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(Article begins on next page)



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*Italian Euromelanoma Day Screening Campaign (2005–2007) and the planning of melanoma screening strategies.*

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## Italian Euromelanoma Day Screening Campaign (2005–2007) and the planning of melanoma screening strategies.

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Keywords: melanoma prevention strategy, melanoma risk factors, melanoma screening campaign, skin cancer, self-surveillance

## Abstract

Although no study has definitively shown that unfocused screening of skin cancer is effective, many campaigns have been organized with the aim of increasing awareness on melanoma risk factors. The objective of this study was to analyse the results of the Skin Cancer Screening Day in Italy during the period 2005–2007, to determine the priorities for melanoma control plans in a Mediterranean country. A total of 5002 patients were screened by dermatologists in 31 cities. Individuals who considered themselves to have many naevi and those with a family history of melanoma showed a higher number of common and atypical naevi. Ten melanomas, 20 basal cell carcinomas and two squamous cell carcinomas were histopathologically confirmed. Our observations provide the following suggestions for melanoma prevention strategies: (a) an unfocused campaign is suitable to inform the public about the importance of self-examination of the skin, but is not useful to identify a larger number of melanomas; and (b) melanoma screening campaigns should focus on a selected population, which meets rigorous risk criteria to maintain higher cost-effectiveness. The financial support to effective melanoma screening programmes could be increased, especially in southern populations where lower levels of self-surveillance and socioeconomic conditions represent risk factors for late identification of melanoma.

## Background

In the past decades in Caucasian populations, melanoma incidence has markedly increased (Lee and Carter, 1970; Magnus, 1973; Osterlind, 1992; Hall et al., 1999; Lo Scocco et al., 2000; De Vries and Coebergh, 2004; Pellacani et al., 2008). Although the recent stabilization of malignant melanoma (MM) mortality rates has been observed (Severi et al., 2000; Cayuela et al., 2005; Lasithiotakis et al., 2006; Pellacani et al., 2008) the MM represents a significant healthcare problem. MM should be an ideal candidate for screening, as it can be detected at an early stage through a detailed skin examination completed by dermoscopy (Vandaele et al., 2000; Massone et al., 2005; Stratigos et al., 2007), and its prognosis improves greatly if it is spotted at an early stage. Thus, many campaigns have been organized (Rampen et al., 1991; Bataille et al., 1999; Vandaele et al., 2000) both with the aim of increasing awareness about melanoma risk factors and educating the population and general practitioners (GP) to detect precocious signs of MM. This goal could be best achieved by a short but intensive campaign involving the media, resulting in a national day of MM,

on which free skin inspections would be offered (Vandaele et al., 2000). Various prevention campaigns based on this concept have been carried out in the USA and Australia during the past few decades (Koh et al., 1996; Geller et al., 2003; Williams et al., 2006b). In Europe, 'melanoma days' have been launched in Belgium, Spain, Greece and Switzerland (Vandaele et al., 2000; Conejo-Mir et al., 2005; Stratigos et al., 2007; Bulliard et al., 2008; Paoli et al., 2009). The Skin Cancer Day (SCD), organized in many European countries since 1999, combines educational aims with the opportunity for early detection of MM (Vandaele et al., 2000) by the promotion of a day dedicated to information on skin cancer and skin examination. During 2005–2007, the Italian SCD was promoted by the Federation of Italian Dermatology Societies.

Although primary prevention through health education campaigns aiming at reducing sun exposure have not yet definitively reduced MM incidence (Karim-Kos et al., 2008), secondary prevention directed towards skin awareness, self-examination and full-body skin examinations by physicians can lead to a reduction in mortality and morbidity (Vandaele et al., 2000; Weinstock, 2006; Koh, 2007; Cainelli et al., 2008; Karim-Kos et al., 2008). However, no study has definitively shown that unfocused screening for skin cancer is cost-effective and further evidence is needed to assess the effectiveness of an unfocused MM prevention programme.

In this study we analysed the data referring to people attending the SCD clinics collected by means of a detailed data sheet distributed all over Italy during 2005–2007, to determine whether individual, demographic, epidemiological and environmental data would help us to better define the target population for screening programmes and crucial factors influencing future strategies for MM campaigns.

## Methods

The screening was conducted both in dermatology departments in a University and Hospital setting and in the private practice of dermatologists during 1 day in May 2005, 2006 and 2007. A standardized questionnaire was published on the website of the Italian Dermatology Society and was freely available to dermatologists interested in participating in the campaign. To alert the population, a clear and intensive campaign was carried out during the weeks before the screening day through various media (i.e. press, radio and the internet) to educate the public on sun protection measures, risk factors, warning signs of skin cancer and self-examination techniques. The SCD campaign offered free skin inspections to people who came to be informed and examined. During this screening, the questionnaire was completed both by patients and dermatologists. On the screening questionnaire, patients compiled the first part providing their personal data. They were also asked to answer multiple choice questions on how they become aware of the campaign, earlier skin inspections, the reason for their visit, their opinion about the main skin cancer risk factors, the rules used to identify a suspicious lesion and how they checked their naevi. Dermatologists then performed a visual inspection of the patient's skin and completed the second part of the questionnaire. They were asked to answer multiple-choice questions on the patient's family history of MM and any other cancer (in first-degree family members), the total number of common and atypical naevi (diameter, >6 mm, irregular edge and nonhomogeneous colour) and the skin type. Thus, if a suspicious lesion was found, the physician was asked to specify its characteristics (size and location), the clinical diagnosis and the medical care provided. Physicians had to declare that all screenings took place in well-illuminated examination rooms and that dermoscopy was performed if necessary. Compiled questionnaires were sent back to the Dermatology Department of Modena for data collection and analysis. Participating

dermatologists were also asked to report on all histopathologically confirmed MMs, diagnosed on screened patients enclosing the histological record.

In addition to the overall analysis on the whole population, data referring to two different geographic areas, obtained by grouping the northern regions and the center-southern regions were evaluated (Williams et al., 2006b). Moreover, data referring to three selected patient groups (individuals with many naevi, those attending skin examination for a suspicious lesion and those with a family history of MM) were considered.

### **Statistical analysis**

Statistical analyses were performed using an SPSS (release 10.0 for Windows, SPSS, Chicago, Illinois, USA) software package. The [chi]<sup>2</sup>-test was used as well for comparing the values. A P value of less than 0.05 was considered statistically significant. Descriptive analyses of responses to all demographic questionnaire items were performed.

## **Results**

During the SCD in 2005, 2006 and 2007, a total of 5002 individuals completing a questionnaire were screened by experienced dermatologists in 38 dermatology departments and doctor's offices of 31 towns. Not all answers were completed by the patients; therefore, the total number in the tables may not always correspond to 5002.

### **Data reported by patients**

The majority of screened individuals were female patients (2723/5002, 54.7%). The median age of the patients was 47.7±17 years (range: 7 months, 94 years). Forty-seven per cent of individuals had attended a secondary school. The reasons reported for attending the SCD clinics (often more than one per patient) were as follows: 36.6% of individuals thought they had many naevi, 33.5% came to be reassured, 10.4% thought they had a suspicious lesion, 10% thought they were at risk for skin cancer and 9.3% thought they had many naevi and wanted to be reassured. The percentage of patients examined for the first time was 55.6% in Northern and 57.1% in Southern Italy. Table 1 explains the patients' methods used to check naevi: only 31% of screened individuals had visited a dermatologist earlier for a general skin examination, whereas 12% had attended a GP office. The media that brought most attention to the public about the SCD was the press (48% from both local and national press). Participants also gained knowledge about the campaign by word of mouth between friends and family members (27.7%). Seven percent of the patients recalled that they had at least one family member with a history of skin cancer and 5.2% of them declared that they had one or two family members with a history of MM. Approximately 80% of screened patients were conscious of the increase in risk factors for skin cancer related to an excessive exposure to ultraviolet radiation, exposure without protection or sunburn. Moreover, colour, size, shape and changes in the moles represented characteristics that drew attention in 20–40% of individuals in the whole examined population.

## Data reported by dermatologists

People attending the SCD clinics (39.9 and 48.8%) showed skin phototypes II and III, respectively; the majority of patients showed less than 10 common naevi and a number of atypical naevi of less than or equal to five (74.1% presented no atypical naevi and 23.2% presented  $\leq 5$  atypical naevi; Table 2).

Dermoscopy was performed only when required, according to the opinion of the dermatologists, in 55.5% of the cases. A total of 1598 patients (35.6%) did not present either atypical naevi or lesions diagnosed to be cancerous but had risk factors, such as family history or previous sunburn, whereas 2420 patients (53.9%) did not show suspicious lesions and did not have risk factors. With regard to the main clinical findings reported by the dermatologists, suspicious pigmented lesions and suspicious basal cell carcinomas were the most commonly reported diagnoses, with 13 lesions showing clinical characteristics of MM. Although a total of 423 (9.4%) lesions were selected for surgical removal, the histopathological diagnosis was available in only 104 cases, consisting of 10 MMs, 20 basal cell carcinomas, two squamous cell carcinomas, 50 benign naevi and other 22 benign skin lesions (such as actinic keratosis, vitiligo, angioma or lipoma). In detail, the 10 histopathologically confirmed MMs (six in 2005, two in 2006 and two in 2007) were diagnosed equally in women and in men. Among these eight cases of MMs, eight were diagnosed in the Northern and two in the Southern Italy. Six were localized on the trunk, three on the limbs and one on the face. Among these MMs, three were in situ and four were thinner than 1 mm. The reason for which such a low number of histopathological examinations had retrieved is that Italian Euromelanoma Day Screening Campaign was a multicentric study and not all the clinics sent histopathological reports to the reference center. Moreover, among patients who had to remove a lesion, not all decided for the surgical intervention.

Table 1 Patients' methods to check naevi

	Total SCD population	Northern population	Southern population
Method for checking own naevi	4706 = 100%	3022 = 100%	1684 = 100%
Self-examination	37.1	39.6	32.6
GP	8.4	8.7	7.8
Dermatologist	24.3	21.3	29.8
Self-examination and dermatologist	5.6	5.9	5.1
Self-examination and GP	2.3	2.3	2.1
GP and dermatologist	0.9	0.9	0.8
No check	21.4	21.2	21.9

GP, general practitioner; SCD, Skin Cancer Day.

Table 2 Phototype and total number of common and atypical naevi in the Skin Cancer Day population

Phototype	4738 = 100%	Total number of naevi	4555 = 100%	Number of atypical naevi	4196 = 100%
I	3.1	0	6.9	0	74.1
II	39.9	< 10	53.1	$\leq 5$	23.2
III	48.8	11–30	27.5	> 5	2.7
IV	7.9	31–50	7.3		
V	0.3	> 50	5.1		

**Table 3 Frequency (%) of common and atypical naevi in patients who thought to have many naevi and in patients attending for other reasons**

Number of common naevi	Patients who thought to have many naevi	Patients with other reasons for the visit	Number of atypical naevi	Patients who thought to have many naevi	Patients with other reasons for the visit
	2045 = 100%	2510 = 100%		1887 = 100%	2309 = 100%
0	4.69	8.7	0	68.36	78.8
< 10	44.40	60.8	≤ 5	27.19 <sup>c</sup>	20.1
11–30	33.06 <sup>a,b</sup>	22.9	> 5	4.45 <sup>c,d</sup>	1.1
31–50	9.93 <sup>b</sup>	2.4			
> 50	7.92	5.1			

<sup>a</sup>Statistically significant ( $P$  value < 0.05) compared with patients with other reasons for the visit belonging to the same group.

<sup>b</sup>Considering together patients with 11–30 and 31–50 common naevi, data are statistically significant ( $P$  value < 0.05) compared with patients with other reasons for the visit belonging to the same groups.

<sup>c</sup>Considering together patients with ≤ 5 and > 5 atypical naevi, data are statistically significant ( $P$  value < 0.05) compared with patients with other reasons for the visit belonging to the same groups.

<sup>d</sup>Statistically significant ( $P$  value < 0.05) compared with patients with other reasons for the visit belonging to the same group.

**Table 4 Frequency (%) of common and atypical naevi in individuals with family history of melanoma and in individuals without family history of melanoma**

Number of common naevi	Patients with family history of MMs	Patients without family history of MMs	Number of atypical naevi	Patients with family history of MMs	Patients without family history of MMs
	234 = 100%	4321 = 100%		219 = 100%	3977 = 100%
0	3.42	7.2	0	65.75	74.5
< 10	44	53.6	≤ 5	31.05 <sup>b</sup>	22.9
11–30	33.3 <sup>a</sup>	27.25	> 5	3.2 <sup>b</sup>	2.6
31–50	8.55 <sup>a</sup>	7.1			
> 50	10.68	4.85			

MM, malignant melanomas.

<sup>a</sup>Considering together patients with 11–30 and 31–50 common naevi, data are statistically significant ( $P$  value < 0.05) compared with patients without family history of MMs belonging to the same groups.

<sup>b</sup>Considering together patients with ≤ 5 and > 5 atypical naevi, data are statistically significant ( $P$  value < 0.05) compared with patients without family history of MMs belonging to the same groups.

## Data referred to selected patient groups

For further analysis, we examined five different groups from our SCD population: individuals from Northern Italy ( $n=3157$ ) and those from the Centre-South Italy ( $n=1845$ ), separately; patients who thought they had many naevi ( $n=2211$ ); who thought they had a suspicious lesion ( $n=514$ ) and with a family history of MM ( $n=249$ ).

Regarding the first two groups, patients from Northern Italy checked their naevi by self-examination in 39.6% of cases versus 32.6% registered in the southern population (Table 1).

With regard to the group of patients who thought they had many naevi, most of them showed, in fact, a number of common and atypical naevi higher than individuals who decided to be examined for other reasons (Table 3).

Half of the patients who thought they had a suspicious lesion had not been examined before. In these patients, indications for surgery were more frequent than in the whole SCD population. Performing dermoscopy in 42% of these cases, dermatologists selected 81 lesions for surgical removal (15.76%); only 28 of these lesions were excised and corresponded histopathologically to three MMs, four basal cell carcinomas, one squamous cell carcinoma, four naevi and other benign lesions. The majority of individuals attending the SCD for a suspicious lesion were female patients, and showed less than 10 common naevi and no atypical naevi; among this group, 3.89 and 2.92% had a family history of skin cancer and MM, respectively.



With regard to the patients with a family history of MM, they had a skin phototype distribution similar to that of screened patients that did not report such a family history. The frequency of MM in patients with a family history was higher, although not significantly, than in other patients. Finally, patients with a family history of MM had a greater number of common naevi and atypical naevi compared with patients without a family history of MM (Table 4).

## Discussion

In this study, we present the data referring to people attending SCD clinics distributed all over Italy during 2005–2007, to identify demographic and epidemiologic aspects helping us to better define the target population for MM prevention strategies. Evidence of this nationwide event, with the participation of 5002 patients screened in 38 different Italian departments – in university and hospital settings – and in private and public ambulances in 31 cities, were collected by means of a detailed questionnaire, which was used by each dermatologist participating in the study.

The prevailing reasons that induced individuals to undergo the SCD examination were a great number of naevi and the need to be reassured. Only 10% of patients came because of a suspicious lesion. Most participants were aware of the rules to identify a MM and of main risk factors for skin cancer, such as excessive exposure to ultraviolet radiation and exposure without protection and sunburn.

People attending the SCD had a median age of 48 years which was similar to the median age reported in the campaigns of Sweden, Greece and Switzerland, where the mean age was 53, 42 and 43 years, respectively (Stratigos et al., 2007; Bulliard et al., 2008; Paoli et al., 2009). The mean age of our study does not correspond to the age at which skin cancer has the highest prevalence (Pellacani et al., 2008), indicating that this way for screening recruitment does not reach the ideal target population. The optimal age at which Italian patients should attend screening is middle age and older men (age >50 years; Geller et al., 2002; Williams et al., 2006a). Our data confirm that women have a modest predominance compared with men in our screening campaign adhesion. Women were more prone to undergo skin screening, perhaps because they are more conscious of their own risk factors and are more likely to seek medical attention compared with men, as also found in previous studies in Greece, the USA and Australia (Koh et al., 1991; Engelberg et al., 1999; Stratigos et al., 2007). Reasons for lower attendance among men compared with women should be investigated because the incidence of MM is higher in men, and in particular older men (Williams et al., 2006a; Perth Department of Health a-z directory page on the Internet, 2004); in fact, recent data show that the occurrence of thick and fast-growing MMs is associated with the male sex and old age (Chamberlain et al., 2002). Therefore, this population subset should be more appropriately targeted by educational messages and screening efforts reaching people so far not available for a preventive examination in the doctor's office (Carli et al., 2003).

The majority of the participants had not been examined before by a physician and did not even perform the self-examination of the skin. This is clearly evident in the population of Southern Italy, where only 40% of screened patients performed self-examination of the skin; in contrast, in the North this practice was followed by 47% of participants. Moreover, attendance of the SCD was much higher in the North with respect to the South. Although 54% of the Italian population lives in the Centre-South Italy, only 36% of our screened individuals originated from this area. These observations suggest that, in countries where the healthcare system is organized at a regional level such as in Italy, screening campaigns should be focused to more effectively cover regions where the public healthcare organization is less efficacious. Although

historically the population in Southern Italy has a lower cancer risk with respect to the Centre and the North, in the last few decades, this epidemiological picture has disappeared; the incidence and mortality rates in these regions are reaching those of the North (Baili et al., 2007), and the distribution of MM has changed (Associazione Italiana Registri Tumori AIRTum: <http://www.registri-tumori.it>).

The prevalent phototypes of the participants were types II and III, comprising more than 85% of the screened population, with a frequency similar to the one observed in the 'Melanoma Monday' in Belgium (Vandaele et al., 2000) and the 'Euromelanoma Screening Day Campaign' in Greece (Stratigos et al., 2007). Of note, the percentage of SCD participants with phototype II (40%) is higher than the frequency generally observed in a Mediterranean population (Carli et al., 1997). Even if the skin phototype evaluation is subjective and the real phototype distribution in the SCD population may move away from these estimates, we can hypothesize that individuals with lighter skin believe they have a greater risk for MM and are more likely to attend screening campaigns. A number of naevi greater than 50 or the presence of at least one atypical naevus (both well-established risk factors for MM in the Italian population) (Carli et al., 1995; Giannotti and Carli, 2001) were found in 5.1 and 25.9% of patients examined, respectively. Thus, the overall examination outcome was that only a small percentage of the individuals examined were considered to be at high risk for MM. With regard to the selected patient groups, we can observe that between individuals who thought they had many naevi, the number of common and atypical naevi was higher than the number of naevi in patients who decided to be examined for other reasons.

We can also observe that in patients who attended because of a suspicious lesion, indications for surgery were more frequent than in the whole SCD population. From these observations, we can gather that, at least in some cases, patients are able to identify by themselves lesions that are really clinically suspicious, and this knowledge may be considered in the modalities for recruitment for a future screening campaign.

With regard to the individuals with a family history of MM, they had a skin phototype distribution similar to those without this history, but had a higher number of common and atypical naevi, well-established risk factors for MM in the Italians (Carli et al., 1995; Giannotti and Carli, 2001), with respect to the whole examined population. Moreover, in individuals with a family history for MM, malignant lesions were found with a higher frequency than in other patients.

The assessment of the efficacy of the information campaign on MM in our screening days is difficult to perform. It is impossible to know whether among our 5002 SCD participants or people who gained knowledge about this initiative, awareness about skin cancer has increased, and whether our efforts have contributed to a future reduction in mortality for MM. Indeed, we can presume that the prevention campaign has been an excellent publicity and a good opportunity for education on recognizing melanoma, has increased knowledge about the importance of skin self-examination, risk factors and the need for dermatological examination, and has spread the message that MM is a curable disease if detected and treated early. In contrast, the SCD screening was unable to find a significant number of MMs among lesions for which an indication for excision was given by dermatologists. Thus, a skin cancer screening campaign on a nonselected population identifies a number of malignant lesions by far lower than the number of malignancies found during ordinary examinations on at-risk patients with selected lesions (self-selected or identified by GPs or dermatologists) in a public healthcare centre. In the United States, a comprehensive review of the results of a similar annual free screening campaign reported a yield of one MM per 667 participants (Geller et al., 2003), whereas in Belgium, the reported yield was one MM per 110 participants (Vandaele et al., 2000). A report from the UK (Holme et al., 2001) gives a yield of one MM per 277

participants and concludes that rapid access to pigmented lesion clinics is a more cost-effective approach in its healthcare system (Mackie et al., 2009).

As already demonstrated with Pap smear test screening for cervical cancer and mammography screening for breast cancer, screening campaigns must be carried out on a selected population, which meets rigorous and proven risk criteria to maintain an appropriate cost-effectiveness. With regard to the Italian Euromelanoma Day Screening Campaign, economic studies have found men over 50 years of age to be the most cost-effective group to target for melanoma screening (Girgis et al., 1996; Freedberg et al., 1999; Williams et al., 2006a).

Future directions should include the coupling of screening examinations to the targeting of high-risk patients. A strategy of skin assessment together with dermoscopic evaluation in patients characterized by family history of MM, phototype I or II and many common and atypical naevi, old age and male sex, especially organized in areas with a lower socioeconomic status, could turn out to be more effective at seeking out MM at a lower cost than the last SCDs in Italy.

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### **Conflicts of interest**

There are no conflicts of interest.

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