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Original Article

Role of frequency doubling technology perimetry in screening of diabetic retinopathy

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Purpose: To study the ability of frequency-doubling technology perimetry (FDT) to detect sight-threatening diabetic retinopathy.

Method: Fifty-eight eyes of fifty-eight patients with established diagnosis of diabetes mellitus with diabetic retinopathy, fifty-five eyes of fifty-five diabetic patients without retinopathy, and forty-one eyes of forty-one normals underwent FDT and dilated stereo-biomicroscopic fundus examination. The sensitivity and specificity of FDT in identification of "sight-threatening retinopathy" (severe and very severe nonproliferative diabetic retinopathy and proliferative diabetic retinopathy) and clinically significant macular edema (CSME) were determined.

Results: For the detection of sight-threatening retinopathy, two abnormal adjacent points depressed to any level on the 20-1 screening program had a sensitivity of 90.5% and specificity of 97.6%. At (assuming a) 10% prevalence of sight-threatening retinopathy in a diabetic clinic, two abnormal adjacent points anywhere in the field depressed to any level has a positive predictive value (PPV) of 48% with a negative predictive value of 98.8%. Sensitivity and specificity for the detection of CSME was poor.

Conclusions: The 20-1 screening program of the FDT is useful in the detection of sight-threatening diabetic retinopathy (PPV 48%). A normal 20-1 test rules out sight-threatening retinopathy. FDT was not useful in the detection of CSME.

Key Words: Clinically significant macular edema, diabetic retinopathy, frequency-doubling technology perimetry, screening, sight-threatening retinopathy

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Early detection of diabetic retinopathy and timely intervention by laser photocoagulation can reduce the incidence of moderate visual loss in macular edema by 50–60% and severe visual loss in proliferative diabetic retinopathy (PDR) by 90%.[1]

Slit-lamp biomicroscopy through a dilated pupil and standard seven-field stereoscopic 30° fundus photography are the current "gold standards" in the evaluation of diabetic retinopathy. However, they suffer the disadvantage of being time consuming, require dilatation of pupil, and can be offered only by a specially trained ophthalmologist.

General practitioners and physicians remain the main key to the identification and referral of all diabetic patients; especially those who might need immediate attention. Numerous techniques such as direct ophthalmoscopy, fundus photography, contrast sensitivity, and color vision by a variety of screeners such as opticians and physicians have been tried as a screening tool with limited success.[2–6] Although all diabetics require ophthalmoscopic evaluation, there is also a need for a rapid test to identify cases which require priority evaluation (and treatment) by an ophthalmologist.

Patients with diabetic retinopathy have a sensitivity loss in the midperipheral visual field detected by white-on-white perimetry; this loss has been correlated with the retinal area of nonperfusion.[7–9] The sensitivity loss was closely associated with microangiopathy and was greater in the midperipheral area than in the paracentral area. Short-wavelength automated perimetry has been shown to offer improved sensitivity for the detection of clinically significant macular edema (CSME)[10] and diabetic visual field defects.[11] Verrotti *et al.* evaluated role of central static perimetry (24-2,HFA) to identify patients at risk of developing diabetic retinopathy in insulin-dependent diabetes mellitus patients prospectively. Their results suggest that the overall probability of retinopathy development was significantly higher in subgroups of patients with lower mean sensitivity in areas 2 and 3 (between 10° and 24° of central 24-2 visual field.[12]

The frequency-doubling technology perimeter (FDT) is a device that can perform a rapid screening test in less than 1

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min per eye.[13] Although FDT seems to be a valid method of screening the central visual field, there have been no publications regarding its use as a screening tool in diabetic retinopathy. This preliminary study was therefore undertaken to study the ability of FDT to detect sight-threatening diabetic retinopathy.

Materials and Methods

Three groups were recruited for this study. As this was not an interventional study, review board approval was not required. In all three groups consecutive patients were enrolled between March 2000 and January 2001, if they fulfilled inclusion and exclusion criteria.

Group 1

This group represents diabetics with retinopathy and comprised 58 eyes (58 patients) with established diagnosis of diabetes mellitus (as per criteria laid down by the National Diabetes Data Group[14]) with following inclusion criteria: age of 30 years or older, evidence of diabetic retinopathy on slit-lamp biomicroscopy of the fundus, and best corrected visual acuity of 20/200 or better. Cataract were graded according to lens opacity classification system III[15] (LOCS III): nuclear opalescence up to grade 3, nuclear color up to grade 3, and cortical cataract up to grade 3 were included.

Exclusion criteria: previous laser photocoagulation, PDR with sequelae (vitreous hemorrhage and tractional retinal detachment), any other eye disorder that could cause a visual field defect, for example, glaucoma or neuro-ophthalmic disorders and an intra ocular pressure of 22 mmHg or more. Patients with cataracts more than the grades mentioned above and those with a posterior subcapsular cataract even of grade 1, in the pupillary area, were excluded.

Levels of diabetic retinopathy were defined according to the American Academy of Ophthalmology as mild non-PDR (NPDR), moderate NPDR, severe NPDR, very severe NPDR, and PDR.[16] As the severe and very severe NDPRs as well as the PDR need priority detection, these were analyzed as "sight-threatening" retinopathy.

Group 2

This group represents diabetics without retinopathy and comprised 55 eyes (55 patients) with established diagnosis of diabetes mellitus with the following inclusion criteria: age of 30 years or older with no evidence of diabetic retinopathy on slit-lamp biomicroscopy, and best corrected visual acuity of 20/20 J_1.

Exclusion criteria: Any eye disease or disorder that could cause a visual field defect and a lenticular opacity greater than the above-mentioned LOCS III grades were excluded.

Group 3

This group comprised 41 eyes of 41 normal subjects with the following inclusion criteria: age of 30 years or older with no ocular abnormalities, except refractive errors and presbyopia, and best corrected visual acuity of 20/20 J_1. Evidence of any ocular pathology was an exclusion criterion.

Consecutive normal subjects were recruited from the outpatient department of the eye hospital. Patients with diabetes mellitus were referred from the Department of Medicine, Christian Medical College, Vellore.

In all groups, in patients whose both eyes fulfilled eligibility criteria, one eye was randomly selected for analysis. If only one eye was eligible, this eye was selected.

All patients underwent a complete ophthalmological examination. This was performed in the following order: The visual acuity and refraction were recorded first. Media opacities were ruled out on distant direct ophthalmoscopy and undilated slit-lamp examination of the anterior segment.

Testing on the FDT (Humphrey Instruments, Welch Allyn, USA) was then performed in the following sequence by a single observer: 20-5 followed by 20-1 screening program. The observer was masked to clinical finding and diagnosis. Both tests were performed as recommended by the manufacturer. The following reliability criteria were used for FDT testing: less than 25% false-positives and false-negatives and less than 20% fixation losses. At least three attempts were made to obtain a reliable test. If patients could not perform reliable fields they were excluded from the study. Two patients from the control group and four patients from the diabetic group had to be excluded owing to inability to obtain reliable fields.

Following FDT, applanation tonometry and gonioscopy were performed, and patients were dilated with 1% tropicamide eye drops for evaluation of the fundus. Stereo-biomicroscopic examination of the fundus was performed by one of the three consultant retinal specialists who were unaware of the patient's visual fields. A Volk 78D or 90D lens or Goldman 3 mirror lens was used. The lens was then graded by LOCS III guidelines[15], and eyes with significant cataract were excluded.

Specificity was first calculated conventionally using the normal group. In order to represent the scenario in different clinics we also calculated "specificity" unconventionally. To represent the scenario in diabetic clinic, specificity was calculated using the "mild + moderate + no retinopathy" group (92 eyes). This group consists of only diabetics; we felt this represents the scenario in a diabetologist's clinic. To represent the scenario in a general practitioners clinic, specificity was also calculated using the "mild + moderate + no retinopathy + normals" group (133 eyes).

We applied a series of diagnostic criteria with increasing degree of stringency. The sensitivity and specificity were calculated for each criterion. Slit-lamp biomicroscopy findings served as the gold standard.

To correlate sight-threatening retinopathy (21 eyes) with FDT recordings, the following seven criteria were applied to 20-1, 20-5 screening program.

Criterion 1: One abnormal point anywhere in the field, depressed to any level.

Criterion 2: Two abnormal nonadjacent points anywhere in the field, depressed to any level.

Criterion 3: Two abnormal adjacent points anywhere in the field, depressed to any level.

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Criterion 4: One abnormal point depressed to any level in the inner ring or the central point.

Criterion 5: Two abnormal points depressed to any level in the inner ring, excluding the central point.

Criterion 6: Central point depressed to any level.

Criterion 7: Central point depressed to any level, and a minimum of two abnormal points in the inner ring depressed to any level.

The goal of screening is to detect disease with a minimum of false-positives.[17] Accordingly, the ideal criterion for a screening test should have reasonably high sensitivity with high specificity. We referred to this as the "best-combination" criterion. To detect CSME, criteria 4–7 were applied to the eyes with CSME (16 eyes) and compared with the "no retinopathy" group.

Sensitivity, specificity, and predictive values were calculated for all criteria using conventional 2 x 2 tables.

Positive predictive value (PPV) was calculated to simulate the prevalence of sight-threatening retinopathy in a diabetic clinic and that in a general physician's clinic. The prevalence used in these calculations was obtained as follows: 7.8% of the general population above the age of 30 years have diabetes and 22.4% of diabetics above the age of 30 years have diabetic retinopathy;[18] 10% of all diabetic retinopathies is what we have called "sight-threatening," and 2.5% of those with diabetes are expected to have such retinopathy.[18] As diabetic clinics are likely to have the more severe cases, we assumed a 10% prevalence of sight-threatening retinopathy for a diabetic clinic. For the general physician's clinic the prevalence of sight-threatening diabetic retinopathy would be the product of prevalence of diabetes (7.8%)[18] and prevalence of sight-threatening diabetic retinopathy (10.7%).[18] The resultant value of 0.83% was used to calculate PPV and Negative Predictive Value (NPV) for the general physician's clinic.

We also assessed the effect of duration of disease, and age and sex of patients on FDT results. For disease duration, all diabetic retinopathy patients were divided into two groups, disease duration less than 10 years and disease duration more than 10 years; test positivity (diagnosed by criterion 3) of FDT was compared between two groups. The level of significance was set at $P < 0.05\%$.

Results

Our study involved 113 eyes (113 patients) with established diagnosis of diabetes mellitus; 103 (103 patients) had type-2 and 10 (10 patients) had Type 1 diabetes mellitus. The mean duration of diabetes was 7.6 years (95% CI: 6.5–8.7).

Fifty-five eyes had no retinopathy, and fifty-eight eyes had some grade of retinopathy as detected by slit-lamp biomicroscopy: mild NPDR 17, moderate NPDR 20, severe NPDR 17, and PDR 4. None had very severe NPDR. Of the 113 diabetic eyes, 25 eyes (22.1%) belonged to known hypertensives (26 in group 1 and 7 in group 2); the mean duration of hypertension was 4.4 years. Table 1 shows the demography of all groups.

20-5 Test

Using the mild + moderate + no retinopathy group to determine specificity, criterion 5 provided the best-combination sensitivity and specificity of 90.5% and 80.5%, respectively.

Similarly, when the mild + moderate + no retinopathy + normal group was used to determine specificity, criterion 5 provided the best-combination sensitivity and specificity of 71.4% and 88.7%, respectively. As the 20-5 test did not perform so well as the 20-1 test, only the results of the latter are presented.

20-1 Test

Sight-threatening retinopathy

Using the normal group to determine specificity, the sensitivity and specificity obtained for each criterion is shown in Table 2. Criterion 2 had a sensitivity of 95.2% and specificity of 95.1%. The highest sensitivity obtained on 20-1 test was 100% (criterion 1) and the highest specificity obtained was 97.6% (criteria 4–7).

Using the mild + moderate + no retinopathy group to determine specificity, the sensitivity and specificity obtained for each criterion is shown in Table 3. Criterion 3 had a sensitivity of 90.5% and specificity of 89.1%. The highest sensitivity obtained on 20-1 test was 100% (criterion 1) and the highest specificity obtained was 97.8% (criterion 7).

Using the mild + moderate + no retinopathy + normal group to determine specificity, the sensitivity and specificity obtained for each criterion is shown in Table 4. Criterion 3 had a sensitivity of 90.5% and specificity of 91.7%. The highest sensitivity obtained on 20-1 test was 100% (criterion 1) and the highest specificity obtained 97.75% (criterion 7).

CSME

Criterion 4 gave the best combination of 50% sensitivity and 93.5% specificity. We did not find any association between age or sex of patients and positivity on FDT. Disease duration and disease positivity also did not have any direct relationship ($P < 0.25$).

Table 1: Demography

	DM without retinopathy	Normal	DM with Retinopathy		
			Mild	Moderate	Severe
Mean age (years) (SD)	50.27 (9.35)	45.3 (7.82)	50.4 (9.04)	52.4 (6.57)	51.2 (8.12)
Male : female	31 : 24	21 : 20	14 : 3	15 : 5	17 : 4
Mean duration of DM (year) (SD)	5.00 (4.1)	NA	7.02 (5.8)	9.9 (6.3)	11.6 (6.2)

DM: diabetes mellitus, SD: standard deviation

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Table 2: Sensitivity and specificity of various criteria on 20-1 program of FDT for sight-threatening diabetic retinopathy, when compared with normal group

Criterion	Sensitivity	Specificity	PPV (%)	NPV (%)
1	21 (100), 95% CI: 94.6–100	35 (85.4), 95% CI: 74.6–96.2	15	100
2	20 (95.2), 95% CI: 86.1–100	39 (95.1), 95% CI: 88.5–100	33.3	99.9
3	19 (90.5), 95% CI: 77.9–100	40 (97.6), 95% CI: 92.9–100	49.5	99.7
4	16 (76.2), 95% CI: 58–94.4	40 (97.6), 95% CI: 92.9–100	45.2	99.4
5	14 (66.7), 95% CI: 46.5–86.9	40 (97.6), 95% CI: 92.9–100	42.5	98.1
6	11 (52.4), 95% CI: 31–73.8	40 (97.6), 95% CI: 92.9–100	36.1	98.8
7	11 (52.4), 95% CI: 31–73.8	40 (97.6), 95% CI: 92.9–100	36.1	98.8

PPV and NPV are calculated for 2.5% prevalence of sight-threatening retinopathy

FDT - Frequently doubling technology perimetry CI- Confidence Interval PPV - Positive predictive value NPV - Negative predictive value

Table 3: Sensitivity and specificity of various criteria on 20-1 program of FDT for detecting sight-threatening retinopathy, when compared with mild + moderate + no retinopathy group

Criterion	Sensitivity	Specificity	PPV (%)	NPV (%)
1	21 (100), 95% CI: 94.6–100	72 (78.3%), 95% CI: 69.9–86.7	33.8	100
2	20 (95.2), 95% CI: 86.1–100	78 (84.8%), 95% CI: 77.5–92.2	40.9	99.4
3	19 (90.5), 95% CI: 77.9–100	82 (89.1%), 95% CI: 82.7–95.5	48	98.8
4	16 (76.2), 95% CI: 58–94.4	86 (93.5%), 95% CI: 88.5–98.5	56.4	97.3
5	14 (66.7), 95% CI: 46.5–86.9	88 (95.7%), 95% CI: 91.6–99.8	63.1	96.3
6	11 (52.4), 95% CI: 31–73.8	89 (96.8%), 95% CI: 93.2–100	64.4	94.8
7	11 (52.4), 95% CI: 31–73.8	90 (97.8%), 95% CI: 94.8–100	72.9	94.9

PPV and NPV are calculated for 10% prevalence of sight-threatening retinopathy

FDT - Frequently doubling technology perimetry CI- Confidence Interval PPV - Positive predictive value NPV - Negative predictive value

Table 4: Sensitivity and specificity of various criteria on 20-1 program of FDT for detecting sight-threatening retinopathy, when compared with mild + moderate + no retinopathy + normal group

Criterion	Sensitivity	Specificity	PPV (%)	NPV (%)
1	21 (100), 95% CI: 94.6–100	107 (80.5%), 95% CI: 74.3–84.8	4.1	100
2	20 (95.2), 95% CI: 86.1–100	117 (88%), 95% CI: 82.5–88	6.2	99.95
3	19 (90.5), 95% CI: 77.9–100	122 (91.7%), 95% CI: 87–96.4	8.4	99.9
4	16 (76.2), 95% CI: 58–94.4	126 (94.7%), 95% CI: 90.9–98.5	10.8	99.8
5	14 (66.7), 95% CI: 46.5–86.9	128 (96.2%), 95% CI: 92.9–99.5	12.9	99.7
6	11 (52.4), 95% CI: 31–73.8	129 (97%), 95% CI: 94.1–99.9	12.7	99.6
7	11 (52.4), 95% CI: 31–73.8	130 (97.7%), 95% CI: 97.7–100	16.1	99.6

PPV and NPV are calculated for 0.83% prevalence of sight-threatening retinopathy

FDT - Frequently doubling technology perimetry CI- Confidence Interval PPV - Positive predictive value NPV - Negative predictive value

Discussion

Various studies in literature have reported the importance of visual field examination in diabetic retinopathy. All studies have used white-on-white or blue-on-yellow perimetry.[7–12] There are no reports of FDT in diabetic retinopathy to compare our results with. We first compared the sight-threatening retinopathy group to the mild + moderate + no retinopathy group. This is the type of scenario in the clinic of a diabetologist. Although all these patients would need to see an ophthalmologist, it makes sense to identify those who need priority referral. We tried to determine whether this was possible.

Assuming a 10% prevalence of sight-threatening retinopathy in this situation, the best-combination criterion on 20-1 screening test provided a PPV of 48% and NPV of 98.8%. That is, half of those referred would indeed have sight-threatening retinopathy. If the test was negative, we would be correct in our prioritization 99% of the time. Only one in a 100 patients with sight-threatening retinopathy would be given a routine referral.

Although data from population-based studies have shown the prevalence of severe grades of retinopathy to be 2.5–3%,[18] it is likely to be higher in a diabetic clinic. For the calculation, we therefore assumed 10% prevalence in the diabetic clinic, but the actual prevalence may be lower. If we assume the prevalence of sight-threatening retinopathy in the diabetic clinic to be to be 5%, the PPV is 30.4% and NPV is 99.4%.

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We know that FDT also detects field defects owing to glaucoma as well as neurological disease. It is also abnormal in patients with cataracts. It could be argued that this would dilute the detection of sight-threatening diabetic retinopathy. But because we are dealing with a diabetic population, most of the abnormalities detected will likely be owing to diabetic retinopathy. Also, the "false-positives" are going to be diabetics, who anyway need to see an ophthalmologist. In an ophthalmologist's clinic, every diabetic should have a dilated fundus examination. Our results suggest a role for FDT as triage in the diabetologist's clinic to detect those who need "immediate" *vs* an elective appointment with the ophthalmologist.

Our second comparison of sight-threatening retinopathy group with mild + moderate + no retinopathy + normals represents the scenario in a general physician's clinic. As the estimated prevalence of sight-threatening retinopathy in this situation is likely to be very low, the PPV is also very poor. Accordingly, unlike in a diabetic clinic we would not expect the FDT to be useful for the screening of sight-threatening diabetic retinopathy in a general physician's clinic.

We were unable to find a suitable criterion to detect CSME. Of the sixteen eyes with CSME, FDT failed to detect eight (one associated with mild NPDR and seven associated with moderate NPDR). In our study 50% of patients with CSME had mild or moderate retinopathy. According to the literature, CSME is far more common with severe NPDR and PDR. Only 12% were reported with mild or moderate disease,[17] but then, these grades of retinopathy are far more common than the severe grades. Our results indicate that CSME associated with higher grades would be detected by the criteria we use but FDT would miss CSME associated with mild and moderate NPDR. However, although the prevalence of CSME in patients with diabetic retinopathy may be as high as 14%, the prevalence in the diabetic population *per se* (that seen in a diabetic clinic) is only 0.9–1%.[17–19] It is also interesting that half of the CSME missed by FDT (four eyes) had subnormal vision $\leq 20/30$ J_2. If this cut-off were made a more reasonable 20/40, we would still detect two (50%) of the CSME associated with mild or moderate disease. Perhaps asking a simple question about the ability to read small newspaper print might achieve similar results. Whereas inability to detect CSME is a weakness of the technique especially in a developed country where prevalence of diabetic retinopathy, CSME, and associated visual morbidity is higher,[20–24] a population-based study in India reported a low prevalence of CSME as well as visual impairment owing to diabetic retinopathy.[18]

A limitation of this study is that we had only 21 patients with sight-threatening retinopathy. The number of patients with PDR was only four and is partly explained by the strict exclusion criteria. We excluded all PDR patients with cataracts and sequelae-like tractional retinal detachment and vitreous hemorrhage, which is the most common presentation if not screened periodically. As both these sequelae present with symptoms that lead to an urgent ophthalmic consultation, the question of screening does not arise here. Thus we considered it appropriate to screen only the "asymptomatic" PDR patients who can benefit from early evaluation and laser treatment.

Of the 113 diabetic eyes, 25 were diagnosed as hypertensives. It could be argued that the presence of hypertension would affect the results. Hypertension, however, is more likely to be present in diabetics, either because of increasing age or renal damage, and such patients are common in clinical practice. According to the United Kingdom Prospective Diabetic Study, 38% of newly diagnosed type 2 diabetics had hypertension.[25] We felt that including diabetics with hypertension will more appropriately reflect the real-life situation that the diabetologist or physician is likely to face.

In conclusion, we have shown that the screening program of FDT can rapidly detect the presence of sight-threatening retinopathy. FDT in screening mode fails to detect CSME associated with mild and moderate NPDR. The results require independent confirmation.

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