a narrower 95% CI ranging from 90.7% to

100%. The negative likelihood ratio (-LR) was reported as 0.75, with a 95% CI of 0.43 to 1.32. The positive predictive value (+PV) was reported as 100%, with a 95% CI ranging from 92.7% to 95.7%.The area under the curve (AUC), representing the overall diagnostic accuracy, was reported as 0.525, with a 95% CI of 0.462 to 0.769(Table 6, Figure 1).

Table (1): Age and gender of included children.

Variables	N= 42 cases
Age	
Mean ± SD	12.65 ± 3.17
Median (range)	13 (6 – 18)
Gender	
Male	21 (50%)
Female	21 (50%)
Weight	
Mean ± SD	46.86 ± 12.11
Median (range)	47.50 (23 – 70)
Height in cm	
Mean ± SD	151.43 ± 15.84
Median (range)	156 (116 – 175)
Body mass index	
Mean ± SD	19.93 ± 1.83
Median (range)	20 (17 – 24)
Systolic blood pressure	
Mean ± SD	109.12 ± 8.06
Median (range)	110 (100 – 130)
Diastolic blood pressure	
Mean ± SD	67.26 ± 6.91
Median (range)	65 (60 – 85)
Duration of DM	
Mean ± SD	7.05 ± 2.11
Median (range)	6 (5.5 – 14)
HbA1c	
Mean ± SD	9.26 ± 1.63
Median (range)	9.5 (6.40 – 13.70)
RBS	
Mean ± SD	245.71 ± 92.13
Median (range)	200 (133 – 475)

DM: diabetes mellitus, HBA1c: Hemoglobin A1c, RBS: Random blood sugar
Categorical variables were expressed as number (percentage); Continuous variables were expressed as mean ± SD & median (range)

Table (2): CBC and albumin/creatinine ratio of the included children.

Variables	N= 42 cases
CBC	
TLC	
Mean ± SD	7.77 ± 0.69
Median (range)	7.80 (6.50 – 10)

Hgb	
Mean ± SD	10.89 ± 0.94
Median (range)	11 (8 – 12.3)
Platelet	
Mean ± SD	314.67 ± 49.89
Median (range)	305 (231 – 120)
Albumin/creatinine ratio	
Mean ± SD	35.71 ± 63.29
Median (range)	25.10 (10.13 – 428.25)

Continuous variables were expressed as mean ± SD & median (range).

Table (3): Comparison between no abnormality and abnormality regarding different variables.

Variables	Diabetic retinopathy	No abnormality	p-value
Age			
Mean ± SD	15.50 ± 2.38	12.36 ± 3.12	0.058
Median (range)	15.50 (13 – 18)	13 (6 – 17.50)	
Gender			
Male	1	20	0.293
Female	3	18	
Duration of DM			
Mean ± SD	9.25 ± 2.22	6.82 ± 1.99	**0.026***
Median (range)	10 (6 – 11)	6 (5.50 – 14)	
HgA1C			
Mean ± SD	10.88 ± 1.65	9.09 ± 1.55	**0.035***
Median (range)	11.50 (8.50 – 12)	9.50 (6.40 – 13.70)	
Random blood sugar			
Mean ± SD	353.00 ± 103.20	229.00 ± 76.51	**0.005***
Median (range)	350 (240 – 472)	200 (133 – 450)	
Albumin/Creatinine ratio			
Mean ± SD	155.28 ± 182.80	23.96 ± 7.34	**<0.0001***
Median (range)	74.12 (44.63 – 428.25)	25 (10.13 – 45.30)	
Total leucocyte count			
Mean ± SD	8.15 ± 0.83	7.73 ± 0.68	0.252
Median (range)	8.30 (7 – 9)	7.80 (6.50 – 10)	
Hemoglobin			
Mean ± SD	10.25 ± 0.96	10.96 ± 0.93	0.156
Median (range)	10.50 (9 – 11)	11 (8 – 12.30)	
Platelet			
Mean ± SD	292.50 ± 12.58	289.82 ± 12.33	0.681
Median (range)	290 (280 – 310)	290 (250 – 350)	

Categorical variables were expressed as number (percentage); Continuous variables were expressed as mean ± SD & median (range); Chi-square test was used for comparing categorical data; Mann Whitney U test was used for comparing continuous data; p value<0.05 is significant.

Table (4): Distribution of the findings of direct ophthalmoscopy and fundus photography.

	Direct Ophthalmoscopy	
	Optic disc	**Macula**
Diabetic retinopathy	0 (0%)	1 (2.4%)
No diabetic retinopathy	42 (100%)	41 (97.6%)

	Fundus photography		
	Optic disc	Macula	Periphery of retina
Diabetic retinopathy	0 (0%)	1 (2.4%)	4 (9.5%)
No diabetic retinopathy	42 (100%)	41 (97.6%)	38 (90.5%)

Table (5): Cross tabulation of direct ophthalmoscopy with fundus photographs

		Fundus photography		Total
		Diabetic retinopathy	No diabetic retinopathy	
Direct ophthalmoscopy	**Diabetic retinopathy**	1	0	1
	No diabetic retinopathy	3	38	41
Total		4	38	42

Table (6): Sensitivity of direct ophthalmoscopy compared to fundus photography.

Sensitivity 95% CI	Specificity 95% CI	+LR 95% CI	-LR 95% CI	+PV 95% CI	-PV 95% CI	AUC
25 (0.6 – 80.6)	100 (90.7 - 100)	-	0.75 (0.43 – 1.32)	100	92.7 (87.8-95.7)	0.625 (0.462-0.769)

LR, likelihood ratio; PV, predictive value; AUC, area under the curve;
CI, confidence interval.

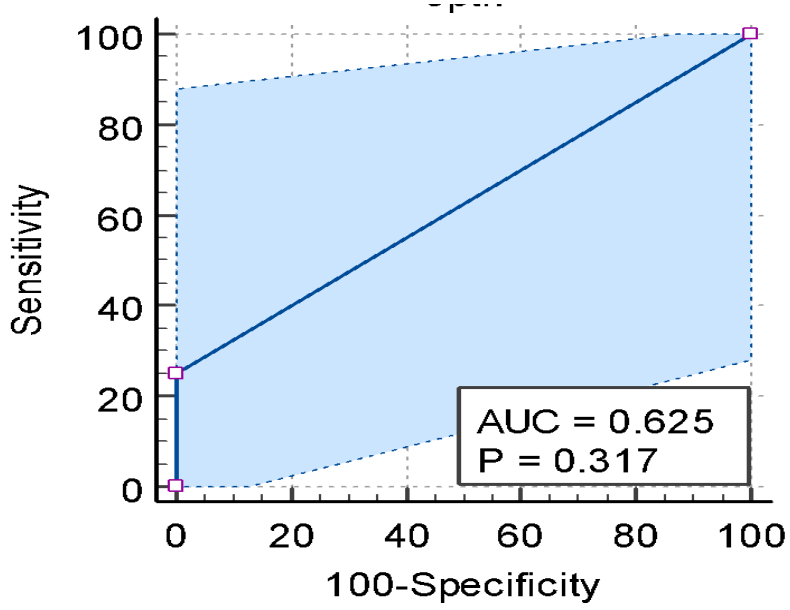

Figure (1):ROC curve analysis of direct ophthalmoscopy as a diagnostic marker for diabetic retinopathy compared to fundus photography.

DISCUSSION

A condition known as type 1 diabetes mellitus has been dramatically more common in the last 30 years. In this autoimmune disorder, immune cells assault pancreatic β-cells, leading to decreased insulin production and

elevated hemoglobin A1C levels [6].

According to previous research, clinical ophthalmic examinations for DR should be initiated three to five years after a diagnosis of type 1 diabetes, with yearly evaluations for children nine years and older. Another option is to have a clinical fundus examination and fundus photos taken of people with type 1 diabetes once a year, beginning at 12 or older [7].

It is recommended that photographic screening for children with type 1 diabetes at 10, regardless of the duration of the ailment, be begun in many countries. If DR were to start at the beginning of puberty, as it usually does, this age would be too early. Prepubescent children have been shown to have DR instances. Image evaluation should be performed every two years without DR and once a year after that if DR is identified or the results are not apparent [8].

With its remarkable sensitivity and accuracy, fundus photography is the gold standard for DR screening. Screening for DR by direct ophthalmoscopy is a cost-effective option, particularly in settings with limited resources. The examiner's proficiency is crucial to this approach's success[9].

A higher prevalence of DR has been linked to higher HbA1c readings, which indicate poor glycemic control. Retinopathy and other diabetic problems are far less likely to occur in patients undergoing intensive diabetes treatment, which seeks to keep blood glucose levels near normal and lower HbA1c [10].

If diabetic retinopathy is to be effectively managed and its progression slowed, early detection and screening using tools like fundus photography and direct ophthalmoscopy are essential. While direct ophthalmoscopy is less expensive and more widely available, fundus photography is superior for spotting retinopathy in its early stages. Timely detection and treatment of retinopathy and other issues connected to diabetes can be achieved through regular ophthalmologic examinations for children with type 1 diabetes, which should begin within three to five years from the start of diabetes and continue annually afterward [11].

The average age of the participants was 12.65 years, with a standard deviation of 3.17. Regarding gender, the study cohort is evenly distributed, with 21 males (50%) and 21 females (50%). The study participants had a mean weight of 46.86 kg (SD = 12.11). Their mean height was 151.43 cm (SD = 15.84). Additionally, their mean BMI was 19.93 (SD = 1.83), and their mean systolic and diastolic blood pressures were 109.12 mmHg (SD = 8.06) and 67.26 mmHg (SD = 6.91), respectively.

Similarly, Participants in the Diabetes Control and Complications Trial (DCCT) who were 13–18 years old when randomized were the subjects of a retrospective analysis of diabetic retinopathy evaluations by Gubitosi-Klug et al. [12]

The mean duration of diabetes was 7.05 years, with a standard deviation of 2.11. For HbA1c levels, the mean was 9.26, with a standard deviation of 1.63. Regarding RBS, the mean was 245.71, and the standard deviation was 92.13.

Similarly, the average duration of diabetes was 9.3 years, and the median baseline hemoglobin A1c level was 9.3%, according to Gubitosi-Klug et al. [12]

Also, with a standard deviation of 6.51 years, Ahsan et al. [13] demonstrated that the average duration of diabetes was 9.17 years. The standard deviation of the HbA1c levels was 3.28%, and the mean was 9.73%.

This study showed that the sensitivity of the direct ophthalmoscopy was reported as 25%, with a comprehensive 95% CI ranging from 0.6% to 80.6%. At the same time, the specificity was reported as 100%, with a narrower 95% CI ranging from 90.7% to 100%.

According to Ahsan et al. [13], a diabetologist's direct ophthalmoscopy had a sensitivity of 55.67 percent and a specificity of 71.27% in detecting retinopathy of any severity compared to other studies. Also, while the specificity was significantly higher at 76.78%, the sensitivity for diagnosing NSTDR (non-sight-threatening diabetic retinopathy) was considerably lower at 37.63%.

While high sensitivity is essential for screening to capture all possible disease cases, lower sensitivity detected in our study meant many patients with retinopathy went undetected. This poses a risk, as missing cases of retinopathy is potentially more dangerous than ruling out those without the disease.

Begum et al. [14] studied 1455 diabetic patients. Non-ophthalmologists' fundus photography was 86.6% sensitive (483/558, 95% CI: 83.5% to 89.3%) in identifying diabetic retinopathy of any kind. With a 95% confidence interval ranging from 75.8% to 81.2%, the specificity was found to be 78.6% (705 out of 897).

Reasons for these discrepancies include different approaches, reference grading scales, and retinopathy levels taken into account when determining sensitivity and specificity. Furthermore, another factor that can impact outcomes is the degree of expertise healthcare providers possess in conducting retinopathy evaluations [15].

When assessing the test's practical use, it is crucial to consider both sensitivity and specificity as well as positive and negative predictive values (PPV and NPV). While PPV shows how many patients were accurately diagnosed based on positive test findings, NPV estimates how many patients were correctly diagnosed based on negative test results [16].

The current study showed that the negative likelihood ratio (NLR) was reported as 0.75, with a 95% CI of 0.43 to 1.32. The positive predictive value (PPV) was reported as 100%, with a 95% CI ranging from 92.7% to 95.7%.

Compared to another study, their research, Ahsan et al. [13] demonstrated that ophthalmoscopy had a positive predictive value (PPV) of 39.76% for detecting any retinopathy, 37.63% for NSTDR, and 52.43% for STDR. The matching conditions had an NPV of 82.51%, 84.96%, and 94.16%. These findings suggest direct ophthalmoscopy might be more effective in detecting healthy eyes than retinopathy.

The fundus photography in the cross-sectional investigation by Fahadullah et al. [17] showed a specificity of 86.3% (1548 out of 1794) and a sensitivity of 72% (400 out of 556). Of the 646 observations, 400 had a positive predictive value of 62%, and 1,548 had a negative predictive value of 90%.

The results of a six-month hospital-based cross-sectional investigation indicated that the performance of general practitioners (GPs) and the ophthalmologist for screening of diabetic retinopathy (DR). The average sensitivity of GPs to evaluate DR was 80.69 [74.8–85.4]; specificity, 92.23 [88.7–96.3]; positive predictive value, 74.1 [70.4–77.0]; negative predictive value, 73.34 [70.6–77.9]; and accuracy, 84.57 [81.8–89.88], agreement between the gold standard and the GPs, calculated using the adjusted kappa coefficient, ranged from 0.74 to 0.92 for DR,

and the percent agreement ranged from 79.3% to 983.9% for DR [14].

The mean duration of diabetes was significantly higher in individuals with DR (9.25 ± 2.22 years) compared to those with no abnormality (6.82 ± 1.99 years), with a p-value of 0.026. Additionally, higher mean HgA1C levels were noted in individuals with DR (10.88 ± 1.65) compared to their counterparts with no DR (9.09 ± 1.55), with a p-value of 0.035.

Moreover, the mean random blood sugar was markedly elevated in individuals with DR (353.00 ± 103.20) compared to those with no abnormality (229.00 ± 76.51), with a p-value of 0.005. Furthermore, the albumin/creatinine ratio was significantly higher in individuals with abnormalities (155.28 ± 182.80) compared to those with no abnormality (23.96 ± 7.34), with a p-value of < 0.0001. No significant difference was found regarding age, gender, and CBC components.

HbA1c measurements are essential to tracking the development of retinopathy. Poshtchaman et al. [19] found that compared to the non-retinopathy group, the retinopathy groups (non-proliferative diabetic retinopathy, or NPDR) and proliferative diabetic retinopathy, or PDR) had significantly higher hemoglobin A1c levels. Diabetic retinopathy is more likely in patients with high glycosylated hemoglobin levels. Thus, to avoid retinopathy, it is advised that diabetic people closely monitor their blood sugar levels.

In the diabetic retinopathy group, no cases exhibited abnormalities in the optic disc, while one showed diabetic retinopathy in the macula. Forty-one cases (97.6%) showed no diabetic retinopathy in the macula.

In the diabetic retinopathy group, 0% of cases exhibited abnormalities in the optic disc, 2.4% showed abnormalities in the macula, and 9.5% showed irregularities in the periphery of the retina. Conversely, in the group without diabetic retinopathy, all patients (100%) displayed normal findings in the optic disc and macula. Moreover, 90.5% of cases in this group exhibited a healthy retina periphery.

One case with diabetic retinopathy was identified by both direct ophthalmoscopy and confirmed by fundus photography. No diabetic retinopathy identified by both direct ophthalmoscopy and confirmed by fundus photography represented 38 cases. No cases were identified as the absence of diabetic retinopathy by direct ophthalmoscopy but confirmed as diabetic retinopathy by fundus photography. Three cases were diabetic retinopathy initially identified as the absence of diabetic retinopathy by direct ophthalmoscopy but later confirmed as diabetic retinopathy by fundus photography.

According to Gubitosi-Klug et al. [12], no participant had significant proliferative or non-proliferative diabetic retinopathy during the study period. A single subject in the intense therapy group had a premature onset of clinically significant retinal edema.

According to research by Brown et al. [21], 58 out of 64 drusen in the posterior pole/macula were discovered using the image-assisted method. In comparison, only 28 out of 64 drusen were detected using standard fundus inspection alone. Of the 135 lesions seen in the posterior pole/macula area, 64 were determined to be drusen. This investigation found 419 lesions in the mid-to-peripheral retina; however, only 15 lesions, or 4.4% of all eyes, were categorized as retinal holes or tears. Statistically, there was no discernible difference between the approaches to identifying these lesions based on this sample size.

This study had several strengths, including addressing a specific research question regarding the accuracy of direct ophthalmoscopy versus fundus photography in diagnosing DR among children with T1DM. This clear objective allowed for a targeted investigation and interpretation of results.By comparing direct ophthalmoscopy to fundus photography, the study contributes to understanding the relative efficacy of these two commonly used screening methods for DR. This comparison allowed for insights into the strengths and limitations of each approach and can inform clinical decision-making.The study's findings directly affect clinical practice, particularly regarding DR screening protocols for pediatric T1DM patients. By identifying the strengths and weaknesses of different screening methods, the study can help healthcare providers select the most appropriate approach for early detection and management of DR.

There are certain limitations in our study. Firstly, the sample size of 42 patients may be relatively small, which could impact the statistical power and precision of the results. A larger sample size might have provided more robust conclusions and allowed subgroup analyses to explore potential factors influencing screening test performance. Secondly, the study was conducted at a single center, which may limit the generalizability of the findings to other populations or healthcare settings. Variations in patient demographics, disease severity, or healthcare practices in different settings could affect the performance of screening tests for diabetic retinopathy.Longitudinal follow-up of patients could provide valuable insights into the effectiveness of screening strategies and their impact on clinical outcomes.

CONCLUSION

Direct ophthalmoscopy's sensitivity and specificity for detecting the presence and severity of DR were found to be lower than the recommended levels set for a DR screening test. This suggests that fundus photography is more accurate than direct ophthalmoscopy for screening DR.

Conflict of Interest or financial disclosure: No any potential conflict of interest to be reported by the authors.

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