Can primary prevention or selective screening for melanoma be more precisely targeted through general practice? A prospective study to validate a self administered risk score

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Abstract

Objectives: To establish whether a questionnaire incorporating MacKie's risk factor flow chart can identify patients at high risk for melanoma so that they can be targeted for primary and secondary prevention. To validate the risk score derived from the questionnaire and test the feasibility of self completion by comparing patients' self reported skin characteristics with a skin examination performed by an experienced general practitioner.

Design: Prospective questionnaire survey followed by a comparative study.

Setting: 16 randomly selected group practices in a health district in Cheshire, United Kingdom.

Subjects: Questionnaire survey—3105 consecutive patients aged 16 years and over attending for a primary care consultation; comparative study—a self selected subsample of 388 of the 3105 patients.

Main outcome measures: MacKie risk group for melanoma. Comparison of high risk skin characteristics reported by patients and those noted during a skin examination by a doctor (κ statistic).

Results: 4.3% of patients (87% women) were in the highest risk group and 4.4% (79% men) were in the second highest risk group, as defined by the MacKie score. Agreement between patients' self appraisal of skin characteristics and clinical skin examinations was reflected in κ values of 0.67 for freckles, 0.60 for moles, and 0.43 for atypical naevi.

Conclusion: This questionnaire helped to identify a group at high risk for melanoma. Furthermore, good agreement was found when the patient's risk scores were compared with results of the clinical skin examination. This risk score is potentially useful in targeting primary and secondary prevention of melanoma through general practice.

Introduction

Malignant melanoma is a comparatively rare but serious form of cancer. Although recent work shows that the incidence for women in Scotland has stabilised, previous figures showed that incidence and mortality for melanoma have increased in the United

Kingdom by more than 50% in the past decade. These may rise further as ozone depletion increases exposure to ultraviolet radiation, the main aetiological factor in skin cancer.¹⁻³

Melanoma has a disproportionate impact on young adults. Eighteen per cent of melanoma cases occur in people aged between 15 and 39 years, but only 4% of all malignant neoplasms are found in this group. In women aged 20-35 years, melanoma is the most common cancer after cervical cancer, and it is the sixth commonest cancer in men. Prevention and early detection are included in the Health of the Nation objectives.⁴ Since the most important prognostic factor is the thickness of the lesion, successful treatment of melanoma depends on early diagnosis and excision.^{5,6}

In Australia, where the incidence of melanoma is high, popular pressure for a screening programme exists. Population screening based on Wilson's criteria would be neither practicable nor cost effective in the United Kingdom.⁷ However, the argument for selective screening has been promoted in other countries.^{8,9} Where resources are limited, a cost effective and selective primary prevention strategy for melanoma is better than costly, poorly targeted secondary prevention.

Public education campaigns in Glasgow, Nottingham, Leicester, and Southampton led to an increase in the number of patients with thin "good prognosis" tumours when they were seen at pigmented lesion clinics.¹⁰⁻¹³ However, more people also presented with non-melanoma skin cancers, for which the benefit of early diagnosis is unknown. Furthermore, the workload of dermatologists and use of resources increased, and routine care of patients was disrupted.¹⁴ The benefits of these education campaigns have therefore to be weighed against the cost of extra procedures for benign lesions and the public anxiety they may engender.¹⁵

Primary and secondary prevention would be practicable if a small group with a high burden of disease could be identified. MacKie has described a promising but untested model to identify people at high risk.^{16,17} MacKie's risk factor flow chart, which incorporates four independent risk factors—freckling, more than 20 moles, presence of atypical naevi, and a history of episodes of severe sunburn—seems suitable for patients to complete themselves.

The need for prospective studies to evaluate MacKie's scoring system has been recognised in three recent review articles by Elwood, Johnson and colleagues, and Morris.^{15 18 19} Elwood points out that studies using various risk criteria have suggested that selecting about 7% of the population who have 35% of all melanomas (that is, an incidence five times that of the average population) is possible. Selective screening of a high risk group would be less costly than population screening as fewer subjects would have to be seen, but the rate of positive results would be higher and proportionately more lives would be saved.

This study aimed to determine the size of the group at high risk of melanoma. It also assessed whether a simple, self completion risk factor questionnaire could be given to establish risk level in a primary care setting and whether this information could help in targeting primary prevention or possibly selective screening.

Method

Risk score construction

We developed a questionnaire and tested it in a pilot study in four general practices. The questionnaire covered individual risk factors, knowledge, and behaviour as they relate to melanoma. This report concentrates on MacKie's four independent risk factors for melanoma—freckles, moles, atypical naevi, and a history of severe sunburn (box).

MacKie's risk factor flow chart was derived from weightings of independent risk factors found in cases and controls matched for age and sex. MacKie's paper gives an algorithm for calculating the risk score.¹⁶

Definitions

Moles were defined as "usually dark brown but occasionally flesh coloured; most often flat but sometimes raised above the surface of the skin; oval or circular, and from 2 mm (like a small bird seed) up to 1 cm or almost ½ inch in size." Atypical naevi were defined as "large moles with an irregular edge or irregular colour." The history of sunburn was obtained by asking "How many times in your life have you had bad sunburn (with peeling of your skin)—never, one or two times, or three or more times?" Questions were designed to be robust, no matter the season in which the questionnaire was completed.

Statistical considerations

We calculated that 2000 subjects would be needed to estimate the prevalence of the highest risk category (containing all four of MacKie's risk factors) at levels of 2% (95% confidence interval 0.05% to 0.5%) and 1% (0.6% to 1.5%). We also calculated that at least 200 subjects would be needed to compare the self report with skin examination by a doctor for the 95% confidence intervals to exclude 50% for sensitivity and 75% positive predictive value (Confidence Interval Analysis, BMJ Publishing group). The average weekly surgery attendance rate of patients aged 16 years and more was determined from six Cheshire group practices and allowance was made for 50% of patients to fail to complete the questionnaire. From these results we calculated that we would need to conduct the survey in 16 practices.

Survey methods

A prospective questionnaire survey was carried out in 16 of 18 group practices randomly selected from a total of 46 in the Crewe and Macclesfield Health Districts, Cheshire. Two practices declined to participate. The area covered by the practices (1544 km²) represents a cross section of urban and rural practices. The questionnaire study took place between September and November 1995, after the health centre staff involved had been briefed and instructed. In each participating practice, all patients aged 16 years and over who attended for a general practitioner consultation during a one week period were invited to complete a questionnaire by the reception staff. They could do this at the time or complete the questionnaire elsewhere and return it postage paid.

Validation exercise

A subsample of eight practices was selected for the validation exercise. These practices were chosen to represent variations in practice type (geography and size) and in the socioeconomic grouping of patients. All patients from these practices who completed the questionnaire (n=1521) were invited to leave their name and address so that they could "help further" with the study. The 834 who did so were invited to make an appointment to see one of the authors (AJ) at their own surgery. At this consultation they could comment on the questionnaire and have a simple skin examination in which the whole body surface, excluding the genital area, was appraised for freckles, moles, and atypical naevi. The number of moles was recorded as none, up to 20, and more than 20.

Statistics

All the questionnaire data were coded and analysed using SPSS software in the Division of General Practice in Cardiff. This information was subsequently collated with the findings from the follow up skin study. The sunburn history was taken at face value from the reply in the questionnaire. Comparison of the self report of skin freckles, moles, and atypical naevi (that is, the other three independent risk factors) and the skin examination was made using the κ statistic.

Ethical approval

Ethical approval for the study was given by the ethical committees of the Crewe and Macclesfield Health Districts.

Results

Altogether 4727 patients attending surgery at the 16 practices were invited to fill in the questionnaire.

Risk factors for scoring the risk of melanoma

Does your skin have freckles or tendency to freckling?	Yes ☐ , No ☐
Does your skin have moles?	None ☐ , ≤20 ☐ , >20 ☐
Does your skin have any large moles with irregular edge or colour?	Yes ☐ , No ☐ , Don't know ☐
How many times in your life have you had bad sunburn?	Never ☐ , 1 or 2 ☐ , 3 + ☐
MacKie's risk factor flow chart ¹⁶ was used to allocate scores of 1-4 for each respondent

Fig 1 Age and sex distributions of the 3105 patients who completed the questionnaire

Of these, 3105 completed it (66% response rate). Figure 1 shows the age and sex distributions of the respondents. The employment status of the sample was representative of the general population.²⁰

Risk factor prevalence

According to MacKie's risk factor flow chart 136 of the 3105 (4.4%) subjects were in the "very increased risk" group; 79% (107) of these were men and 21% (29) women. Altogether 134 (4.3%) people were in the "worryingly high risk" group, and here the proportions of men and women were almost reversed; 13% (17) were men and 87% (117) women (table 1). These two groups combined covered 8.7% of the total sample population. The questionnaire study showed that statistically significantly more women than men in our sample population had skin types 1 and 2, fair or red hair (relative risk factors), freckles, and more than 20 moles (table 2). This may help explain the differing proportions of men and women in the two highest risk groups.

MacKie's risk factor flow chart was used to calculate the median excess risks for melanoma in the combined high risk group. These were 60-90 times the base risk in men and 40 or more times the base risk in women. The median excess risk was 60 or more times base risk in the "worryingly high risk" group (4.3%) and the "very increased risk" group (4.4%).

Table 1 Derivation of the MacKie risk factor score and distribution of risk scores in the study population. Values are numbers (percentages)

Risk group	Risk score	Total (n=3105)	Men (n=896)	Women (n=1730)
Marginally increased risk	1	1529 (49.2)	613 (40.1)	916 (59.9)
Increased risk	2	827 (26.6)	159 (19.2)	668 (80.8)
Very increased risk	3*	136 (4.4)	107 (78.7)	29 (21.3)
Worryingly high risk	4*	134 (4.3)	17 (12.7)	117 (87.3)
Missing data		479 (15.4)		

*Groups 3 and 4 form a high risk group comprising 8.7% of the total sample.

Table 2 Risk factors in the sample population and in men compared with women. Values are numbers (percentages)

Risk factor	No answering questions	Risk factor present		P value
		Men	Women	
Skin type 1 and 2	2912	433/998 (43.4)	1091/1914 (57.0)	<0.0001
Fair or red hair colour	2963	292/1005 (29.1)	623/1958 (31.8)	<0.0001
Freckles present	2944	304/997 (30.5)	989/1947 (50.8)	<0.0001
20 or more moles	2944	77/996 (7.7)	270/1948 (13.9)	<0.0001
Atypical naevi present	2947	124/1001 (12.4)	226/1946 (11.6)	0.250
One or more episodes of sunburn	2981	753/1008 (74.7)	1427/1973 (72.3)	0.162

Validation exercise

Altogether 834 of the 1521 (55%) patients who completed questionnaires in the eight practices offered to "help further" with the study, and of these 388 (46%) attended for a skin examination. The self reported skin characteristics of the 388 patients were compared with their clinical examination results and the κ values (where 1.0 = perfect agreement) were 0.67 (95% confidence interval 0.59% to 0.73%) for freckles—good agreement; 0.60 (0.51% to 0.67%) for moles—moderate to good agreement; and 0.43 (0.43% to 0.54%) for atypical naevi—moderate agreement.

Discussion

Full population screening programmes for malignant melanoma are unlikely in the United Kingdom because the incidence is moderate and NHS resources are limited. We did not set out to assess the predictive value of the risk score, because this would have demanded a prohibitively large prospective study.¹⁹ However, we believed that by identifying a high risk group, a more selective approach to prevention of melanoma in primary care might be developed that would be more cost effective in time, resources, and outcome. It might also cause less anxiety among the population than expensive, high profile public education campaigns and the occasional provision of special pigmented lesion clinics. If people were able to determine their own risk score, the targeting of such a high risk group would be feasible.

Studies in which mole counts on different parts of the body have been used to identify people at risk from melanoma have shown disparate conclusions.²⁰⁻²¹ The MacKie model, however, uses four independent risk factors which we considered could be appraised easily by patients. This combination of factors is more likely to give a true value of the number of people at increased risk. Several workers have recommended regular skin examination of people at high risk of melanoma.^{9,21} Our questionnaire study showed that 8.7% of the respondents were at "high risk," and a good measure of agreement existed with the results of the skin examination for the three, physically recordable high risk factors—freckles, moles, and atypical naevi. The MacKie risk factor flow chart showed that this combined high risk group had a median excess risk for melanoma of 60-90 times base risk in men and 40 or more times base risk in women.

Targeting the high risk group

Should the 4.3% of patients in the "worryingly high risk" group (with a median excess risk of 60 or more times base risk) be the only ones targeted for primary prevention? These findings show that such a restriction would result in a mainly female target group (table 1). The reasons for this are evident from table 2, which shows that significantly more women than men had high risk skin characteristics. This suggests that the 4.4% of subjects in the "very increased risk" group (also with a median excess risk of 60 or more times base risk) should be included in the target group.

How should this high risk group be targeted? General practitioners vary in their dermatological interests, training, and expertise, and this needs to be considered. Selective screening would mean that each

practice would have to have either a general practitioner trained in dermatology or a dermatological nurse practitioner. Several researchers have emphasised the roles of both doctors and nurses in primary and secondary prevention of melanoma.^{9 23-25} A dermatological nurse practitioner (who could supervise one large group practice or several smaller practices) would have to be trained by and have regular contact with the local dermatology department, either directly or through an interested, trained general practitioner.

With this structure in place, all patients aged 16 years and over on a practice list could complete and return a questionnaire. Defaulters could be prompted by follow up letters or telephone calls. The high risk patients identified could be invited to attend for a skin examination by the nurse or doctor. Any patient with a suspicious looking lesion could then be referred (if necessary by a "fast track" facility) to the dermatology department at the local hospital for an opinion and treatment as appropriate (secondary prevention). These high risk people would all be advised about limiting their exposure to the sun (primary prevention), instructed about the major and minor clinical signs of suspected malignant melanoma, and encouraged to check their skin regularly and to seek early medical advice about moles that change in appearance. Practice patients with malignant melanomas who present spontaneously would also have to be incorporated into the system and managed appropriately. In addition, the close relatives of patients with malignant melanoma could be examined, given advice, and offered surveillance.

In a practice population of 10 000, about 700 patients would be invited to attend for skin examination and advice. The initial screening could be carried out over say a 12-18 month period. Once a total practice population had been covered, patients

Key messages

- Successful treatment of melanoma depends on its early diagnosis and excision
- The MacKie risk factors score flow chart was used to identify a group of patients at high risk of melanoma from a sample of general practice patients who had completed a questionnaire
- A good measure of agreement was achieved when self appraisal of high risk skin characteristics by patients was compared with a clinical skin examination
- A self report risk score is a feasible means of identifying high risk patients and targeting prevention of melanoma

reaching the age of 16 years and new patients of 16 years and over, would be asked to complete the skin questionnaire, and those who failed to do so would have to be followed up. Any patients requiring surveillance would need to be seen at appropriate intervals.

Various models of service provision could be developed to use a risk score for primary and secondary prevention of melanoma. The current situation, however, is clearly inefficient. Fig 2 shows the differences between the present provision of high profile campaigns and pigmented lesion clinics with the service that could be provided by targeting a high risk group in a primary care clinic. It shows the possible implications in terms of increased staffing, clinical activity, and the costs of each approach. This exercise, organised on a national scale, could achieve a full selective screening programme for melanoma in the United Kingdom.

Conclusion

We are confident that this method of identifying a group at high risk for melanoma can be used in other practices in the United Kingdom and that it would facilitate selective screening, preventive advice, surveillance, and secondary referral measures where appropriate. Although primary prevention is effective, the setting up of pigmented lesion clinics on a national basis would be uneconomic in the United Kingdom. A more rational approach is required, and these results support the targeting of primary and secondary prevention on an identifiable high risk group in general practice.

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Fig 2 Melanoma prevention: the current situation and proposals for targeting a high risk group in general practice showing differences in public education and clinical activities and costs

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Commentary: Start with the KISS principle

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The article by Jackson et al asks the question whether a self reported questionnaire can enable selective screening or primary prevention of melanoma to be more precisely targeted towards groups at risk and thereby enhanced. To answer these questions it is important to define the issues and to deal with aspects of primary prevention and secondary prevention (or selective screening) separately.

Primary prevention

Primary prevention strategies attempt to reduce or limit exposure to carcinogens so as to prevent or slow down cancer.¹ The criteria for effective primary prevention consist of recognisable risk factors, modifiable risk factors, and a demonstrated need for a primary prevention campaign.

In the case of melanoma there are constitutional risk factors about which little can be done, such as skin type, response to sunlight, and the tendency to freckle and develop moles on exposure to sunlight. Exposure to sunlight, however, particularly in large episodic doses during childhood, is a behavioural component that is amenable to change. The success that the sun smart campaign in Australia has had in modifying the attitudes and behaviour of young Australians confirms this.²

Whether or not this change is worth while in the United Kingdom will depend on the incidence and impact of melanoma in the community. The designation of prevention of skin cancer as a Health of the Nation objective shows that such activities are perceived as worth while. The consequences of such change include a shift in cultural norms, and there is a risk of discouraging children from otherwise healthy outdoor summer sporting activities such as cricket and swimming.

The potential benefits of such a primary prevention campaign on diseases other than melanoma also needs to be considered. These benefits include reduction in non-melanoma skin cancer and premalignant keratoses, which currently place a considerable burden on

the NHS, and reduced photoageing and wrinkling of the skin.

The suggestion that primary prevention programmes could be enhanced by targeting high risk groups requires careful consideration and further validation. In the Australian experience, the necessary increased complexity required to convey a message to a target group tended to diminish the message. Care would need to be taken to ensure that advice to "stay out of the midday sun" and "slip on a shirt, slap on a hat, and slop on some sunscreen—especially if you have a lot of moles, freckles, atypical moles, or previous sunburns" is not interpreted by those not belonging to this target group as carte blanche to go unprotected into the midday sun. This is important, as the designated target group excludes at least 10% of people at risk of melanoma and an even greater percentage of people at risk for non-melanoma skin cancer.

Secondary prevention

Secondary prevention strategies attempt to detect cancer or its precursors while its capacity for metastasis is low and it can still be cured by local treatment. Secondary prevention tactics include educating people to recognise warning signs and to seek early medical attention, case finding, and population based screening programmes which aim to identify previously undetected melanomas.³

One strategy for early diagnosis involves educating the public to recognise suspicious signs and see the doctor early and educating primary care practitioners and specialists to appropriate lesions for biopsy. Mackie has shown that recognition of melanoma can be improved and that this leads to an increase in the number of patients presenting with thin melanoma.⁴

An additional strategy involves case finding, where primary care physicians are asked to routinely examine patients' skin for melanoma when they present for unrelated matters. Currently more than a fifth of melanomas are first detected by a doctor, before the

patient has noticed anything wrong, and such a strategy has the potential to increase that number.

Population screening

A third method of secondary prevention is population screening (box). Screening for melanoma involves an examination of the entire skin surface (excluding the genital area) and takes 5-10 minutes. The cost is of the consultation fee for the physician. It is free of major discomfort and side effects but is inconvenient.

Potential problems with population based screening for melanoma are that the sensitivity and specificity have not been quantified and the cost is substantial. Population-wide screening is not recommended by the International Union Against Cancer and is not being advocated in Australia, mainly because the performance and validity of the test procedure is unknown.

Screening of self selected people at high risk, as advocated by Jackson et al, has considerable appeal, but before the current protocol is accepted more information is required on several aspects. The value of the test procedure is not known, and in particular general practitioners' ability to detect melanoma has not been measured. If nurses were to do the examination, their expertise would require validation. Some general practitioners have difficulty doing skin examinations, and some well trained nurses could be expected to have similar difficulties.

Secondly, more information is needed on the cost of the procedure. The Jackson protocol involves inviting the entire British population to fill in a questionnaire, contacting the 30 or so million who fail to respond, and then examining 8.7% of those in the high risk groups—

Effective population based screening

Criteria:

- Safe and effective
- Acceptable to the general public
- Highly sensitive and specific
- Reasonably priced

Risks:

- Unnecessary intervention
- Increased anxiety
- False reassurance
- Increased workload with consequent disruption to routine services

5-6 million people. The cost would be substantial and should to be compared with the potential savings that would be achieved by early detection of melanoma.

It is also not known whether advice to "watch your moles for change in size, shape, or colour if you have lots of moles, freckles, atypical moles, or previous sunburns" does not inadvertently tell people that they need not watch moles for change in size, shape or colour if they don't have "lots of moles, freckles, atypical moles, or previous sunburns."

Until these issues are resolved, public education programmes would be wise follow the Australian model and adopt the KISS principle: keep it simple, stupid.

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Taking equity seriously: a dilemma for government from allocating resources to primary care groups

Gwyn Bevan

General practitioner fundholding seemed to threaten equity of access to health care in the NHS in two ways: fundholders' patients have been treated more quickly than patients from non-fundholding practices in the same authority,^{1,3} and there are suspicions that fundholders have been funded more generously than have health authorities, who supply funds to non-fundholders.^{3,6} The new Labour government has now announced its intention of abolishing fundholding and has introduced policies that are intended to remedy both types of inequity.^{2,7,8} Because of endemic variations in medical practice, however, this is not possible—leaving the government on the horns of a dilemma over which type of equity it intends to achieve. It will have to choose either common waiting times or an equitable allocation of resources, and these choices have quite different policy implications.

The equity dilemma

The NHS was created with the objective of reducing inequity,^{9,10} but this raises questions over which type of

Summary points

GP fundholding is criticised for having introduced two types of inequity into the NHS

Fundholders' patients have been treated more quickly and may have been funded more generously than patients from non-fundholding GPs

New government policies are intended to introduce common waiting times and equitable funding for patients from all types of practices

Variations in medical practice preclude achieving both common waiting times and equitable funding across general practice populations

The government will have to choose which type of equity is to have priority for its new primary care groups

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