Screening for diabetic retinopathy in France

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SUMMARY

Ocular complications of diabetes, particularly retinopathy, are the major cause of blindness in the working age population in industrialised nations. Laser photoagulation has shown definite results in reducing visual morbidity with many more likely to benefit if diagnosed early enough. Institution of an efficient screening programme aimed at detecting patients at risk when they can still be effectively treated has been recognised as an urgent priority worldwide. In France, a signatory to the Saint Vincent’s Declaration, an analysis of the national healthcare database reveals a gross inadequacy in the current extent of screening for diabetic retinopathy. The possible causative factors have been analysed and the necessary corrective measures, some of which are already under way, have been discussed. Ideally, screening by ophthalmologists at recommended intervals have been advised by national and professional health care associations. This has not been feasible owing to the lack of organised planning and serious manpower deficit caused by a progressive decline in the number of ophthalmologists. Recently, the need for an efficient, widely-available and user-friendly screening tool has led to the evaluation of multifield fundus photography in real time using digital nonmydriatic camera in comparison with more established methods of detecting diabetic retinopathy. Lastly, the future possibility of involving in France non-ophthalmologists like endocrinologists or general practitioner or non medical profession like orthoptists after proper training to meet the necessary manpower shortage has been addressed. Optimal use of telemedicine along with establishment of preferential reference channels for newly discovered cases of sight-threatening cases of retinopathy are public health priority necessary to give to the screening of diabetic retinopathy its full efficiency.

Key-words: Diabetic retinopathy · Screening · France · Nonmydriatic camera.

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RÉSUMÉ

Dépistage de la rétinopathie diabétique en France

Les complications oculaires du diabète, en particulier la rétinopathie, constituent la principale cause de cécité de l’adulte en âge de travailler au sein des pays industrialisés. Il est largement prouvé que la photoagulation rétinienne par le laser permet de réduire ses complications, d’autant plus efficacement que le diagnostic de rétinopathie est posé suffisamment tôt. Aussi, la mise en place d’un programme de dépistage efficace des diabétiques à risque de rétinopathie compliquée, au stade ou elle peut encore être traitée de façon efficace, est une priorité absolue au travers le monde. En France, un des pays signataires de la déclaration de Saint Vincent, l’analyse des données des registres de santé publique montre de notables insuffisances dans l’étendue de ce dépistage. Les raisons de ces insuffisances, ainsi que les mesures correctrice qui s’imposent, dont certaines sont en train d’être mises en place à l’heure qu’il est, sont discutées. Idéalement, un dépistage réalisé par des ophtalmologistes à intervalle défini, est reconnu par les instances nationales et les associations professionnelles. Cependant, celui-ci s’est avéré en pratique irréalisable en raison de l’absence de stratégie de dépistage réellement définie et surtout du déclin continu du nombre d’ophthalmologistes. Récemment, la nécessité de disposer d’un outil de dépistage efficace qui soit à la fois largement disponible et facile d’utilisation a conduit à l’évaluation de rétinographes numériques dit « non mydriatiques » donnant un résultat en temps réel. Leur efficacité est comparable à celle des méthodes classiques et reconnues de dépistage de la rétinopathie diabétique. Enfin, les possibilités futures d’impliquer en France des médecins non ophtalmologistes comme les endocrinologues ou les généralistes, ou encore des professions non médicales comme les orthoptistes, dès lors qu’ils bénéficient d’une formation appropriée, sont étudiées. L’utilisation optimale de la télémédecine et la création de réseaux de soins efficaces pour la prise en charge des nouveaux cas dépistés constituent aussi des priorités de santé publique qui donneront au dépistage de la rétinopathie diabétique tout son sens.

Mots-clés : Rétinopathie diabétique · Dépistage · France · Rétinographe non mydriatique.

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Mankind is on the verge of a global epidemic of diabetes. Diabetic retinopathy has emerged as the most common cause of blindness in people of working age in industrialised countries with a worldwide prevalence of about 5% and currently threatens about 30 million citizens in Europe [1, 2]. The problem has assumed such enormous proportions mainly because its early stages are asymptomatic. Herein lies the importance of screening which detects those at risk before symptoms occur when treatment outcome is still optimal. Timely intervention can help to prevent blindness in about 98% of those at risk [2]. It is also a cost-effective option, as shown in studies carried out in the United States, with a potential of annual net savings of more than $472.1 million for the federal government and about 94,304 person-years of sight for the society [3, 4]. Available literature was searched in Medline and relevant articles were reviewed to assess the current state of screening for diabetic retinopathy in France vis-a-vis the world with a purpose to estimate the magnitude of the problem and identify the lacunae as a first step towards initiating certain definitive measures in the form of a proposed screening programme in our local community.

**Situation worldwide**

The number of people worldwide who have diabetes is expected to increase by more than 120% from 155 million in 1995 to almost 330 million by 2025 [5]. Epidemiologic studies indicate that after 15 years of evolution of diabetes, retinopathy affects 98% of patients with type I disease and about 60-85% of patients with type II disease, of whom nearly 5% patients in each group suffer from vision-threatening complications, including blindness [6, 7]. The magnitude of the problem, which, fortunately, has an effective solution in sight, has compelled international organisations like the World Health Organisation, International Diabetic Federation and the various national governments to identify screening for diabetic retinopathy as a priority inclusion in their respective health programmes [8, 9]. The major multicentric studies like the Wisconsin epidemiologic study, Diabetic Retinopathy Study, Early Treatment Diabetic Retinopathy Study (ETDRS), Diabetic Retinopathy Vitrectomy Study and the United Kingdom Prospective Diabetes Study have provided valuable information on the demographic features, natural history and management protocol of diabetic retinopathy [6, 7, 10-14]. These studies clearly established the beneficial effect of laser photocoagulation in preventing further visual loss. Based on this, professional organisations like the Royal College of Ophthalmologists (UK), the American Academy of Ophthalmology and the National Health and Medical Research Council (Australia), have laid down specific screening and treatment guidelines [15, 17]. In Europe, where the prevalence of diabetes is expected to increase to about 50 million by 2025, this policy of preventive management was reaffirmed by the Saint Vincent’s declaration which has set a five-year target to reduce new blindness by one-third [1, 8].

**Situation in France**

In France too, the scenario is no different. Diabetic retinopathy is the foremost cause of blindness in the working age group and the third most important cause in the elderly (more than 50 years) age group [18]. In the absence of large population-based blindness surveys in France, we do not yet have precise epidemiological data pertaining to the visual morbidity caused by this disease. However, the figures are not expected to vary greatly from that of the neighbouring European nations where the prevalence of blindness has been reported to vary between 2.3% in type I disease as seen in the EURODIAB study to 1.2-1.4% in type II disease as reported in various local populations [19-21]. A study carried out by the French national health insurance for salaried workers Caisse Nationale de l’Assurance Maladie des Travailleurs Salarisés (CNAMTS) in 1999 performed a detailed statistical analysis of the French healthcare database covering the entire population of metropolitan France [22, 23]. The results confirmed the epidemiological forecasts which had predicted a significant increase in the prevalence over past few years. This study indicated a current prevalence of 3.06% (90% type II and the rest type I) with an augmentation by 4.8% over the past 5 years, which equates to a total increase in the number of diabetics by 26.4%. This increase was ascribed to various factors: demographic (increased life expectancy), social (sedentary life style, obesity) and medical (improved screening and diagnostic facilities). The study also demonstrated the enormous economic burden incurred by the state. In 1998, the French Social Security spent €4.9 billion for diabetes care, which represented 4.7% of its overall expenses and the high costs were attributed principally to the management of complications. With the problem currently threatening more than 2.5 million diabetic citizens, which is further expected to increase by 25% before 2025, the French association for study of diabetes and metabolic diseases Association de Langue Française pour l’Etude du Diabète et des Maladies Métaboliques [1] and the national agency for accreditation and health evaluation Agence National d’Accréditation et d’Evaluation en Santé (ANAES) have outlined specific recommendations for surveillance and screening of retinopathy [24]. But unfortunately due to various reasons, as discussed later, the institution and coverage of the screening programme is highly inadequate in order to effectively tackle the burgeoning problem.

The French national health agency recommends dilated fundus examinations for all diabetic patients by slitlamp biomicroscopy with a contact or a noncontact lens at least annually or more frequently, depending on the severity and associated risk factors [24]. It might be interesting to note that indirect biomicroscopy is the preferred mode of retinal
examination in France unlike indirect ophthalmoscopy which is popular elsewhere but is virtually nonexistent here. With only about 5200 ophthalmologists, which equates to one for every 400 diabetics, it poses a difficult target to achieve, more so because not all diabetic patients are seen by an ophthalmologist [25]. The condition is likely to worsen in the near future considering the fact that the number of ophthalmologists in France, in tandem with other specialists, is facing a steady decline, with the projected figure likely to fall by 50% to about 2500 by 2015 [26]. Moreover, with the increasing life expectancy and a progressively aging population, age-related disorders of the eye eg. cataract, glaucoma and age-related macular degeneration command the maximal attention of the ophthalmologist. Also, ophthalmology being classified as a surgical discipline, the majority of the newly formed specialists are increasingly orienting their practice towards ocular surgery, mainly cataract and refractive in preference over the medical aspects like diabetic eye disease [25].

Among other factors contributing to the inadequate screening include insufficient knowledge and application of the ALFEDIAM recommendations by the treating physician and the lack of awareness concerning visual loss as a possible complication of diabetes on the part of the patient [27]. A questionnaire survey done on 400 patients of type 2 disease in the French departments of Eure and Seine-Maritime revealed that only 36.8% of the population surveyed were aware of the possibility of visual loss due to diabetes [28]. The ALFEDIAM, therefore, lays stress on the preventive and curative principles of healthcare and emphasizes on a good collaboration between the ophthalmologist, the diabetologist and the general physician (GP) to cover the population at risk. A consensus panel between the general practitioners and the diabetologists based on the guidelines of the Saint Vincent recommendations set up at the French department of Essonne between 1994 and 1998 has shown definite results with increase in the rate of ophthalmological follow-up from 61% to 68% [29].

**Standard of care**

Though diabetologists perform periodic eye checkups as part of the total package of diabetes care, the quality of screening may not achieve the desirable standards mainly due to limited facilities like lack of experience with biomicroscopy, hence necessitating use of the direct ophthalmoscope, which is a poor screening tool because of its small two dimensional field of view. This fact is supported by studies which using ophthalmoscopy report sensitivities widely varying between 35-68% for any degree of retinopathy, sometimes reaching as low as 27% for sight-threatening disease [30, 31]. The situation is even worse for GPs, who although are easily accessible to the patients, have limited experience in diagnosing and grading retinopathy and they too use a direct ophthalmoscope. Studies carried out to evaluate the screening by GPs often report poor sensitivity ranging from 41-66%, which is far from adequate [32, 33]. Moreover, the teaching of direct ophthalmoscopy being no longer in vogue in French faculties of medicine since more than 20 years, most of the current generation of practitioners are unfamiliar with the device, thus putting into serious doubt its utility as a screening tool.

The problem of lack of qualified manpower to carry out the task of screening has been worsened by a healthcare policy peculiar to France ie. absence of optometrists. In many countries, optometrists after proper training and accreditation, carry out effective screening, achieving high levels of efficacy (sensitivity between 72-100%, specificity between 77-94%) as shown in various studies [34-36]. They have good access to the patients, thus ensuring a wide coverage as well as possess adequate knowhow required to perform baseline ophthalmic evaluation. They can be suitably trained to perform indirect biomicroscopy or grade retinal photographs, and also to identify cases which need referral, all of which are essential for effective screening and at much lower costs [35, 37]. In France, until now, the orthoptists dispense binocular vision corrections, perform functional investigations and visual rehabilitative procedures but do not involve in direct patient care. Optical practice based screening programmes have been tried at various centres, often with success, especially with combined modalities [38, 39]. The participation of orthoptists after proper training and accreditation, could therefore, in the near future, help to extend the benefits of early detection of retinopathy to a much wider currently underserved population.

**Possible alternatives**

Apart from advocating the need for supplementary manpower, more and more stress is also being laid on alternative techniques like retinal photography with newer advances like nonmydriatic camera and digital imaging which shows significant agreement with ophthalmoscopy and biomicroscopy [40-42]. Retinal photographs when taken by wide angle cameras (45°) with mydriasis and read by trained graders perform as well as general ophthalmologists and could be more reliable than ophthalmoscopy in detecting retinopathy with sensitivity reported to range from 78%-86% and specificity between 86-100%, depending on degree of retinopathy [41, 43]. Nonmydriatic photography also compares well with the standard seven-field 35 mm stereo technique with high significant agreement noted in several studies [40, 43-45].

Retinal photography provides excellent documentary evidence about the state of retinopathy, which can be used for quality assurance without recalling the patient and also eliminates the fallacies of human assessment. It can be carried out in a variety of settings, from clinics to mobile vans, thus extending the benefits of screening to remote areas [46, 47]. The photographs can be taken by any technician or paramedical personnel like a hospital nurse after minimal
training and can be transmitted through telemedicine linkage, as with the newer digital cameras, to suitably trained graders, either orthoptists, GPs or even junior doctors. The newer nonmydriatic cameras are also more patient-friendly and cost-effective [47, 48]. Various studies demonstrate the improved performance of non-ophthalmologists in the assessment of fundus photos when compared with a standard specialist opinion, indicating their possibility of involvement in screening, thereby improving the coverage and considerably saving medical time [32, 37, 49]. The advent of digital imaging has facilitated data storage and transmission, facilitating maintenance of a central reference centre useful for patient recall and monitor quality control.

Future trends

At the time of writing, there is yet to be any organised systematic national programme for screening diabetic retinopathy in France. In a study performed with the database established by the CNAMTS in 1994, out of 8247 patients enrolled, only 47% underwent annual retinal examination [27]. Fundus evaluation is performed in few centres annually as part of routine package of diabetes care and mostly when the patient presents with a symptom, and that can happen too late when the disease has progressed far enough. The aim of this paper is to review the current situation prior to initiating certain measures to tackle this silent but steadily progressive public health problem.

Efforts have already begun in this direction with the identification of diabetes as a public health priority by the government in 1998 and announcement of an €18 million National Plan Diabetes in 2001 targetted to prevent its progression [50]. A recently concluded study which has shown good agreement (88-95%) between the nonmydriatic camera and the traditional 35 mm films as per ETDRS standards has justified the acceptance of the former as the preferred screening too [45]. Plans are ongoing to equip peripheral screening centres with nonmydriatic cameras for onsite digi-
eral photodocumentation coupled with telemedical linkage to a central reference centre where ophthalmologists can grade the images, thereby making retinopathy screening by experts accessible to a much wider population. The pilot project has already commenced in Paris with the installation of the nonmydriatic retinograph in the Endocrinology department of Hôpital Bichat where fundus photographs of all diabetic patients are taken routinely and telemetered to the Ophthalmology department at Hôpital Lariboisière for interpretation. The process of upgradation of ophthalmologists with the purpose to further encourage their participation in patient care have already begun with the announcement of a national decree to this effect [51]. Considering the current paucity of available specialist ophthalmic care, we have begun a clinical research trial (Projet Hospitalier de Recherche Clinique regional 2003-28/04) at our hospital (covering a local population of about 500 000) to evaluate the benefits of educating hospital diabetologists in detecting retinopathy using five images obtained by a non mydriatic camera (Topcon TRC NRW6s, Tokyo, Japan) (Fig 1). All the patients attending the endocrinology department are routinely undergoing digital photographic screening followed by simultaneous and comparative grading by diabetologists (after adequate training) and ophthalmologists (reference standard). This is an attempt to make screening possible in the primary care settings rather than the ophthalmologists clinic where a waiting period of 6-9 months may be necessary to obtain a consultation in our region. Application of advanced image analysis software for automated detection of retinal pathology currently being developed in various centres may become a reality in the near future [52].

But above all, establishment of a national programme for screening based on a universally acceptable, efficient (ie. with good sensitivity and specificity) and costeffective strategy associated with efficient organisation at the grassroot level to ensure wide coverage and adequate postscreening followup is of paramount importance. Adequate monitoring of the quality of service is also essential as also maintenance of a central databank to generate a patient recall system and audit its effectiveness. A concerted effort by the government health departments, patients’ and professional associations will be necessary for the successful implementation of the programme.

References


