Evaluation of a screening program for diabetic retinopathy in a primary care setting Dodia (Dépistage ophtalmologique du diabète) study

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SUMMARY

Objectives: The aim of this observational study was to evaluate the screening for diabetic retinopathy (DR) using eye fundus photography taken by a nonmydriatic camera and transmitted trough the Internet to an ophthalmological reading centre, as compared to a dilated eye examination performed by an ophthalmologist.

Methods: A total of 456 and 426 diabetic patients were included by two different groups of primary care physicians (PCPs), 358 being screened with the non-mydriatic camera (experimental group) and 320 with dilated eye fundus exam (control group).

Results: The proportion of screened patients for whom PCPs received a screening report within the 6-month follow-up period was 74,1% for the experimental group and 71,5% for the control group. Screening for DR was negative in 77,6% of patients with eye fundus photographs *vs* 89,6% with dilated eye examination. DR was diagnosed in 62 patients (17,3%) with eye fundus photographs versus 31 with dilated eye examination (10,4%). Referral to an ophthalmologist was required in 59 reports of patients with photographs (16.5%), 23 of them due to high grade DR. Finally, the non-mydriatic camera was found of little inconvenience by patients.

Conclusion: The telemedical approach to DR screening proved to be effective in providing primary care practitioners with information about their patient's eye status. This screening method allowed to identify patients requiring prompt referral to the ophthalmologist for further complete eye examination. In conclusion, this study provided successful results of DR screening using fundus photography in primary care patients, and strongly supports the need to further extend this screening program in a larger number of French sites.

Key-words: Diabetic retinopathy · Screening · Fundus photography · Telemedicine.

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RÉSUMÉ

Évaluation d'un programme de dépistage de la rétinopathie diabétique dans le cadre de la médecine générale

Objectif : Le but de cette étude était d'évaluer une technique de dépistage de la rétinopathie diabétique (RD) par photographies du fond d'œil, prises avec un rétinographe non mydriatique et transmises par Internet à un centre de lecture ophtalmologique, par rapport à la technique habituelle de dépistage par un ophtalmologiste après dilatation du fond d'œil.

Méthodes : Un total de 882 patients ont été inclus dans l'étude par 2 groupes de médecins généralistes. Trois cent cinquante-huit patients ont eu un dépistage par photographies du fond d'oeil (groupe expérimental) et 320 un dépistage par un ophtalmologiste (groupe témoin).

Résultats : Le pourcentage de patient dépistés et pour lesquels le médecin généraliste a reçu un compte-rendu de l'examen de dépistage après 6 mois de suivi a été de 74,1 % dans le groupe expérimental et de 71,5 % dans le groupe témoin. Les résultats du dépistage de la RD ont été négatifs chez 77,6 % des patients dans le groupe expérimental *vs* 89,6 % dans le groupe témoin. Une RD a été diagnostiquée chez 62 patients (17,3 %) après photographies du fond d'œil *vs* 31 après examen du fond d'œil par un ophtalmologiste (10,4 %). Cinquante-cinq patients (16,5 %) ont été adressés à un ophtalmologiste dans le groupe expérimental, dont 23 pour une RD sévère. L'examen par photographies du fond d'œil a été jugé comme peu gênant par la grande majorité des patients.

Conclusion : Le dépistage de la RD par photographies du fond d'œil, télétransmises à un ophtalmologiste pour interprétation est efficace pour renseigner les médecins généralistes sur le statut rétinien de leurs patients. Cette technique de dépistage permet d'identifier les patients qui nécessitent d'être adressés rapidement à l'ophtalmologiste pour un examen plus complet. En conclusion, les résultats de cette étude sont en faveur d'une extension de cette technique de dépistage à d'autres sites de dépistage en France.

Mots-clés : Rétinopathie diabétique · Dépistage · Photographie du fond d'œil · Télémédecine.

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Diabetic retinopathy (DR) is the leading cause of visual impairment and blindness in the working population of industrialized societies [1]. However, it remains largely preventable with proper screening, followed when required by laser photocoagulation therapy [2, 3]. The effectiveness of the laser treatment depends on the accuracy and timely detection of retinopathy. As stated by experts in a number of international and local guidelines, regular screening for diabetic retinopathy and education of patients is critical in limiting visual loss [4, 5].

In France, an annual retinal examination has been recommended for all patients diagnosed with diabetes [6, 7]. In spite of a number of guidelines and educational programs developed to increase awareness of diabetes complications, patients fail to undergo periodic eye examination. A recent study conducted between 1998 and 2000 by the CNAMTS (*Caisse nationale d'assurance maladie des travailleurs salariés* — National Health Insurance Fund) showed that less than 50% of diabetic patients had consulted an ophthalmologist within the last year [8].

Conventional DR screening consists in eye fundus examination performed by an ophthalmologist after pupillary dilation. An alternative method now widely used to increase DR screening is colour fundus photography obtained without pharmacological dilation of the pupil and with only little inconvenience for the patient [9-11]. It is based on the acquisition of eye fundus digital photographies that can be stored and transmitted electronically for further review by an expert site. DR screening programs with eye fundus photography have been successfully implemented several years ago in North European countries [12, 13].

The aim of the study was to evaluate the DR screening procedure using eye fundus photography taken by a non-mydriatic camera and transmitted trough the Internet to an ophthalmological reading centre, as compared to a dilated eye examination performed by an ophthalmologist. Both screening procedures were separately evaluated by two different groups of French primary care practitioners located in Paris area. The performance of the non mydriatic camera has been already compared to standard evaluations in a small patient sample. The method demonstrated high sensitivity and specificity to detect DR and it was concluded that this camera is a validated tool for DR screening [14]. As a result, the objectives of this study were primarily to assess whether this new method applied in a larger population sample would increase DR screening and improve general practitioners awareness on their patient's retinal status, and secondarily to evaluate the patient's satisfaction towards this screening method.

Methods

General methods

This was an observational study with a control group. Two different groups of primary care practitioners were recruited to screen diabetic patients consulting them within a 6-month period. Investigators from the experimental group were primary care practitioners (PCPs) from the *Réseau de Santé Paris-Nord* (North Paris Health network). Investigators from the control group belonged to the *ARES-92* network. Both networks were selected on a voluntary basis. The control group was chosen on the basis of close geographic location to the experimental group, similar density of private ophthalmologists in the area, and similar social and demographic characteristics of the living population.

Patients

Investigators were asked to screen for the study all consulting patients diagnosed with type 1 or type 2 diabetes. Patients meeting the inclusion criteria were then included and referred to DR screening, either to the non-mydriatic camera for eye fundus photographs without pupillary dilation (experimental group) or to an ophthalmologist for a dilated eye examination (control group). Patients were not included in the following cases: if the primary care practitioner had the report of an eye fundus examination performed within the 12 previous months, if patients already had documented diabetic retinopathy, if they refuse to participate in the study, or for the experimental group, if they preferred to consult their ophthalmologist directly. All patients enrolled were identified with a study number in order to ensure confidentiality of data and to comply with the French law (*CNIL, Commission nationale informatique & Liberté*). Data were collected throughout the study: at screening with an initial questionnaire for the patient demographic and clinical characteristics, after the inclusion with the collection of screening reports sent by the reading center and/or the ophthalmologist, and at the end of the study with a final questionnaire addressing the patient's outcome and satisfaction towards the screening procedures.

Screening procedures

Eye fundus photographies

The non-mydriatic camera was set up in a screening center located in the North of Paris close to the practitioners offices from the experimental group, as described in a previous paper [15]. The evaluation was performed by an orthoptist. All patients underwent visual acuity measurement and non mydriatic digital fundus photographies without pupillary dilation. Retinal photographies were taken in a darkened room after 5 min of adaptation to the dark, with the Topcon TRC-NW6S camera (Topcon Europe, Rotterdam, NL). Five 45° non stereoscopic images of overlapping fields were taken for each eye: the macula including the optic disc, and one of each of the nasal, temporal, superior and inferior retinal field. The images were captured in true colour (24 bits) with a resolution of 1490×960 pixels and were directly viewed by the photographer, so that the process could be repeated immediately if the images were unsat-

isfactory. The duration of the evaluation did not exceed 15 minutes. The digital images were transmitted through the Internet to the reference site (Ophthalmology Department, Lariboisière Hospital) for central analysis by two trained ophthalmologists (PM and AE). Screening results were sent both to practitioner and patient. The screening report included: the diagnosis of DR if detected, the severity of DR and a systematic advice to consult an ophthalmologist for further eye fundus examination in case of moderate non proliferative diabetic retinopathy or worse according to the ALFEDIAM classification [7], macular edema or uninterpretable photographies.

Conventional eye fundus examination

Patients from the control group were directly referred to their ophthalmologist for dilated eye fundus examination.

Data analysis

Data monitoring and analysis were performed by Cemka-Eval (Paris, France). Statistical analyses were performed using SAS software, version 8.1. Statistics were mainly descriptive, using mean + standard deviation (SD) and [min; max] values. When performed, comparative analyses used the Student's t test for parametric data and the Chi2 test for non parametric data, with a significant level of 5%. Primary outcome measure was the proportion of diabetic patients meeting the inclusion criteria and referred to DR screening in each group, for whom the GPs had received the report of their DR screening examination during the 6 months of follow-up. Secondary evaluation criteria consisted of the number of patients diagnosed with DR following each screening process, the proportion of patients requiring further eye exam in case of positive screening with the non-mydriatic camera, and finally the patient's satisfaction to each screening procedure: mean delay to DR screening, accessibility to the screening site, visual impairment during testing.

Results

Investigators and patients selection

A total of 192 primary care physicians from the *Réseau de Santé Paris Nord* (experimental group) and 438 from *ARES 92* (control group) were asked to be part of the study. A total of 104 and 93 respectively accepted to participate as investigators, and finally 68 (65,4%) and 53 (57%) included at least one patient, with a median number of patients screened of 8 ([min; max] = [1; 45]) and 13,5 ([min; max] = [1; 57]) in each group.

A total of 1374 diabetic patients (experimental group, 667; control group, 707) were screened for the study from April 1st to November 1st, 2002 *(Tab I)*. Of the patients screened, eye exam had been already performed during the previous year in 20.2% in the experimental group and 31.3% in controls, while diabetic retinopathy was already documented in 6.3% and 6.6% respectively. As not meeting the inclusion criteria (i.e. with an eye exam > 1 year and no documented DR), these patients were not included. Finally, 882 patients (experimental group, 456; control group, 426) meeting the inclusion criteria and willing to participate, were included in the study. Last patient's final questionnaire was completed May 1st, 2003.

Baseline characteristics of patients

Most of the baseline characteristics of patients included were comparable in each group *(Tab I)*. Male patients included overrated the female population and mean age was 60 in both groups. Yet, diabetes had been diagnosed significantly more recently in the experimental group than in controls (6.4 ± 6.6 years *vs* 8.1 ± 8.0, Wilcoxon's test, $p = 0.0011$) and patients were more frequently treated with diet alone in the experimental group (12.6% *vs* 7,9%, Chi2 test, $P = 0.002$). Most frequent medication was oral antidiabetics in both groups (experimental group, 87.4%; control group, 92.1%), suggesting that the majority of patients had type 2 diabetes. Hemoglobin A_{1c} dosing was available in 90% of patients. Mean HbA_{1c} was moderately elevated (< 8%), suggesting that diabetes was rather well controlled in both groups. Previous screening for DR had been performed at least once in the past in 338 patients from the experimental group (74.1%) and in 329 controls (77.2%). The result of this former DR screening was known to the practitioner for less than half patients and the report was stored in the patient's file only for 31 and 2 patients respectively (9.2% and 6%).

Screening for diabetic retinopathy — primary outcome measure

The patient outcome is presented in *Figure 1* and *2* for each respective group. A total of 417 patients from each group completed the study whereas 39 patients from the experimental group (8.6%) and 9 controls (2.1%) were considered lost to follow-up (Chi2 test, $P < 0.001$). Noticeably, 23 of the 39 patients lost to follow-up in the experimental group attended the screening visit, received photographs and had a screening report available. Screening for DR was therefore performed in 358 patients included in the experimental group (78.5%) and at least in 320 patients included in the control group (75.1%), on the basis of the number of screening reports received by the practitioner for this latter group.

Finally, data describing the patient outcome in the final questionnaire could be analyzed in 417 patients from the experimental group and 417 for the control group *(Tab II)*. The proportion of diabetic patients referred to DR screening and having completed the study, for whom the primary care physician had received a screening report within the 6-month follow-up period (primary outcome measure) was 74.1% in the experimental group and 71.5% in the control group (Chi2 test, NS). Mean delay from the patient's inclu-

Table I
Patient flow and baseline characteristics of patients included in the study.

	Experimental group	Control group	Level of significance P [1]
	Patient flow		
Screened	**667**	**707**	
Not included	211	281	NS
Eye exam < 1yr	135 (20.2%)	221 (31.3%)	
Documented DR	42 (6.3%)	47 (6.6%)	
Patient's refusal	78 (11.7%)	48 (6.8%)	
Included	**456**	**426**	
	Baseline characteristics		
	(n = 456)	(n = 426)	
Sex (M/F)	284/170	264/161	NS
	62.6%/37.4%	62.1%/37.9%	
	(m: 2)	(m: 1)	
Age (yrs)	60.5 ± 12.8	60.8 ± 13.6	NS
Diabetes duration (yrs)	6.4 ± 6.6	8.1 ± 8.0	P = 0.0011
Diabetes treatment			
Diet alone	57 (12.6%)	33 (7.9%)	P = 0.002
Medication:	397 (87.4%)	392 (92.1)	
Oral antidiabetics	319 (70.2%)	318 (74.5%)	NS
Insulin	28 (6.2%)	32 (7.5%)	
Both	12 (2.6%)	9 (2.2%)	
Not determined	38 (8.4%)	33 (7.9%)	
Measurement of Hb A_{1c}			
n	412 (90.4%)	386 (90.6%)	NS
%	7.6 ± 4.4	7.8 ± 1.8	NS
Time interval from last dosing (days)	122 ± 198	102 ± 168	NS
Previous DR screening			
Never done	105 (23%)	91 (21.4%)	NS
Performed at least once	338 (74.1%) (m: 13)	329 (77.2%) (m: 6)	
With known results	151 (44.7%)	153 (46.5%)	
With report in the patient's file	31 (9.2%)	2 (6%)	

Parametric data are expressed as mean ± standard deviation. Non parametric data are expressed as number (n) and %. HbA_{1c}, rate of A_{1c} glycosylated haemoglobin, expressed in %; m: missing data; M/F: male/female ratio; NS: not significant; DR: diabetic retinopathy. [1] Student's test for parametric values, Chi 2 test for non parametric values.

sion to the report's receipt was 65.7 ± 58.6 days and 78.8 ± 72.2 days respectively (Student's test, P = 0.03).

DR screening results

As presented in *Table III*, screening for DR was negative in the majority of patients from both group: diabetic retinopathy was absent in 278/358 patients screened with non dilated eye fundus photographs (77.6%) and in 267/298 of the patients reports with dilated eye examination (89.6%). Conversely, DR was diagnosed in 62 patients (17.3%) with eye fundus photographs, and rated non proliferative-mild grade in 39, moderate in 22 and severe in 1 patient. Eye fundus photographs could not be analysed in 18 patients (5%), requiring further eye examination. With dilated eye examination performed by an ophthalmologist, DR was diagnosed in 31 patients reports (10.4%), graded non proliferative in 18, proliferative in 4 and not detailed in 9.

Among the 358 patients who were screened with fundus photographs, 59 (16.5%) were referred to an ophhtalmologist, either for high grade of DR (n = 23) or other reason (n = 36).

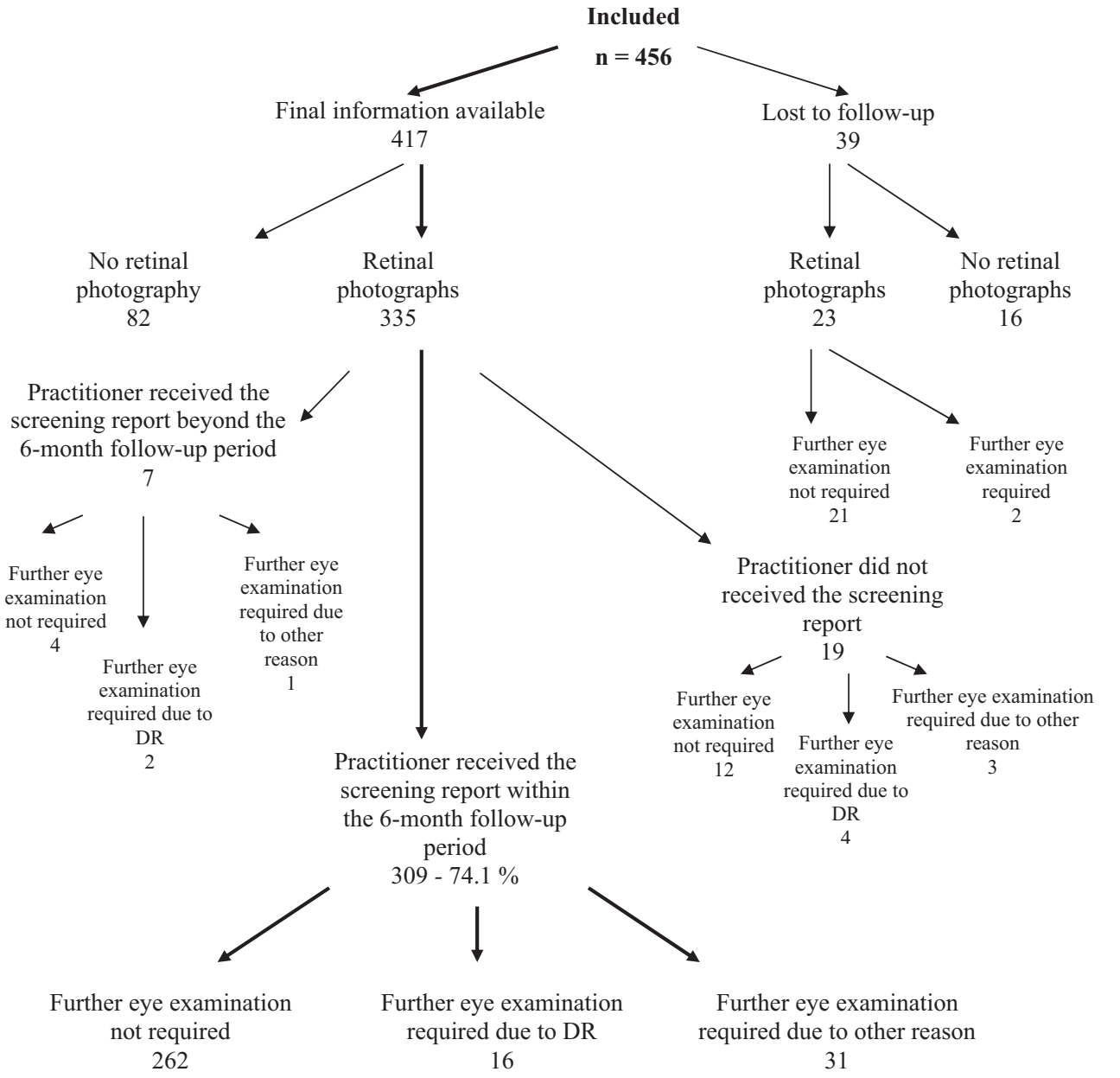

Figure 1
Patient outcome in the experimental group (retinal photographs). DR, diabetic retinopathy.

Patient outcome following DR screening with eye fundus photographs

In the experimental group, three hundred and nine general practitioners said they had received a screening report after the 6-month follow-up period. The majority of them indicated no requirement for further eye exam (262/309, 84.8%). Referral to an ophthalmologist was necessary in 47 patients (15.2%), either due to high grade diabetic retinopathy (n = 16) or to other reason (n = 31, mostly cataract and ungradable photographs). A total of 13 patients out of 16 diagnosed with DR in the experimental group were actually referred by their practitioner to an ophthalmologist. Diabetic retinopathy had been rated non proliferative-moderate grade in all 13 cases. The ophthalmologist's report was available for 8 patients: DR was confirmed by the ophthalmologist in 5 patients (4 diagnosed with the moderate non proliferative grade and 1 diagnosed with proliferative retinopathy), it was unconfirmed in 1, and could not be diagnosed in 2 due to cataract.

Patient satisfaction

The patient's satisfaction was assessed in 336 patients from the experimental group and 283 from the control group. Mean delay from the patient's inclusion to the

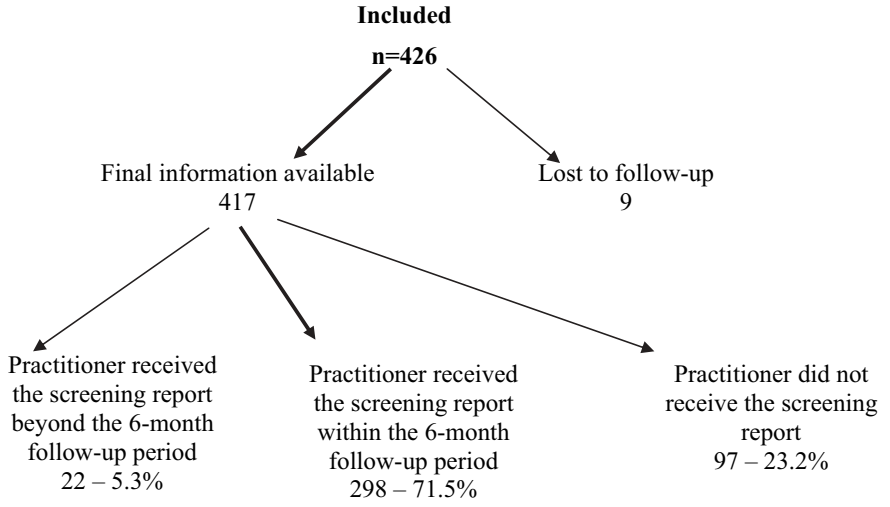

Figure 2
Patient outcome in the control group (dilated eye fundus exam). DR, diabetic retinopathy.

screening visit with eye fundus photography was 29.6 ± 43 days and was considered acceptable for 99% of patients (data not available for the control group). The duration of testing was found acceptable in 96% patients from the experimental group as compared to 82% in controls (Chi2 test, P < 0.001). Visual impairment induced by the flash during testing was graded absent or only mild in 86% patients with eye fundus photographies as compared to 66% with dilated eye exam (Chi2 test, P < 0.001). Accessibility to the screening center/ophthalmologist's office was considered not difficult or only slightly difficult in 82% patients from the experimental group *vs* 93% from the control group (Chi2 test, P < 0.001). Finally 99,1% of patients from the experimental group were ready to have their next annual screening exam performed with the non-mydriatic camera.

Discussion

In this observational study, we report the first telemedical approach to screen for diabetic retinopathy in a French primary care setting. The objective was to evaluate the efficacy of a DR screening program using non dilated eye fundus photographs as compared to conventional screening with dilated eye fundus exam performed by an ophthalmologist.

In an attempt to avoid patient's selection bias, two different networks of primary care practitioners were selected to enrol diabetic patients, on the basis of similar characteristics (close location, same density of ophthalmologists, same demographic characteristics).

In the experimental group (n = 456), a number of patients did not attend the DR screening visit (n = 98) and 39 did not attend the end-of study visit. In the control

Table II
Screening for diabetic retinopathy — primary outcome measure.

	Experimental group Non-mydriatic eye fundus photography	**Control group** Eye exam by an ophthalmologist	**Level of significance P** [1]
Included	456	426	
Study completion			
Final information available	417 (91.4%)	417 (97.9%)	
Lost to follow-up	39 [2] (8.6%)	9 (2.1%)	P < 0.001
Primary outcome			
Screening report available within the 6-month follow-up period	309/417 (74.1%)	298/417 (71.5%)	NS

Data are expressed as number (n) and %; DR: diabetic retinopathy.
[1] Chi 2 test; [2] a total of 39 patients were considered lost as final information was not available but 23 of them had received retinal photographs at the screening center.

Table III
Screening results for diabetic retinopathy.

	Experimental group Non-mydriatic eye fundus photography n = 456	**Control group** Eye exam by an ophthalmologist n = 426
Screening results [1]	358	298
DR diagnosis		
No DR	278 (77.6%)	267 (89.6%)
DR	62 (17.3%)	31 (10.4%)
Not gradable	18 (5%) [2]	—
DR grading		
NPDR	62	18
Mild	39	—
Moderate	22 [3]	—
Severe	1	—
PDR	0	4
Not detailed	—	9
Other findings		
Cataract	14 (3.9%)	16 (5.4%)
Other	11 (3.2%)	20 (6.7%)
Screening report		
Further eye exam not required	299 (83.5%)	
Further eye exam required	59 (16.5%)	
Due to DR/Other reason	23/36	

Data are expressed as number (n) and %; DR: diabetic retinopathy; NPDR: non proliferative diabetic retinopathy; PDR: proliferative diabetic retinopathy.
[1] Screening results were obtained from the reference reading site for the experimental group and from the ophthalmologist's report for the control group;[2] 6 patients presented cataract; [3] 2 patients presented macular edema.

group, practitioners did not receive the screening report of 97 patients, suggesting that either patients did not attend the DR screening visit with the ophthalmologist, or because the ophthalmologist did not send any report to the practitioner, and finally 9 patients did not attend the end-of study visit. The findings of an elevated number of patients lost to DR screening and lost to follow-up suggest that the screening process of this study was obviously more convenient to patients visiting the same practitioner at regular intervals but was of limited action with "occasional" patients. Additionally, these findings also reflect the difficulty of implementing clinical studies in a primary care practice.

Most of the baseline demographic and medical characteristics of the study patients matched those of the national samples representative of French diabetic patients [8, 16]. Diabetes, i.e. glycemic level, appeared to be even better controlled in this study population since greater frequency of dosing was reported in both patient groups. In contrast, diabetes eye complications were less carefully monitored as only 20.2% and 31.3% of patients screened in the experimental and control groups had received eye fundus exam < 1 year prior to their enrolment. In comparison with published data, 39.1% and 41.5% of the diabetic patients from the CNAMTS study had received an annual "ophthalmologic consultation" in 1998 and 1999 respectively [8]. This rate raised to 43% in 2001 in the ENTRED study [16]. However, in any of these studies was it mentioned whether or not eye fundus exam was performed during the "ophthalmologic examination". This may explain why data from the CNAMTS and ENTRED overrated those of the present study. In patients included, more than 20% claimed that they had never received any eye fundus examination, although diabetes had been diagnosed 6.4 to 8 years prior to the study on average. When eye fundus exam had ever been performed in the past, the ophthalmologist's report was found in the GP's file for less than 10% of patients. All these findings suggest that the recommendations of the ALFEDIAM and ANAES for an annual DR screening for retinopathy [6, 7] were not properly applied in this population. They also emphasize the need for ophthalmologists and primary care professionals to improve mutual communication and to increase the information level on their diabetic patients.

Both screening procedures helped to improve screening for diabetic retinopathy in this study. In study conditions, PCPs were more sensitized to the need for DR screening and patients received better information about the screening

process. As a result, a total of 358 and at least 320 patients with no documented DR and no recent (< 1 year) eye fundus exam received DR screening, either with non mydriatic digital photographs or with conventional dilated eye fundus exam. The proportion of patients screened for DR for whom the PCP had a screening report within an accurate timing (i.e. primary outcome measure) was higher in the patient group who received eye fundus photographs as compared to dilated eye fundus (74.1% *vs* 71.5% respectively), although the difference did not reach statistical significance. However, all data together tended to favour the screening procedure using eye fundus photographs. Mean time interval to receive screening reports at the GP's office was shorter with the non-mydriatic camera. Most patients who received eye fundus photographs were satisfied with the delay to the screening visit and with the accessibility of the screening center. Visual impairment due to the testing was low, the acceptability of the camera being partly linked to the absence of pupil dilation. Finally almost all patients demonstrated satisfaction towards this screening method and were ready to have their next annual screening exam performed in same conditions with the non-mydriatic camera.

The screening network (i.e. screening center — reference reading site — primary care office) demonstrated efficacy in tracing the patient's exam. A total of 309 screening reports out of 358 patients screened with the non-mydriatic camera were received at the practitioner's office. Screening reports were sent by postal mail in this study. Noticeably, data were obtained in primary care settings located in Paris area, showing the highest density of practicing ophthalmologists in France, 18.5/100000 inhabitants as compared to the national mean of 9/100000 [17]. DR screening with conventional dilated eye exam would probably not have been as effective as it was within the study interval if the study had been implemented in areas with lower density of ophthalmologists (for instance, Nord-Pas de Calais, < 5/100000; Lozère 2.7/100000). In contrast, greater flexibility may be offered with screening programs using telemedicine. Here, the screening program with the non-mydriatic camera took place in a centre located in Paris. But as digital photographs were electronically transmitted, it could have been implemented anywhere else according to the needs, independently from the location of the ophthalmological reading site.

Not surprisingly, the prevalence rate of DR in this study (experimental group, 17.3%; control group, 10.4%) was slightly lower than other published data, since patients previously diagnosed with DR had been already discarded, and only patients whose retinal status was unknown were included in the study population. In comparison, 21% of patients with type 2 diabetes from the British UKPDS study had retinopathy at the time of diabetes diagnosis [18]. In the French CODIAB study, 34% of patients diagnosed with type 2 diabetes presented non proliferative retinopathy and 10% had a proliferative retinopathy [19]. In the recently published Liverpool eye study, 27% of newly identified patients with type 2 diabetes had diabetic retinopathy at baseline [20].

The number of diabetic patients diagnosed with retinopathy was more frequent in the group who received non-mydriatic photographs. It could be suggested that patients were less controlled with their diabetes and blood pressure and were more likely to present diabetic retinopathy [21-24]. However, baseline data do not support the hypothesis of a differential medical condition between the study groups. Actually, the finding of higher number of DR diagnosis is not too surprising as fundus photographs have proven to be as much effective and even more reliable than ophthalmoscopy in detecting diabetic retinal lesions [13, 25-28]. The sensitivity achieved with the Topcon camera to diagnose mild to moderate retinopathy was found 92% to 100% and specificity was 85 to 88% in the former validation study [14].

Finally, the screening procedure with eye fundus photographs primarily allowed to identify a number of sight-threatening cases of DR needing referral to the ophthalmologist (16 patients). The proportion of ungradable images (5%) requiring additional eye fundus exam was found acceptable and comparable to other non mydriatic screening methods [29, 30]. Secondarily, DR screening with the non-mydriatic camera allowed to identify a majority of patients who were free of diabetic retinopathy and did not need further eye examination. As a result, a number of ophthalmological consultations could be spared and more medical time could be spent by the ophthalmologist for the affected DR cases and urgent conditions. The objective of DR screening was strictly fulfilled in this study, since the aim was not to replace the need for comprehensive eye examinations but rather to detect patients who required prompt referral to an ophthalmologic and potentially needed rapid treatment.

In France, approximately 2 million of individuals affected with diabetes may need an annual eye fundus exam. The prevalence of the disease is now 3% while a 50% increase is expected up to 2025, according to the World Health Organization (WHO). Eye fundus examinations will be required more and more frequently as diabetes is progressing. This will cause an increased charge in the medical care. According to forecasts, the number of ophthalmologists in France should decrease from 5600 to 3000 in 2020 [31]. Ophthalmologists will be unlikely to ensure annual screening of all diabetic patients within the next years. All these findings suggest that yearly screening for retinopathy using new screening programs is likely to be developed in order to satisfy the unmet need. Of course, screening with eye fundus photographs is not to be an exclusive method to detect retinopathy and to replace the ophthalmologist in the global management of diabetic eye complications. It should rather be proposed as an annual exam for non complicated cases, and systematically completed with comprehensive eye examination performed by an ophthalmologist at regular 2-4 year intervals.

Conclusion

The present study demonstrated that the use of digital retinal images taken in a screening center and transferred electronically to an ophthalmologic site for analysis was a suitable method for detecting and grading DR in primary care patients, and for filtering eye-threatening cases requiring complete eye analysis by an ophthalmologist. The screening procedure proved to be effective, allowing primary care practitioners to share the diagnosis with their patient on accurate timing, and finally increasing their awareness about their patient' eye status. Most patients who received non dilated eye fundus photographs were satisfied with the delay and accessibility to screening and low functional impairment during testing. The present study strongly supports the need to extend this screening program to a larger number of different French sites.

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