Screening for diabetic retinopathy in a rural French population with a mobile non-mydriatic camera

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Abstract

\textbf{Aim.} – The aim of this study was to evaluate the yield of diabetic retinopathy (DR) screening in a rural population using a mobile non-mydriatic camera.

\textbf{Methods.} – The 72 least medicalized areas of Burgundy were the target areas. An orthoptist took fundus photographs using a Topcon TRC-NW6S non-mydriatic camera (four fields: posterior pole; nasal; temporal; and upper). Interpretations were done in the Department of Ophthalmology according to the classification of the French Language Association for the Study of Diabetes and Metabolic Diseases (Alfediam).

\textbf{Results.} – Between 2004 and 2006, 1974 diabetics were screened—676 the first year, and 1298 in the second. The rate of non-interpretable photographs was 13%. Of the 1974 screened patients, there were 103 cases of DR (5.2%), comprising 70 mild non-proliferative DR (68%), 21 moderate non-proliferative DR (20.4%) and 12 severe non-proliferative DR (11.6%). The mean age of the patients with a DR was 66.7 ± 10.9 years, with a mean duration of diabetes of 16.5 ± 9.8 years. Only 35 (34%) patients were aware of their HbA\textsubscript{1c}, which had a mean value of 7.8%. Only 19 had visited an ophthalmologist in the year before screening (18.4%). After the initial screening, 90.5% of the patients consulted an ophthalmologist as recommended.

\textbf{Conclusion.} – Screening improved the quality of the ocular follow-up in diabetics in this rural area. However, improvements in management are needed to lower the cost of such a programme.

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Résumé

Dépistage de la rétinopathie diabétique en zone rurale avec un rétinographe non mydriatique itinérant.

\textbf{But.} – Le but de cette étude était d’étudier l’apport du dépistage de la rétinopathie diabétique dans une population rurale.

\textbf{Méthodes.} – Les 72 cantons les moins médicalisés de Bourgogne ont été retenus. Une orthoptiste a pris des photographies du fond d’œil avec un rétinographe non mydriatique en quatre champs. L’interprétation a été réalisée dans le service d’ophthalmologie selon la classification de l’Alfediam.

\textbf{Résultats.} – Entre 2004 et 2006, 1974 diabétiques ont été dépistés : 676 la première année et 1298 la seconde. Le taux de photographies non interprétables était de 13 %. Parmi ces 1974 patients, 103 présentaient une rétinopathie diabétique (RD) (5,2 %), dont 70 débutantes non proliférantes (68 %), 21 modérées non proliférantes (20,4 %), et 12 sévères non proliférantes (11,6 %). L’âge moyen des patients porteurs d’une RD était de 66,7 ± 10,9 ans et la durée du diabète était de 16,5 ± 9,8 années. Seulement 35 patients connaissaient leur hémoglobine glyquée (34 %) pour une valeur moyenne de 7,8 %. Seulement 18 patients avaient bénéficié d’une visite ophtalmologique l’année précédant le dépistage (18,4 %). Après le dépistage, 90,5 % des patients ont effectivement consulté un ophtalmologiste.

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In any industrialized country, diabetic retinopathy (DR) is the main cause of blindness among people who are less than 50-year-old [1] and the third most important cause of vision loss in the elderly [2,3]. However, a number of studies have shown that timely treatment can prevent such loss of eyesight due to diabetic retinopathy [4–6] or macular oedema [7]. Because the condition is often asymptomatic in its early phase, regular evaluation is critical in the management of diabetic retinopathy. In 2006, guidelines from the Accreditation and Health Evaluation Agency (Anaes) and the French Agency for the Safety of Health Products (Affsaps) [8] recommended an annual fundus examination for all diabetics.

The increase in the size of the elderly population, the epidemic of obesity and other social changes such as poor-quality food, a lack of sports activities and a sedentary lifestyle [9,10] have all contributed to a global epidemic of diabetes mellitus (DM) [11]. Thus, the number of people worldwide with DM, mainly type 2, is expected to increase by more than 120% from 1995 to 2025 [12,13]. Furthermore, if we include those with adult-onset DM who have not yet been diagnosed, these numbers will probably double [14].

In 1999, an analysis of the French healthcare database found an overall prevalence of diabetic patients of 3.06% in the general population, representing about two million people [15]. It also demonstrated the high cost of diabetes—up from 3680 € in 1998 to 3914 € in 2000 [16]. About 30% of these patients have DR and 10% have a sight-threatening form [17]. After 15 years of DM progression, DR will affect 98% of patients with type 1 disease and 60–85% of patients with type 2 disease and nearly 5% in each group will suffer some kind of vision-threatening complications [18,19].

In 2002, the Representative National Cohort of Diabetic Patients (échantillon national témoin représentatif des personnes diabétiques [Entred]) study [20] provided information to better characterize, evaluate and monitor the health status of people being treated for DM. In Burgundy, for example, the prevalence of 3.27% for non-insulin-dependent DM (n = 53,000) is among the highest in France. The study also showed that screening for microvascular complications is insufficient, especially for ocular conditions. Indeed, 32% of the participants could offer no information on their retinal status and only 43% reported that they had benefited from an eye fundus examination during the year [20].

The lack of ophthalmologists is a major public-health problem [21]. Burgundy is one of the areas where DR screening is affected by the wide variability of the healthcare on offer. In 2008, Burgundy had the four French areas with the lowest densities of general practitioners (GPs) [22]. Furthermore, it is an area with the greatest increase in the proportion of patients who are 75-year-old or over (9.3% vs 7.6% in the rest of France) [23].

Screening for DR with a non-mydriatic camera is becoming more and more popular as it provides a reliable method, with both good specificity and sensitivity for the detection of DR [24,25] and is also cost-effective [26]. Furthermore, fundus photography has been recognized as the preferred method for screening for DR by the Liverpool conference [27], the HAS 2007 [28] and in the French recommendations for DR screening (www.sfo.asso.fr). Indeed, mobile screening is particularly useful for contacting patients who would otherwise not be included in any recommended screening programme. For these reasons, a regional screening programme based on a mobile non-mydriatic camera was initiated in Burgundy.

1. Patients and methods

1.1. General organization

A preliminary assessment was carried out to determine the areas of priority, using the following indicators: diabetes prevalence in the area; density of GPs; distance to nearest eye-care centre; and medical “disadvantaged” areas (by criteria of the regional health observatory). From this evaluation, 72 areas were selected, corresponding to the least medicalized areas, distributed in four regions of Burgundy (Cote d’Or, Nièvre, Saône and Loire, and Yonne). In addition, Burgundy-based ophthalmologists were invited to participate in the campaign by examining any patient without delay if requested to do so after screening and forwarding a detailed report of the examination. Funds for the campaign were endorsed by the Regional Healthcare Agency (Union régionale des caisses d’assurance maladie [Urcam]).

1.2. Recruitment source

A campaign was devised to improve recruitment, based on information on screening and its organization, including GPs and endocrinologists in Burgundy (Fig. 1). Before each screening session, GPs, as well as pharmacists and private practise nurses, were contacted by mail, and posters and brochures distributed for their offices. Information about DR aimed at GPs, a media campaign running in regional newspapers and a toll-free telephone number dedicated to the programme were set up 2 weeks before the beginning of enrollment in the selected areas. Finally, we obtained the help of the major health-insurance providers in delivering a message to all previously known diabetic patients about the screening programme in their mailed reimbursements.
1.3. The study population

All diabetics who did not have regular ophthalmological follow-ups were invited to benefit from the free-access screening. Local diabetes associations were closely involved in the project by answering the toll-free phone calls. They also emphasized the need for an annual examination for diabetic patients and attempted to focus on patients who did not have regular eye examinations (no examination for at least a year).

1.4. Image-acquisition programme

The Topcon TRC-NW6S non-mydriatic camera provides 45° retinal colour photographs without pupillary dilatation. Patients were screened by a trained orthoptist while a volunteer of the regional diabetic association collected the clinical and epidemiological information. Retinal photographs were taken in communal rooms during the first year and in the truck during the second year. Four 45° non-stereoscopic images of four fields were taken for each eye—one image was centred on the macula, including the optic disc and one each of the nasal, temporal and superior fields. In addition, the orthoptist measured intraocular pressure (IOP) three times in each eye, using an air tonometer (Topcon CT 80A) and retained the average of the three measurements; an IOP > 21 mmHg was considered the lowermost limit for ocular hypertension (OHT). Images were stored in JPEG format on a hard disk and the data were harvested in the Department of Ophthalmology.

1.5. Image reading centre

DR status was evaluated according to the Alfediam classifications by trained members of the Department of Ophthalmology (Table 1). Briefly, mild non-proliferative (NP) DR was defined as a few microaneurysms, whereas moderate NPDR referred to intermediate cases that were more than mild, but less than severe NPDR, which was characterized by diffuse intraretin-
Table 2
Regions of Burgundy screened, with number of patients and ophthalmologists per capita.

<table>
<thead>
<tr>
<th>Regions of Burgundy</th>
<th>Patients n (%)</th>
<th>Number of sites</th>
<th>Patients detected by site (average n)</th>
<th>Frequency by site (min–max)</th>
<th>Ophthalmologists per capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nièvre</td>
<td>415 (21)</td>
<td>17</td>
<td>24.4 ± 8</td>
<td>2–52</td>
<td>1/16,000</td>
</tr>
<tr>
<td>Sâone and Loire</td>
<td>720 (36.5)</td>
<td>22</td>
<td>32.7 ± 11</td>
<td>9–56</td>
<td>1/16,000</td>
</tr>
<tr>
<td>Yonne</td>
<td>540 (27.4)</td>
<td>18</td>
<td>30 ± 15</td>
<td>10–60</td>
<td>1/18,000</td>
</tr>
<tr>
<td>Côte d’Or</td>
<td>299 (15.1)</td>
<td>16</td>
<td>18.6 ± 13</td>
<td>0–72</td>
<td>1/12,000</td>
</tr>
<tr>
<td>Total</td>
<td>1974 (100)</td>
<td>73</td>
<td>27 ± 13</td>
<td>0–72</td>
<td>1/15,000</td>
</tr>
</tbody>
</table>

Table 3
Clinical characteristics of the population with and without diabetic retinopathy (DR).

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Age (years)</th>
<th>Rate of HbA1c (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total screened</td>
<td>1974</td>
<td>67.2 ± 10.9</td>
<td>7.3 ± 1.3</td>
</tr>
<tr>
<td>Those with DR</td>
<td>103</td>
<td>66.7 ± 10.9</td>
<td>7.8 ± 1</td>
</tr>
</tbody>
</table>

2.1. Characteristics of the population

Within the 72 areas, 1974 diabetics (676 and 1298 patients in the first and second year, respectively) were screened. The average number of patients by area was 27 ± 13 and their distribution was not proportional to the demographic spread of each region. This can be explained by the distribution of screening sites in each region, which was according to accessibility of healthcare facilities.

The distribution of diabetic patients by area is presented in Table 2 and the demographic characteristics of the screened population are shown in Table 3. The mean age was 67 ± 10.9 years (range 6–95) with a gender ratio (M/F) of 1.28.

In addition, 73% of patients claimed to have 100% coverage by the national health system and 2.6% of patients claimed to have universal coverage (CMU). As regards the photographs, 13% (n = 257) were considered ungradable, while 72.8% (n = 1428) were gradable with no anomalies.

2.2. Diabetes characteristics

The average diabetes duration was 10.3 ± 9.1 years, with about one-third that were less than 5 years (4.9% were less than 1 year and 28.7% were 1–5 years). Only 39.8% of patients were aware of their glycated haemoglobin (HbA1c) levels, which had a mean rate of 7.3 ± 1.3%.

The majority were receiving non-insulin-based treatment (79%), while insulin treatment was used by 18% of the screened population, and diet only in 3% of cases.

The time elapsed since the last ophthalmological consultation is shown in Table 4. Screening detected ocular pathologies other than DR in 288 patients (14.5%). We found 217 cases of suspected glaucoma (11%), thanks to an increased IOP and/or a suspicious-looking optic nerve head. We also detected 41 other non-diabetic retinal anomalies (2%) and 8 (0.4%) abnormal vitreous bodies with no haemorrhage (Table 5).

2.3. Characteristics of the patients with DR

A total of 103 patients (5.2%) presented with DR, including 70 cases of mild NPDR (68%), 21 with moderate NPDR (20.4%) and 12 with severe NPDR (11.6%). Diffuse or focal macular oedema was seen in 22 patients (1.1%).

The mean age of these patients was 66.7 ± 10.9 years (range 26–93), which did not differ statistically from that of the general screened population (P = 0.714). However, the 16.5 ± 9.8 years since the onset of diabetes was longer than for the general...
screened population \(P < 0.001\). Also, significantly more of these patients—48 (46.6%)—were using insulin treatment than in the general screened population \(P < 0.001\), and glycated haemoglobin was reported for 35 patients (34%) with an average of 7.8 ± 1.1%, a statistically significant difference versus the general screened population \(P = 0.02\). The time lapsed since their last ophthalmological consultation was: less than 1 year for 19 (18.4%) patients; 1–2 years for 38 (36.9%) patients; 2–5 years for 28 (27.2%) patients; less than 5 years for 10 (9.7%) patients; and never for 7 (6.8%) patients. One patient did not answer the question.

For these 103 patients, the ophthalmologists’ reports confirmed the severity of the retinopathy in 90.9% of cases.

### 2.4. Follow-up of the screened individuals

The delay between the screening and follow-up mail was 39 ± 9 days, due to the time needed for the photographs to be interpreted and the results to be sent. An ophthalmological consultation was recommended for 572 patients (28.97%) for DR or other anomalies, and around 90% \(n = 518\) of the patients attended this control consultation. The mean delay between the screening and ophthalmological consultation was 100 ± 45 days.

### 2.5. Cost of the campaign

The total cost of the screening campaign was 280,763 €, of which 115,710 € (41.2%) was for the initial acquisition of equipment (truck, non-mydriatic camera and air-puff tonometer). The mean cost per screening session and per patient was around 3899 € and 142 €, respectively. The mean cost to screen a patient with DR was 2726 €.

### 3. Discussion

The present study aimed to evaluate the value of a screening programme targeted at a rural population using a mobile non-mydriatic camera. Over the two-year study period, we screened 1974 diabetics, which represented 17% of the diabetic population of the least medicalized areas of France. The average age was older (67 years) and there were more men than women (M/F ratio = 1.28) compared with the general French population (63.1 years, M/F ratio = 1.04)\[^{15}\]. We found that the ophthalmological follow-up of diabetics did not fulfill French guidelines and that only a minority (33%) had an annual fundus examination. Similar rates of non-compliance have been observed in other studies and range from 33% to 63.2% \[^{29–34}\]. In the Caisse National d’Assurance Maladies des Travailleurs Salariés (CNAMTS) study, 39.1% and 41.5% of the diabetic patients underwent an annual ophthalmological consultation in 1998 and 1999, respectively \[^{15}\]. This rate increased to 43% in 2001 in the Entred study \[^{20}\]. However, such poor follow-up has implications for long-term costs in the care of diabetics and social costs in general. Moreover, the average rate of HbA1c (7.3%) is higher than the Alfediam recommendation (6.5%). Worse still, only 39.8% of the patients were aware of it, suggesting poor knowledge of diabetes and its care. These findings reflect a serious need to improve French diabetes primary care and follow-up.

In our study, taking four photographs for each eye appeared to be a good compromise and the fundus photographs taken with the non-mydriatic camera were suitable for DR screening even without pupillary dilation \[^{25,26}\]. Some authors have commented on their questionable quality \[^{35}\]. However, the specificity and sensitivity to detect moderate-to-severe DR are more than 80% and 90%, respectively \[^{25}\].

The lack of awareness of the need for eye care, especially in the absence of symptoms and no prior formal diabetes education, is a major barrier to regular screening for many people with diabetes \[^{14,29}\]. Other well-known factors contributing to poor follow-up are younger age, type 2 diabetes with or without insulin use and shorter diabetes duration \[^{29}\]. A lack of access to a care provider is another contributory reason \[^{31}\]. Our programme attempted to solve the latter by offering a non-mydriatic examination and by facilitating eye-care access. Furthermore, screening was preceded by a major information campaign directed at both health professionals and patients to improve their knowledge of diabetes complications and the need for regular eye examinations.

In fact, the recommendation to undergo a full ophthalmological consultation after screening has found mild NPDR is questionable. However, the aim of our campaign was to encourage patients to regularly visit their ophthalmologist, as even a mild presentation can lead to a more severe stage of the disease. A mobile non-mydriatic camera had already been used for screening RD in rural areas \[^{35,36}\]: in France, the Artois vascular prevention programme (Réseau de prévention vasculaire Artois [Prevart]) organized several DR screening programmes with a mobile non-mydriatic camera. The last one, from March 2005 to January 2006, screened 628 diabetics, among whom 595 benefited from fundus photographs and 76 DR (12.7%) cases were detected. These values are slightly higher than ours, although the rates of ungradable photographs are similar (9.6%) \[^{37}\].

In the present study, DR was observed in only 5.2% \(n = 103\) of the patients whose fundus photographs were gradable, a lower
rate than has been observed in other studies. Different studies have found different DR rates in a diabetic population, ranging from 15.9% to 22% [26,33,38]. Indeed, other French screening programmes, such as the North Paris, Rediab and Resoladi, found DR rates among the screened population of 11.8–22.7%. In our screened population, the average diabetes duration was 10.3 years, one-third of which were less than 5 years, which might explain our low rates of DR. Surprisingly, we found no cases of proliferative retinopathy, which is discrepant with the literature [39]. It may be that our screened patients were more concerned about their disease, as our programme was voluntary. Also, despite being too high, the mean rate of HbA1c was not seriously high (7.3%). The large percentage (90.5%) of patients responding to the screening programme was further proof of their investment in their own disease management. Nevertheless, 12 patients (0.6%) were found to have a vision-threatening form of DR requiring laser treatment, which was the main goal of the study.

Our 13% rate of unreadable photographs was higher than that for Gomez-Ulla et al. (5%) [40], similar to that found by Cavallerano et al. (13%) [41] and better than several studies with rates ranging from 35% to 44% [24,38,42]. The reason for the lack of gradability was a blurred image, frequently due to the presence of cataract or shadows in the image because of small pupils or poor visibility. As with other studies, the quality of images was closely correlated with age [43,44]. The high rate of ungradable photographs may be partly explained by the number of fields we used—four—instead of the two now recommended by the official French guidelines for screening DR [28]. In fact, an increased number of fields leads to more unreadable photographs [31]. It appears that the rate of ungradable images can be improved by the quality of darkness in the room where the examination is performed. This is why, for the second year of screening, the non-mydriatic camera was kept inside the truck. However, this proved to have no effect on the rate of ungradable images, which increased from 10.4% in 2005 to 14.3% in 2006. However, the mean age of the patients was slightly lower in 2005 than in 2006 (66.3 ± 11.2 years and 68 ± 10.6 years, respectively).

As the image quality does not appear to be higher when taken by an ophthalmologist [45], our camera operator was always the same trained orthoptist and the image review and evaluation were performed by the hospital’s trained ophthalmologists. In 2004, the American Telemedicine Association, Ocular Telehealth Special Interest Group and the National Institute of Standards and Technology Working Group established the Telehealth Practice Recommendations for Diabetic Retinopathy. Three components to evaluate a DR telehealth programme were defined: the clinical; technical and operational; and business elements [46]. It was also stipulated that only individuals qualified or specially trained for the task should perform official grading and retinal interpretation of retinal images. In the future, it should be interesting to participate in a national screening programme for DR that applies well-defined reading-quality criteria to a preexisting screening network, such as the DODIA OPHDIA Network, developed in the Île-de-France [47,48]. Another step would be to allow free access of GPs to their patients’ data to avoid transmission delay of the interpretation results.

We faced a few problems during this screening programme. First, the mean cost of screening a patient with DR was very high (2726 €) compared with the mean annual cost of a diabetic (3914 €) [16] and the mean cost per patient was much higher than the cost of an eye consultation. This is directly related to the low rate of DR. Indeed, we noted that 8.3% (n = 163) of patients had already had a consultation the year before the screening. Therefore, these patients were not the target population of our campaign. In our study, multivariate analysis identified two risk factors for DR—being elderly and having insulin treatment. To improve the medical and economic efficacy of the campaigns to come, it is probably important to target recruitment particularly at this higher-risk population. Ramsey showed that the direct cost of DR in the year following its identification was $5537 and $7397 for those aged 40–64 years and 18–39 years, respectively [49]. In comparison, our programme was cheaper. The fact that around 90% of our patients had an eye examination after the screening is an interesting finding, assuming that these patients are then reintegrated into the healthcare system. However, the need for early detection of non-ocular degenerative disorders (such as neuropathy) related to diabetes should be an alternative to exclusively ophthalmological screening. In France, we have around two million diabetics who require at least an annual fundus examination and the increased prevalence of the disease in the years up to 2020 will require a dramatic increase in the need for medical care at the same time that the number of ophthalmologists in France is decreasing [21]. That is why yearly screening using new programmes such as the mobile non-mydriatic camera or teledmedicine are likely to be developed to identify the patients who need prompt treatment or, at least, careful follow-up.

4. Conclusion

DR provides an ideal model for disease management by screening programmes: it is an ocular manifestation of a chronic pathology with effective evidence-based management proven to preserve vision. In addition to providing an accurate diagnosis and early treatment, the challenge in establishing a screening programme for DR lies in reaching as many at-risk people as possible while using simple, available and cost-effective modalities. The major task of any future campaign will be to target only those patients at risk to reduce the costs of such a screening programme.

Conflict of interest

The authors have no proprietary or commercial interest in any materials discussed in this article.

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