Validation of the Self-Assessment of Melanoma Risk Score for a melanoma-targeted screening

Gaëlle Quéreux[a], Jean-Michel N'Guyen[b], Myriam Cary[c], Olivier Jumbou[c], Yves Lequeux[c] and Brigitte Dréno[a]

Melanoma is nowadays a major public health problem because of its increasing incidence. Targeted screening for patients at a high risk for melanoma is being promoted. The aim of our study was to assess the effectiveness of a targeted screening on the basis of the self-selection of high-risk individuals with the Self-Assessment of Melanoma Risk Score (SAMScore). Our main objective was to prove that this score allows the selection of a group of patients who are at a higher risk and in whom more melanomas may be detected. This prospective study was carried out in France in 2009. Consecutive patients, while visiting their doctor's office, filled out a melanoma risk factor questionnaire. Patients were assessed as being at high risk or not according to the SAMScore, and patients at a high risk were examined both by their general practitioner and by a dermatologist. The efficiency of the selection tool corresponded to the ratio of the prevalence of melanoma in a population selected with the SAMScore to the prevalence in the general population. A logistic model with a random effect was used. A total of 7977 patients filled out the questionnaire. Among the 2404 patients at high risk, histologically proven melanoma was screened in 10 cases: two in-situ and eight invasive melanomas. The SAMScore efficiency assessed was equal to 11.54 ($P=0.0016$). In conclusion, in this strategy, to detect a new case of melanoma, it is necessary to screen 11 times fewer patients than with a nontargeted screening. This is the first study to confirm the efficiency of a targeted screening on the basis of self-selection of high-risk individuals. *European Journal of Cancer Prevention* 00:000–000 © 2012 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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[a]Skin Cancer Unit, INSERM, 892, [b]Epidemiology and Biostatistics Department, PIMESP and [c]West Melanoma Network, Nantes University Hospital, Nantes Cedex, France

Correspondence to Brigitte Dréno, MD, PhD, Skin Cancer Unit, Nantes University Hospital, INSERM, 892, 1 place Alexis Ricordeau, 44093 Nantes, Cedex, France
Tel: +33 240 083 118; fax: +33 240 083 117;
e-mail: brigitte.dreno@wanadoo.fr

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Introduction

Melanoma is nowadays a major public health problem because of its increasing incidence, as ~197 000 new melanoma cases are diagnosed annually worldwide (Ferlay *et al.*, 2010), and mortality rates for melanoma are still increasing in some countries (Geller *et al.*, 2006; Linos *et al.*, 2009). There is an urgent need to develop effective melanoma prevention programs to reduce this mortality.

Following melanoma treatment, survival is strongly inversely related to tumor thickness at diagnosis (Balch *et al.*, 2009), suggesting that early diagnosis is the principal factor for improving the prognosis of patients with melanoma. We can assume that screening for early melanoma may improve the survival rates for this disease. Furthermore, it has been shown that the proportion of thin melanomas observed in screening programs is higher than that observed in usual care (Helfand *et al.*, 2001; Fry and Verne, 2003; Aitken *et al.*, 2010).

Nevertheless, mass screening for melanoma is not recommended worldwide, especially in countries where the incidence is high (Wolff *et al.*, 2009), owing to insufficient evidence that screening the general population reduces morbidity and mortality (Williams *et al.*, 2006). Moreover, mass screening for melanoma has very high costs (Losina *et al.*, 2007). In 2001, the third United States preventive Task Force concluded that 'evidence is lacking that skin examination by clinician is effective in reducing mortality or morbidity from skin cancer'. However, it called for studies to help identify patients at high risk for melanoma (Wolff *et al.*, 2009). This strategy of targeted screening has also been recommended by the French National Authority for Health (HAS, 2009).

One of the most critical challenges for skin cancer screening programs is the identification of high-risk individuals. To lower the cost of such a screening program, it is essential to base it on a self-selection of high-risk participants through self-assessment of melanoma risk factors without the intervention of a doctor. To achieve these objectives, user-friendly tools that can be used during a routine checkup are needed to predict individual risk for melanoma. This is why we created and validated a self-administered questionnaire for individuals that could allow them to assess melanoma risk factors by themselves (Quereux *et al.*, 2010). Then, we carried out a case–control study using this self-administered questionnaire to determine the risk factors for melanoma and thus developed an individual score of

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melanoma risk factors: the Self-Assessment of Melanoma Risk Score (SAMScore) (Quereux *et al.*, 2011).

The aim of our study was to assess the feasibility and effectiveness of a strategy for targeted screening of melanoma on the basis of the self-selection of high-risk individuals through self-assessment of the risk factors of melanoma, using the previously created SAMScore. We aimed to prove that this score was indeed effective in allowing the selection of a small group of patients who are at a higher risk and for whom more melanomas may be detected.

Materials and methods

Selection of patients at a high risk for melanoma

A patient was considered to be at a high risk for melanoma or not with the SAMScore that was assessed according to the answers provided by the patient on the self-administered questionnaire.

The self-administered questionnaire had been created previously within our network, the 'West Melanoma Network', a French network of dermatologists, general practitioners (GPs), and nurses involved in the prevention and treatment of melanoma (Quereux *et al.*, 2010). This questionnaire was developed using risk factors established for melanoma in the literature (Gandini *et al.*, 2005a, 2005b, 2005c). It included seven questions on the phototype, number of melanocytic naevi, freckling tendency, severe sunburn during infancy, life in a country at low latitude, a history of previous personal melanoma, and a history of melanoma in a first-degree relative (Fig. 1). The questionnaire was designed to be simple and comprehensive for individuals without any medical knowledge. This questionnaire had been tested previously to assess the accuracy of the information provided by the patients on their own melanoma risk factors and especially naevi count and freckles (Quereux *et al.*, 2010).

The SAMScore is a score enabling the assessment of whether an individual is at a high risk of melanoma or not according to the answers provided on the self-assessment questionnaire. The SAMScore was designed thanks to a previously conducted case–control study (Quereux *et al.*, 2011). In this study, several methods (logistic regression, combinatorial analyses) were compared to optimize both the sensitivity and the specificity thresholds and it was shown that combinatorial analyses yielded better results than logistic regression. Thus, this combinatorial analysis allowed us to obtain a score on the basis of a combination of three criteria: the SAMScore. According to this score, patients are considered at a high risk (positive SAMScore) if at least one of the following three criteria is verified: presence of at least three risk factors (among the seven risk factors explored by the self-assessment questionnaire); a patient younger than 60 years of age with more than 20 naevi on the arms; and a patient 60 years old or older with the presence of freckles (Fig. 1).

Design of the study

A prospective study was carried out in the Pays de Loire Region (located in the West of France) (Fig. 2). Forty-six GPs, representative of the French GP population, agreed to participate in the study. The geographical area represented a cross section of urban and rural medical practices. The entire procedure of the study was explained individually to the GPs, but they were not specifically trained to make an early diagnosis of melanoma. The study took place between June and October 2009. Over a 1-month period, 1 or 2 days per week, all the consecutive patients aged older than 18 years, who visited their doctor's office for a consultation, were invited to fill out the melanoma risk factor self-assessment questionnaire, alone, without any help, while they were waiting in the waiting room. Each GP was asked to collect questionnaires from $\sim$200 patients.

At the beginning of the consultation, the physician checked the answers provided by the patient and assessed whether the patient was considered at a high risk using the criteria established previously in the SAMScore (Quereux *et al.*, 2011). If an individual was identified as being at a high risk, the GP carried out a whole-body skin examination and reported it on a document specifying the anatomic location and the suspected diagnosis for the suspicious lesion(s). A suspicious lesion was defined as any lesion observed during a routine check-up for which the GP would have asked for an expert opinion by referring the patient to a dermatologist.

All patients identified as being at a high risk, with or without visible skin lesions, were then systematically advised to undergo a whole-body skin examination by a dermatologist. This dermatologist was either the patient's dermatologist or one that the GP recommended. After completing a full-skin examination, the dermatologist specified on the document transmitted by the GP whether the suspicious lesion observed was benign or not. The dermatologist was also asked to report any other suspicious lesion. In the case of a suspicious lesion, the dermatologist had to specify whether an excision was needed or only a follow-up. The dermatologist carried out the excision if needed.

Statistical considerations

The main aim of the study was to show that the SAMScore allowed the detection of more melanomas. We defined the efficiency of the SAMScore as the ratio of melanoma prevalence in the population selected using the SAMScore to the melanoma prevalence in patients with a negative SAMScore, estimated as the prevalence in the general population. A logistic model with a random effect was used to include the clustered structure of data (Santos *et al.*, 2008). We established the hypothesis that patients with a negative SAMScore consulting their GP

Fig. 1

Questionnaire:

1. How old are you? …….

2. Gender: ☐ Male ☐ Female

Answer each question by checking the corresponding square

3. What type of skin do you have?

☐ Skin-type I: very fair skin, blond or red hair, light eyes (blue or green), never tan and always sunburn after sun exposure

☐ Skin-type II: fair skin, blond or light-brown hair, light eyes (blue or green), usual sunburn

☐ Skin-type III: deep skin, brown hair, light to medium eye colour

☐ Skin-type IV: olive skin, dark-brown hair, brown eyes

☐ Skin-type V: brown skin, black hair, black eyes

☐ Skin-type VI: black skin, black hair, black eyes

4. Do you have freckles?

☐ yes ☐ no

5. How many moles do you approximately have on both arms?

☐ more than 20 ☐ fewer than 20

6. Have you had one or more episodes of severe blistering sunburn during childhood or teenage years?

☐ yes ☐ no

7. Did you live more than one year in a country where sunshine is high (Africa, French West Indies, South of United States, Australia…)

☐ yes ☐ no

8. Have you been diagnosed with melanoma in the past (it is a skin cancer, arising in melanocytes, skin cells that make skin pigment)?

☐ yes ☐ no

9. Has any of your first-degree relatives (parents, children, brother or sister) ever had melanoma?

☐ yes ☐ no ☐ don't know

Self-Assessment of Melanoma Risk Score: SAMScore

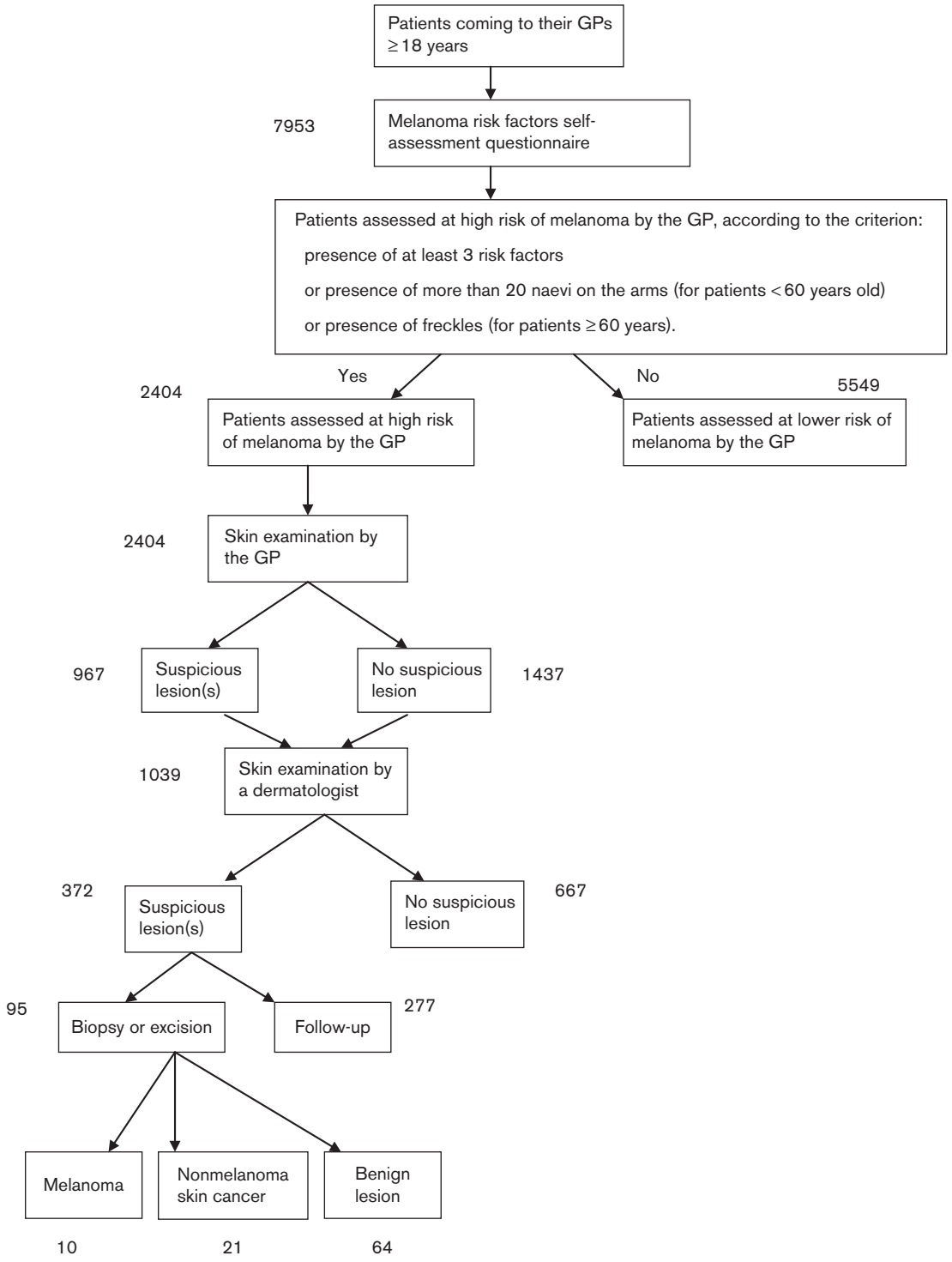
According to the SAMScore, a patient is considered at risk of melanoma if at least one of these 3 criteria is verified:

- First criterion: Presence of at least 3 risk factors among the 7 following risk factors: phototype I or II, freckling tendency, number of melanocytic naevi >20 on both arms, severe sunburn during childhood or teenage years, life in a country at low latitude, a history of previous melanoma, a history of melanoma in a first-degree relative
- Second criterion: A subject under 60 years of age and a number of melanocytic naevi >20 on both arms
- Third criterion: A subject of 60 years old or over and a freckling tendency

Questionnaire used for the self-assessment of melanoma risk factors and Self-Assessment of the Melanoma Risk Score.

had the same melanoma risk as the general population. In France, this prevalence of melanoma can be estimated at 30.8/100 000 [Office statistique des Communautés européennes (EUROSTAT), 2003]. We analyzed the data using the SAS statistical package 9.2 (SAS Institute Inc., Cary, North Carolina, USA) and its GLIMMIX procedure.

Fig. 2



Design of the study. GP, general practitioner.

Ethical approval

The protocol was approved by the ethical committee of Nantes (Pays de la Loire, France).

Results

A total of 7977 patients filled out the self-administered questionnaire between June and October 2009.

Table 1 Melanoma risk factors among the 7953 patients who filled out the questionnaire and among the 2404 patients assessed as being at a high risk according to the Self-Assessment of Melanoma Risk Score

	% of patients with the risk factor among the 7953 patients who filled out the questionnaire	% of patients with the risk factor among the 2404 patients assessed at high risk with the SAMScore
Patients with freckles	32.8% (2577/7864), 89 MD	57.6% (1362/2366), 38MD
Patients with more than 20 nævi on both arms	24.6% (1921/7795), 158 MD	49.1% (1573/3201), 103 MD
Skin-type I or II	43.6% (3409/7823),130 MD	56.8% (1308/2304), 83 MD
Severe blistering sunburn during childhood or teenage years	42.1% (3300/7832), 121 MD	56.6% (1309/2315),89 MD
More than 1 year living in a country at low latitude	9.5% (744/7860), 93 MD	10.2% (238/2328), 76 MD
A history of previous melanoma	2.0% (160/7821), 132 MD	4% (94/2310), 94 MD
A history of melanoma in a first-degree relative	8% (492/6096), 1734 unknown, 123 MD	14.1% (254/1799), 515 unknown, 90 MD

MD, missing data; SAMScore, Self-Assessment of Melanoma Risk Score.

Twenty-four participants were younger than 18 years of age and were excluded from the study. Among the 7953 participants included, there were 3199 men and 4577 women (177 missing data), aged from 18 to 100 years (median = 50 years). Table 1 summarizes the melanoma risk factors of these patients. The two main factors were phototype I or II (43.6%) and severe blistering sunburn during childhood or teenage years (42.1%). The majority of patients (53%) had none or only one risk factor and less than 2% had five or more risk factors. Among these 7953 patients, 2404 had at least one of the three criteria of the SAMScore verified and were thus assessed as being at a high risk of melanoma. There were 782 men and 1604 women (18 missing data), aged from 18 to 100 years (median = 45 years). Table 1 summarizes the melanoma risk factors of these 2404 patients assessed as being at a high risk by the SAMScore.

Skin examination of the 2404 patients assessed at a high risk of melanoma

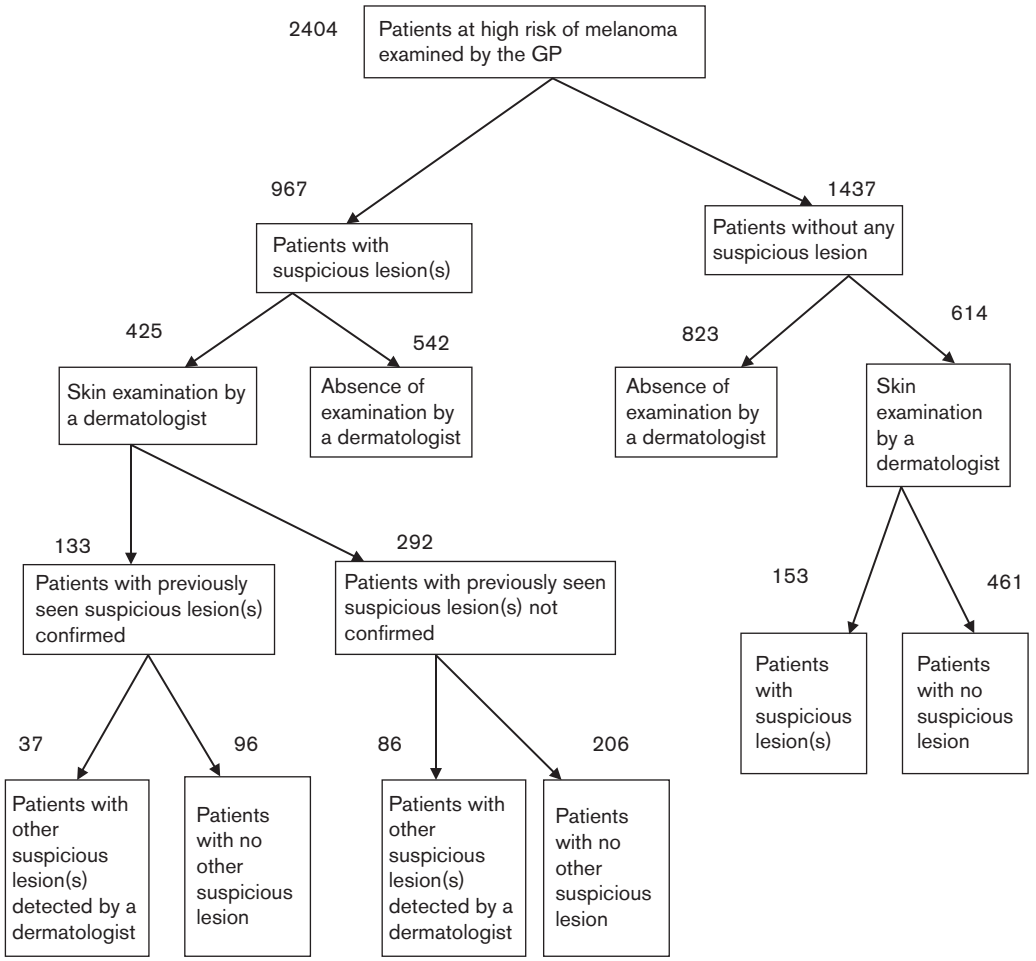
All the 2404 patients considered to be at a high risk by the SAMScore were advised a full-skin examination by their GP. All of them accepted it. Among these 2404 patients, 967 (40.2%) had at least one suspicious lesion that was observed during the skin examination. All the 2404 patients at a high risk were advised to consult a dermatologist for a more thorough examination, but only 1039 of them (43.2%) consulted. The comparison of patients who did not opt for a skin examination by a dermatologist and those who did showed that those who did not opt for a skin examination by a dermatologist were younger (43.69 ± 15.61 vs. 49.8 ± 15.69 years, $P < 0.0001$), had more melanoma risk factors (2.62 ± 1.15 vs. 2.45 ± 1.2, $P = 0.0003$), and had more frequently 'a number of naevi of more than 20 on the two arms' (72.2 vs. 56.5%, $P < 0.01$).

Of the 1039 patients examined both by the GP and then by the dermatologist, the dermatologist observed at least one suspicious lesion in 372 patients (36%) (Fig. 3). For 133 patients (36% of these 372 patients), this suspicious lesion had been observed previously by the GP (Fig. 3). For the 372 patients with at least one suspicious lesion observed by the dermatologist, the dermatologist decided on a follow-up for 74% of cases and performed a biopsy or an excision for 26% (95 cases). We obtained the data from cutaneous histological analysis for 95 patients. A benign lesion was detected for 64 patients (67% of excisions). These benign lesions were 52 naevi, two actinic keratoses, three seborrheic keratoses, three actinic lentigo, one lentigine, one histiocytofibroma, one neurofibroma, and one melanonychia. A nonmelanoma skin cancer (histologically proven) was detected in 21 cases (22% of excisions): 17 basal cell carcinomas, three squamous cell carcinomas, and one atypical fibroxanthoma. A histologically proven melanoma was screened in 10 cases. Patients with a melanoma were six women and four men, aged between 47 and 76 years (median: 64 years). Among these 10 melanomas, there were two melanomas *in situ* (lentigo malignas); the others were eight invasive superficial spreading melanomas (six Clark II, two Clark III) and the median thickness was 0.31 mm (0.21–0.45 mm). Six of these 10 melanomas (one melanoma *in situ*, one Clark III, four Clark II) were detected by the GP and confirmed by the dermatologist and four (one melanoma *in situ*, one Clark III, two Clark II) had not been observed by the GP and were screened by the dermatologist. The median thickness was not statistically greater ($P = 0.66$) for melanomas screened by GPs (0.35 mm) than those screened by dermatologists (0.24 mm).

Efficiency of the selection tool

According to the melanoma prevalence estimations observed in France, among the 5549 (7953–2404) patients with a negative SAMScore, the number of melanoma expected could be estimated at $(30.8 \times 5549/100\,000) = 1.7$, and rounded to 2. Among the 2404 patients with a positive SAMScore, 0.74 patients with a melanoma were expected. In our study, selecting patients at a high risk by the SAMScore, 10 melanomas were detected among 2404 patients. Using a logistic model with a random effect (Table 2), the efficiency of the targeted screening using the SAMScore could be assessed as equal to 11.54 ($P = 0.0016$). In other words, to detect a new case of melanoma, it would be necessary to screen 11.54 times more patients if the SAMScore was not used compared with a targeted screening on the basis of the SAMScore.

Fig. 3



Concordance between skin examinations performed by the general practitioners and the dermatologists. GP, general practitioner.

Table 2 Efficiency of the Self-Assessment of Melanoma Risk Score to screen patients at a high risk for melanoma, according to the estimated melanoma prevalence in France (two melanomas among the 5549 patients with a negative Self-Assessment of Melanoma Risk Score vs. 10 melanomas among the 2404 patients with a positive SAMScore)

Effect	Estimate	SE	DF	*t*-Value	Pr>|*t*|	Lower	Upper
Intercept	−7.9279	0.7072	46	−11.21	<0.0001	−9.3515	−6.5043
SAMScore risk	2.4497	0.7750	7905	3.16	0.0016	0.9306	3.9689
Ratio of prevalences	11.54	–	–	–	–	–	–

SAMScore, Self-Assessment of Melanoma Risk Score.

The average cost per case of melanoma detected was found to be equal to €4956 as follows:

$$[(2404\times A)+(967\times B)+(95\times C)]/10,$$

where A is the supplementary cost for a cutaneous examination by a GP (€5), B is the cost of a dermatologist examination (€36), and C is the cost of a cutaneous excisional biopsy (€28.8).

Discussion

Our strategy using the SAMScore for a targeted screening of melanoma allowed the detection of 10 patients with melanoma among the 2404 individuals who were examined. According to the estimations of melanoma prevalence in France, among the 2404 patients examined, the number of melanoma expected would have been equal to 0.74. Thus, in this strategy on the basis of the selection of individuals with the SAMScore, to detect a new case of melanoma, it is necessary to screen 11.54 times fewer patients compared with a nontargeted screening.

It is difficult to compare the impact of our strategy with other screening programs conducted previously because the population targeted and the equipment used may be

quite different from one study to another. The potential impact of melanoma-targeted screening has mainly been tested using Simulation Markov models (Freedberg *et al.*, 1999; Losina *et al.*, 2007). The two screening strategies that were the most cost effective were a one-time melanoma screening of the general population over the age of 50 years and a screening every 2 years in siblings of patients with melanoma (Losina *et al.*, 2007). It has been shown previously that including those patients who are at a high risk of melanoma in specific digital follow-up programs enables the detection of melanomas with a low suspicion index and in their early stages (Schiffner *et al.*, 2003; Wang *et al.*, 2004; Haenssle *et al.*, 2006; Kittler *et al.*, 2006; Salerni *et al.*, 2011). However, these studies require the use of specific equipment and patients must be provided with attentive care by specialized staff using a digital dermoscopic device. This type of strategy can only be proposed for a very small part of the population who are at the highest risk. To date, the current gold standard for melanoma screening in the general population is a skin examination. For screening programs conducted previously and based only on skin examination, 0.2–0.3% of patients screened by total body skin examination were found to have melanoma (Koh *et al.*, 1996; Carli *et al.*, 2003; Aitken *et al.*, 2006; Argenziano *et al.*, 2011). In our study, this value was higher: as many as 0.4% of patients examined were found to have melanoma, which is probably because of the selection of patients using the SAMScore.

A very crucial factor in terms of the melanomas detected in our study is that their Breslow index was small. All the invasive tumors were less than 1 mm thick and the mean and median Breslow index were 0.32 and 0.31 mm, respectively. By comparison, in 2000, in the USA, melanomas with a thickness of 1 mm or less represented 61 and 66% of new melanomas diagnosed in men and women, respectively (Linos *et al.*, 2009). This is important because, so far, the Breslow index has been the strongest prognostic factor in melanoma and the 5-year survival rate for melanoma increases with a decrease in the depth of the primary lesion.

This study confirms that GPs are able to diagnose melanomas, because as many as two-thirds of the melanomas that were detected were first observed by GPs (and confirmed later by dermatologists). This is of particular interest because the GPs who participated in the study were not specifically trained to detect suspicious pigmentary lesions before starting the study. It is noteworthy that, in our study, GPs carried out the skin examination and identified melanomas in their own patients. This suggests that they can carry out melanoma screening but they do not do so in their routine practice. This result is consistent with previous studies carried out in the primary-care setting. The self-reported rate at which GPs screen for skin cancers among their patients remains low (only 17–32%) and is unfortunately not increasing (Geller *et al.*, 1992; Oliveria *et al.*, 2001a, 2001b; Santmyire *et al.*, 2001; Geller *et al.*, 2004; Valachis *et al.*, 2009). In our strategy, the SAMScore plays the role of an 'alert' facilitating the screening.

It is thus essential that GPs carry out melanoma screening because GPs have a unique opportunity to detect skin cancer early, given the large number of patients seen for routine health checkups. One of the main obstacles for GPs for melanoma screening is the lack of time (Geller *et al.*, 2004). This is why we based our strategy on the self-assessment of melanoma risk factors done by the patients themselves and thus reduced the time that is currently used by the medical community.

In terms of the cost of this screening strategy, the average cost per case of melanoma detected was found to be €4956. Obviously, the economics of melanoma screening is much more complicated because this direct cost of screening has to be compared with the direct cost of treating newly diagnosed melanoma, the survival advantage derived from shifting late disease to earlier disease, the financial burden of treatments for advanced disease, and the indirect economic gain achieved from the lives saved. A complete analysis of the cost of melanoma screening needs to be carried out with complex models using these variables (Tsao *et al.*, 1998).

Another important point in terms of the strategy is that it raises the question of screening individuals who may not have spontaneously sought skin cancer screening. It is an important advantage compared with melanoma campaigns, which are known to concern only persons who are aware of melanoma dangers. Patients who seek melanoma screening are not necessarily the patients who are at the highest risk for developing or dying from melanoma (Janda *et al.*, 2006; Andrulonis *et al.*, 2010; De Giorgi *et al.*, 2010).

Nevertheless, there are several limitations to this study. First, our findings may not be applicable to all populations because the study was carried out in only one geographic location. However, we are confident that the results obtained are representative of a larger area but also of the entire European territory because Nantes is a big town located in the middle of France (latitude) and it is a place where all skin types are prevalent. We aim to test the SAMScore in the near future in a larger territory. Second, we only obtained information from the dermatologist's skin examination for half of the patients. Another limitation in our study was that patients with a negative SAMScore were not examined and there may thus be false negatives, as in all screening programs.

To our knowledge, the current study was the first to assess the efficiency of a targeted screening on the basis of self-selection of high-risk individuals. The results obtained provide evidence that, using the tools we created, more melanomas can be screened. These tools can be used easily in routine primary-care practice and

allow GPs to identify among their patients those at a high risk of melanoma. These patients can be advised to have a skin examination and provided with preventive advice on sun protection. In the next step, using this SAMScore, we will aim to identify a cohort of patients at a high risk of melanoma and then follow this cohort over a period of several years, examining them once a year to check whether any melanoma has developed.

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Conflicts of interest

There are no conflicts of interest.

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