Developing a Screening Program to Detect Sight-Threatening Diabetic Retinopathy in South India

Perumalsamy Namperumalsamy, MD
Praveen K. Nirmalan, MD, MPH
Kim Ramasamy, MD

OBJECTIVE — To develop a screening protocol for detection of sight-threatening diabetic retinopathy in South India.

RESEARCH DESIGN AND METHODS — We performed ophthalmic examinations, including posterior segment examination, using indirect ophthalmoscopy to detect sight-threatening retinopathy in patients with diabetes in screening camps targeting a high-risk population.

RESULTS — We examined 3,949 persons with diabetes in 32 screening camps over a 13-month period beginning July 2001. Most of the patients (93.6%) were aware of their diabetic status, and 84.2% of those aware of their diabetes status were on treatment. One-fifth of those screened had evidence for any retinopathy; only 6.1% of these persons had evidence of past ophthalmic treatment for retinopathy. Only one-quarter of those diagnosed with worse than mild retinopathy came for follow-up to the base hospital within 2 months.

CONCLUSIONS — Screening high-risk groups for sight-threatening retinopathy using indirect ophthalmoscopy may be a useful short-term alternative for India until retinal photography becomes affordable. In addition to strategies to improve coverage, strategies for better follow-up of subjects screened also need to be evolved.

Diabetes Care 26:1831–1835, 2003

Diabetic retinopathy is recognized as one of the ocular diseases with public health implications in India due to several reasons, including 1) an estimated 57 million people in India may be diabetic by 2025 (195% increase from 1995) and 2) the risk of sight-threatening retinopathies is higher in diabetic adults (1–5). A recent population-based cross-sectional study from South India estimated a 1.3% prevalence of diabetic retinopathy among those aged ≥50 years (1). Although the current prevalence of diabetic retinopathy seems to be relatively low, the estimated increase in the magnitude of diabetes in India and the potential for a consequent higher prevalence of diabetic retinopathy suggest an immediate need to establish control measures so that diabetic retinopathy does not become a major cause for vision impairment and blindness. Such control measures will have to, however, bear in mind possible barriers that prevent optimal eye care service uptake previously reported from this population (6,7). Attempts to address barriers to cataract surgery in India have focused primarily on community outreach programs to improve access to the underserved populations and to reduce costs to patients and have succeeded in increasing uptake to some extent (8). Although it may seem logical that a similar approach can be adopted for diabetic retinopathy, the low population prevalence suggests a possible low yield of diabetic retinopathy in outreach programs targeting entire populations, with consequent implications on sustainability of programs. Targeting high-risk groups such as known diabetic individuals for community screening may help to increase yield of diabetic retinopathy cases without compromising sustainability of the program.

We initiated a pilot project in Tamil Nadu state of south India to address the potential epidemic of diabetic retinopathy, especially sight-threatening diabetic retinopathy in India. This project had two main objectives: 1) to develop a screening protocol to detect sight-threatening retinopathy and a service delivery model appropriate and financially feasible for India, and 2) to determine current levels of awareness regarding diabetes and retinopathy and develop educational materials to improve awareness of diabetic retinopathy. This study reports on the screening program of high-risk groups for sight-threatening diabetic retinopathy in South India.

RESEARCH DESIGN AND METHODS — We selected three districts (Madurai, Thuni, and Coimbatore) covering a population of 7.5 million people and an estimated 375,000 persons with diabetes and with a reasonable representation of the socioeconomic and urban-rural distribution of the population of the state of Tamil Nadu for this project. Two of these districts were from southern Tamil Nadu, and one was from Central Tamilnadu. The selected districts were similar to other districts of the state; the districts had an agriculture-based economy, and most residents lived in ru-
Screening for diabetic retinopathy

Among the local community was initiated were chosen based on the convenience of involved with diabetes care. Campsites and medical practitioners, and others in-partnership with diabetologists, internists and medical practitioners, and others involved with diabetes care. Campsites were chosen based on the convenience of the partner and included a mix of rural and urban sites. Publicity for each camp among the local community was initiated 1 month before the actual camp. Publicity involved telecasts through visual media, including television, movies, leaflets, and newspapers, direct approach to medical practitioners in the area to request them to refer their diabetic patients to the camp, direct intimation to diabetic patients based on a list provided by local medical practitioners, posting of message boards in prominent places, and use of local volunteers to spread word regarding the camp. The cost for each screening was approximately $175 (U.S.).

Screening for diabetes and diabetic retinopathy was performed simultaneously at the screening camps. Subjects who were not previously aware of their diabetic status underwent random blood glucose measurement; an individual with a random blood glucose measurement ≥140 mg/dl was considered suspect for diabetes. Any subject either considered suspect for diabetes or who were previously aware of their diabetes status were referred for ophthalmic examination at the campsite.

Before ophthalmic examination, details pertaining to age, sex, occupation, and address of subjects were elicited and recorded. A brief history of diabetic status, including treatment details and current symptoms, if any, was elicited from eligible subjects. Presenting visual acuity of subjects (with eyeglasses if the subject usually wore eyeglasses) was measured using Snellen charts at 6-m distance. We refracted subjects with vision worse than 20/60 in either eye using streak retinoscopy and trial lenses. Anterior segment examinations and intraocular pressure measurements using Schiotz tonometry were recorded for subjects. Pupils were dilated for subjects other than those considered to have shallow anterior chambers on anterior segment examination. After pupillary dilatation of the subjects, ophthalmologists trained in management of vitreoretinal disease performed retinal examinations with direct and indirect ophthalmoscopy using a 20-diopeter lens in a masked manner. We did not use slit-lamp biomicroscopy for the posterior segment examinations.

Diabetic retinopathy was categorized using a modified classification based on the retinopathy levels used by Klein et al. (9). Retinopathy was classified as nonproliferative diabetic retinopathy (NPDR), severe NPDR, and proliferative diabetic retinopathy (PDR). NPDR included levels 1–3, severe NPDR included levels 4 and 5, and PDR included levels 6 and 7, as described by Klein et al. (9). The presence of clinically significant macular edema (CSME) was assessed using indirect and direct ophthalmoscopy. We considered subjects who had severe NPDR, PDR, or CSME to have sight-threatening retinopathy. Subjects with retinopathy worse than mild NPDR were referred for further examination to the base hospital. Subjects with no or minimal retinopathy were advised to schedule follow-up with their regular ophthalmologists at yearly intervals. We did not perform fundus photography at the campsite due to the high costs involved, which precludes its use as a screening tool in most developing countries. In the absence of retinal photography, we considered indirect ophthalmoscopy with a 20-diopeter lens as the gold standard at the screening camp. Retinal photography was, however, performed on those presenting for follow-up at the base hospital and compared with results obtained using indirect ophthalmoscopy at the screening campsite.

We used Stata version 7.0 software (Stata, College Station, TX) for statistical analysis. Subjects whose pupils could not be dilated were excluded from our analysis. Odds ratios (ORs) and 95% CIs are presented. CIs of the prevalence estimates have been calculated using a binomial approximation of normal distribution. P values <0.05 have been considered statistically significant.

We obtained verbal informed consent from each subject before ocular examinations. The Institutional Review Board of Aravind Medical Research Foundation, a unit of Aravind Eye Care System, Madurai, India, approved the examination protocol.

RESULTS — We conducted 32 community screening camps targeting a high-risk population between July 2001 and September 2002, an average of two screening camps each month. We examined 3,949 subjects in these screening camps, an average of 123 subjects for each camp. The mean age of subjects was 54.1 years (SD 11.1, range 10–95) and 2,815 subjects (71.3%) were men.

A large proportion of those (n = 3,696, 93.6%) who attended the camps had previously been diagnosed as diabetic. After excluding the 252 persons who were not previously aware of their diabetic status, the median duration of diabetes among subjects was 48 months (range 1–636). Among subjects who were previously aware of their diabetic status, 3,115 (84.2%) were on treatment for diabetes, including 1,789 (48.4%) on diet control, 2,472 (66.9%) on oral medications, and 169 (4.6%) using insulin injections. A total of 19 subjects (0.51%) had evidence of past focal laser treatment: 1 (0.03%) with grid laser, 27 (0.73%) with pan retinal photocoagulation, and 1 (0.03%) with vitrectomy in one or both eyes.

A total of 562 subjects (13.3%) complained of defective vision; the median duration of defective vision was 12 months (range 1–240). A total of 240 individuals (6.2%) without eyeglasses had visual acuity <6/60 in both eyes, and 32 (3.1%) of the 1,023 subjects who wore eyeglasses had vision <6/60 in both eyes.

We could not perform fundus examination with indirect ophthalmoscopy in 44 subjects (1.1%), primarily due to suspected shallow anterior chambers (data based on direct ophthalmoscopy was recorded for these 44 persons). We could not comment on the retinal status using either indirect or direct ophthalmoscopy for an additional 65 subjects (1.6%), primarily due to age-related cataracts precluding fundus views.

The prevalence of diabetic retinopathy in our population was 20.4% (95% CI 19.0–21.8); the prevalence of diabetic retinopathy increased with age (P < 0.001) (Table 1). The age-sex adjusted prevalence of retinopathy among subjects aged ≥50 years was 22.3% (20.6–23.9). Diabetic retinopathy was more common among subjects who were previously...
Data are n (%). *Does not include 109 persons for whom retina could not be visualized using indirect ophthalmoscopy.

Table 1—Diabetic retinopathy levels by age among 3,840 persons screened using indirect ophthalmoscopy*

<table>
<thead>
<tr>
<th>Age-groups</th>
<th>None</th>
<th>Mild</th>
<th>Moderate-severe</th>
<th>Proliferative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤30 years</td>
<td>64 (95.5)</td>
<td>2 (3.0)</td>
<td>1 (1.5)</td>
<td>0 (0.0)</td>
<td>67 (1.7)</td>
</tr>
<tr>
<td>31–30 years</td>
<td>1,179 (84.1)</td>
<td>115 (8.2)</td>
<td>89 (6.4)</td>
<td>19 (1.4)</td>
<td>1,402 (36.5)</td>
</tr>
<tr>
<td>51–70 years</td>
<td>1,841 (76.3)</td>
<td>232 (10.8)</td>
<td>217 (10.1)</td>
<td>62 (2.9)</td>
<td>2,152 (56.0)</td>
</tr>
<tr>
<td>&gt;70 years</td>
<td>174 (79.5)</td>
<td>28 (11.9)</td>
<td>17 (7.8)</td>
<td>2 (0.9)</td>
<td>219 (5.7)</td>
</tr>
<tr>
<td>Total</td>
<td>3,058 (79.6)</td>
<td>375 (9.8)</td>
<td>324 (8.4)</td>
<td>83 (2.2)</td>
<td>3,840 (100.0)</td>
</tr>
</tbody>
</table>

CONCLUSIONS—Although the need for a national diabetic retinopathy screening program in India was recognized in 1998 (2), national or regional screening initiatives are yet to be launched. Data from our project suggest that screening high-risk groups for retinopathy within communities may be useful as a short-term strategy to detect sight-threatening diabetic retinopathy in India. One-fifth of those screened had evidence of diabetic retinopathy; only 6.1% of those identified with retinopathy had undergone any previous treatment for retinopathy. Our results also suggest that indirect ophthalmoscopy can be used as a screening tool until the costs of retinal photography become more affordable in India. Our results also suggest the need for an eye care program to work more closely with internists for more effective coverage of diabetic subjects. This may require provision of additional training to internists for screening for retinopathy. Our results suggest that many diabetic patients who consult internists do not currently receive referrals for eye examinations. Further studies are also required to understand the barriers that prevent patients from uptake of services offered through such screening programs, especially the reason for low female uptake, to determine costs of providing treatment to patients with diabetic retinopathy, and to determine better strategies for follow-up of subjects.

A significantly higher specificity for ophthalmoscopy compared with nonmydriatic photography for detecting worse than mild retinopathy has been previously reported; however, the difference in sensitivity between ophthalmoscopy and nonmydriatic photography was not statistically significant (10,11). Studies have reported a much higher sensitivity for mydriatic retinal photography compared with ophthalmoscopy for the detection of worse than mild retinopathy (10,12–16). Although the British Diabetic Association recommends a sensitivity of 80% and a specificity of 95% for screening tests, investigators in most developing countries may have to choose between direct or indirect ophthalmoscopy due to the relatively high costs of photography. Neither mydriatic nor nonmydriatic fundus photography is currently financially feasible for developing countries due to the costs involved. Our results suggest the need to ensure that residency programs in India and other developing countries equip residents with adequate skills to perform indirect ophthalmoscopy.

We found that 84.2% of subjects who were aware of their diabetes status were receiving treatment; however, only 6.1% of subjects with any retinopathy had evidence of ocular treatment, suggesting the need for improved networking between internists and ophthalmologists to ensure regular eye checkups and appropriate treatment for diabetic subjects.

Table 2—Diabetic retinopathy levels by duration among 3,640 persons screened using indirect ophthalmoscopy*

<table>
<thead>
<tr>
<th>Duration</th>
<th>None</th>
<th>Mild</th>
<th>Moderate-severe</th>
<th>Proliferative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤5 years</td>
<td>2,201 (87.4)</td>
<td>171 (6.8)</td>
<td>123 (4.9)</td>
<td>23 (0.9)</td>
<td>2,318 (85.6)</td>
</tr>
<tr>
<td>6–10 years</td>
<td>590 (69.8)</td>
<td>119 (13.9)</td>
<td>118 (13.7)</td>
<td>30 (3.5)</td>
<td>857 (22.3)</td>
</tr>
<tr>
<td>11–15 years</td>
<td>154 (59.5)</td>
<td>44 (17.0)</td>
<td>51 (19.7)</td>
<td>10 (3.9)</td>
<td>259 (6.7)</td>
</tr>
<tr>
<td>16–20 years</td>
<td>79 (58.5)</td>
<td>24 (17.8)</td>
<td>18 (13.3)</td>
<td>14 (10.4)</td>
<td>135 (3.5)</td>
</tr>
<tr>
<td>&gt;20 years</td>
<td>34 (47.9)</td>
<td>17 (23.9)</td>
<td>14 (19.7)</td>
<td>6 (8.5)</td>
<td>71 (1.9)</td>
</tr>
<tr>
<td>Total</td>
<td>3,058 (79.6)</td>
<td>375 (9.8)</td>
<td>324 (8.4)</td>
<td>83 (2.2)</td>
<td>3,840 (100.0)</td>
</tr>
</tbody>
</table>

Data are n (%). *Does not include 109 persons for whom retina could not be visualized using indirect ophthalmoscopy.
It is possible that selection bias may affect the prevalence estimates we reported, in that subjects were self-selected for the screening camps. Therefore, it is likely that subjects who presented at the screening camps may not be truly representative of the diabetic population of the three districts. However, the age-sex-adjusted prevalence of diabetic retinopathy (for those aged ≥50 years) in our study was similar to the prevalence reported from a recent population-based assessment of self-reported diabetic individuals in a south Indian district (1). The proportion of female subjects screened was, however, much lower in our project. Although we did not find any significant differences between sexes for prevalence, the sex difference in subjects screened assumes significance in that we are probably missing a sizeable number of women with diabetes. Further studies are necessary to determine whether barriers to uptake of services that may exist are different for men and women and to determine strategies to increase uptake of services by women.

Although we provided treatment (after further follow-up examinations at the base hospital) to an additional 7.3% of subjects identified as having worse than mild retinopathy during screening, it is a matter of concern that less than one-quarter of subjects with moderate to severe or proliferative retinopathy presented for follow-up. Although it may be possible that a larger proportion of subjects may have presented for follow-up to hospitals closer to their residence, we do not have data to support or refute this inference. Considering that only 6.1% of subjects with any retinopathy had any evidence of past ocular treatment, this result suggests the need to determine better strategies for follow-up of patients screened.

We believe that an approach focusing on detecting sight-threatening retinopathy rather than any retinopathy may be more useful until India has an appropriate number of qualified vitreoretinal specialists or until all ophthalmologists become conversant with indirect ophthalmoscopy and at least medical management of vitreoretinal diseases, including diabetic retinopathy. It is entirely possible that we may have missed cases of early retinopathy due to the absence of retinal photography and the reliance on 20-diopter lenses for indirect ophthalmoscopy. However, treatment for mild diabetic retinopathy is primarily management of diabetes, which can be performed by internists. Training internists to detect retinopathy using ophthalmoscopy and ensuring timely follow-up of such patients may be a better alternative to population screening focusing on picking up even mild retinopathy, especially because there is potential to miss cases in the absence of retinal photography, which is currently not financially viable for screening in India. Screening programs, however, are to be viewed as a short-term strategy to increase awareness; focus must be on improving patient inflow to eye care centers for sustained coverage.

If 5% of the estimated population of 7.5 million people are diabetic (17) and 20% of the diabetic population have retinopathy (as suggested by our data), there should be an estimated 75,000 persons with diabetic retinopathy in the project area. If we assume that 6.1% (based on our proportion of subjects who had evidence for prior laser/vitrectomy) of these persons had visited an ophthalmologist previously, this will leave ~70,000 diabetic individuals who require screening for retinopathy, suggesting that current coverage achieved by us through the screening program is not sufficient for the region. Increased coverage can be achieved if more eye care programs initiate screening in the region through a coordinated effort involving everyone concerned with diabetes care. Educating doctors, nurses, and patients regarding diabetes and retinopathy is essential if screening programs are to have an increased coverage and to ensure better follow-up for patients with diabetes or retinopathy.

Acknowledgments — This project was supported by a generous grant from the Lions Clubs International Foundation (LCIF) through a SightFirst project (SF-742).

References
15. Kinyoun JLMD, Fujimoto WY: Ophthalmoscopy versus fundus photographs for detecting and grading diabetic retinopa-