Aid to diagnosis of melanoma in primary medical care

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Abstract

Objective—To evaluate an intervention designed to reduce the number of benign melanocytic lesions excised from the skin.

Design—A randomised controlled field trial based in the medical practices of two cities. Examination of histopathological reports of 5823 melanocytic skin lesions excised over the intervention period and in the preceding six months

Intervention—Medical practitioners were offered an algorithm and use of an instant developing camera.

Setting and subjects—Over 50 medical practitioners, mostly in general practice, in each of two cities in tropical Queensland, Australia.

Main outcome measures—Percentages of benign (neither malignant nor potentially malignant) melanocytic lesions excised during the two year intervention period.

Results—There were no significant differences in the percentages of benign lesions reported in the intervention and control cities before the intervention started (93.6% and 94.0%, respectively), but there was a significant difference afterwards (88.8% and 93.8%, $P < 0.001$). There was no difference in the percentage of invasive melanomas excised per month in the intervention city (3.4%) compared with control city (3.4%).

Conclusion—Clinical diagnostic accuracy may be enhanced by offering to clinicians managing suspicious melanocytic skin lesions a simple algorithm and a camera with which to record the appearance of lesions objectively.

Introduction

Although several new techniques for helping in the diagnosis of cutaneous melanoma are being developed—for example, epiluminescence microscopy¹ and computer image analysis²—visual inspection is still the essential part of the diagnosis. Diagnosis is difficult because early melanomas share many of the clinical characteristics of other pigmented skin lesions, especially melanocytic naevi, which are much more common.³⁻⁵ Evidence from New Zealand suggests that 4% of the white population annually consult a primary care physician about a melanocytic lesion for assessment of malignancy; around 20% of these consultations result in excision of the skin lesion.⁶ Excision rates of melanocytic lesions are high in Australia^{7,8} and result in substantial annual health costs—only 1% of melanocytic lesions excised from the under 40 age group are malignant.⁸ While there are several possible reasons for removing benign skin lesions, including problems with discomfort and unsightliness, it is thought that most are removed to exclude malignancy as in New Zealand. These patterns of consultation and excision are likely to reflect those in similar white populations in the United States and Europe.

When a patient presents with a pigmented skin lesion the outcome may be straightforward because the lesion is manifestly benign, and simple reassurance of the patient is all that is required or the lesion may be suspicious enough to justify its surgical removal to exclude malignancy. The similar clinical appearance of benign naevi and early melanomas, however, means

that it is often impossible to exclude malignancy at one visit.⁹ In these instances, recommended management is to record the appearance of the lesion and review it after an interval of time to determine if any of the changes associated with malignancy have occurred.¹⁰ Behaviour of a pigmented lesion over time is believed to be more important than its immediate appearance at time of presentation.¹¹

Given the critical importance of the documentation of suspicious change in a pigmented lesion on the one hand and the extremely high excision rates of benign lesions we have observed locally⁸ on the other, we explored the possibility of decreasing the number of false positive diagnoses without increasing the number of false negatives. To that end we designed a randomised controlled field trial to investigate whether providing a structured diagnostic approach would help in the differential diagnosis of melanoma. An essential component of this was an objective means of recording change in clinical appearance of a suspicious lesion. We hypothesised that providing primary care doctors with a simple diagnostic algorithm and a camera would lead to a reduction in the proportion of benign melanocytic lesions (mostly naevi) excised without reducing the rate of invasive melanomas and potentially invasive melanocytic lesions excised.

Methods

Two provincial cities in central Queensland were selected for the trial on the basis of their similarity: both are relatively isolated tropical cities near the coast with populations of around 55 000 and 65 000 people working in industries with substantial agricultural and tourist components. The cities are sufficiently far apart that an intervention in one city was unlikely to affect clinical behaviour in the other. The city to receive the active intervention was chosen at random. Each city is served by about 50 general practitioners with additional junior hospital doctors who also are involved to a limited extent in primary care. At the outset we visited each doctor who practised within a 15 km radius of the central post office in both cities and whose practice included the management of skin cancer as a primary responsibility to explain their possible role in the study and invite them to participate. Thus, as well as general practitioners and junior hospital doctors we visited surgeons and dermatologists, asking them to give permission for a copy of the histology report of every melanocytic skin lesion they excised over the next two years to be sent to us by the pathology services concerned. In addition, reports from the previous six months were collected as a baseline and to check that excision rates of benign and malignant melanocytic lesions were comparable between the two cities.

For each melanocytic skin lesion that was excised the relevant doctor received a questionnaire asking about reasons for excision; the level of pressure (if any) exerted by the patient to have the lesion removed; and who (if anyone) referred the patient. If the patient had been referred another questionnaire was sent to the referring doctor. Doctors in the city randomised to receive the intervention were offered a protocol to assist in the management of any melanocytic lesion for which a diagnosis of malignancy was entertained. The protocol consisted of an algorithm (figure 1) which was

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Algorithm for clinical management of patients with suspicious naevi

a modified and simplified summary of "best clinical practice,"¹⁰ and incorporated the discretionary use of a camera. This was a Polaroid instant developing camera and came attached to a plastic enclosure which fixed the lens distance from the skin, thus requiring no adjustment by the user for either focus or the flash exposure. One camera was left in each participating practice and hospital after a demonstration of its use. One minute after a lesion was photographed a lifesize colour print was available to be filed with the patient's notes as an objective record of the lesion's clinical characteristics. It was made clear that the responsibility for managing pigmented skin lesions lay with each doctor and that the protocol and camera were offered only as an aid to diagnosis and management.

We pilot tested the protocol including the method of collecting histology reports with eight general practitioners and three different pathology services in a separate city and showed it to be acceptable and feasible. At the end of the study a self administered questionnaire to evaluate the use of the camera was posted to all the doctors in the intervention city who were still living there.

TABLE 1—Comparison of characteristics of patients* having lesions excised at baseline and after intervention, between and within cities. Figures are numbers (percentages) unless otherwise stated

Detail	At baseline		P value	After intervention		P value
	Control city	Intervention city		Control city	Intervention city	
Total No of lesions excised	752	606		2468	1997	
Sex:						
Male	326 (44)	277 (46)	0.396	1013 (42)	897 (45)	<0.05
Female	425 (56)	329 (54)		1426 (58)	1091 (55)	
Age (years):						
<20	206 (28)	166 (27)		637 (26)	461 (23)	
20-29	197 (26)	173 (29)	0.680	694 (29)	510 (26)	<0.001
30-39	162 (22)	117 (19)		538 (22)	454 (23)	
≥40	182 (24)	149 (25)		551 (23)	549 (28)	
Median age (years) (range)	28 (0-94)	27 (7-93)	0.956	28 (1-87)	30 (2-90)	<0.05
Site of lesion:						
Head and neck	170 (24)	132 (22)		518 (22)	418 (21)	
Trunk	375 (52)	349 (59)		1315 (56)	1043 (53)	
Arms	76 (11)	47 (8)	0.187	240 (10)	231 (12)	0.318
Legs	89 (12)	63 (11)		270 (11)	241 (12)	
Buttocks	5 (1)	4 (1)		28 (1)	21 (1)	

*Those for whom data were missing were excluded.

We assumed that every melanocytic lesion excised by local practitioners in the study was submitted for histological examination, as in Queensland with its high annual incidence of melanoma¹² this is standard medical practice. On the basis of the histology reports we classified excised melanocytic skin lesions as invasive melanoma (level II and above), potentially malignant (either premalignant—that is, in situ melanoma and lentigo maligna—or atypical or dysplastic naevi, whose presence may have clinical importance for future surveillance of a patient for melanoma), or benign—that is, halo, compound, dermal, intradermal, Spitz, balloon cell, blue, junctional, combined, or unclassifiable types of naevi, and lentigenes.

We obtained consent from all 53 medical practitioners approached (45 general practitioners, seven surgeons, and one dermatologist) in the control community and 52 out of 55 medical practitioners (48 out of 51 general practitioners and all four surgeons) in the intervention community. Over the two year intervention period nine new treating doctors entered and two left the control community, and seven new doctors entered and five left the intervention community. All new incoming doctors agreed to take part except for one general practitioner in the intervention city. The populations in each city had undergone similar growth (under 2% in each city between the census years of 1986 and 1991). Pathology laboratories supplied aggregate data on the melanocytic lesions excised by the medical practitioners who did not participate. There were no changes in reporting procedures of the pathology laboratories during the period of the trial.

All data analysis was performed before the code identifying the city was broken. Comparisons were made between the cities at baseline and between and within cities after intervention with respect to age, sex, classification of lesion, and anatomical site grouped as head and neck, trunk, arms, legs, and buttocks. Differences in proportions were analysed univariately by the χ^2 test and in median age and thickness of melanoma by the Wilcoxon two sample test. Estimates of the magnitude of the intervention effect were finally adjusted for the potential confounding effects of sex, age, and site of the lesion by using multivariate logistic regression analysis. Differences between cities with respect to changes from baseline to after intervention were examined by fitting an interaction term to these multivariate models.

Results

COMPARISON AT BASELINE

In the six months before the introduction of the intervention a total of 1358 melanocytic lesions were reported by the pathology laboratories: 752 (55%) from the control community and 606 (45%) from the intervention community (table I). The distributions of excised cutaneous melanocytic lesions by sex and age of patients and site were similar for both cities. Although the percentage of lesions that were non-invasive melanomas was lower in the control city than in the intervention city (96.1% v 98.2%; $P < 0.05$), there was no difference by city in the proportion of benign lesions—that is, lesions that were neither invasive nor potentially malignant ($P = 0.73$; table II). The median thickness of the melanomas excised in both cities was similar ($P = 0.34$). Similarly the median numbers (2.5% and 97.5% percentiles) of excisions per doctor were similar at 8 (1, 46) and 7 (1, 38) for the intervention and control cities, respectively.

COMPARISON AFTER INTERVENTION

During the 24 months after the intervention was introduced a total of 4465 lesions were excised and

TABLE II—Comparison of characteristics of excised melanocytic lesions* at baseline and after intervention between and within cities

Detail	At baseline		P value	After intervention			
	No (%) for control city	No (%) for intervention city		Control city		Intervention city	
				No (%)	Average†	No (%)	Average‡
Total No of lesions excised	752	606		2468	617	1997	499
Diagnosis:							
Benign naevus	666 (89)	537 (89)		2210 (90)		1621 (81)	
Lentigo	39 (5)	23 (4)		101 (4)		145 (7)	
Dysplastic naevus	10 (1)	18 (3)		27 (1)		83 (4)	
Hutchinson's melanotic freckle	3 (0)	6 (1)	0.012	13 (1)		27 (1)	
Melanoma	32 (4)	15 (2)		113 (5)		114 (6)	
Other	2 (< 1)	7 (1)		4 (< 1)		7 (< 1)	
Total No of potentially malignant lesions‡	45	39	0.731	153	47	224	68
Total melanomas:							
Level I	3	4		30	8	30	8
Levels II+	28	11	0.133	82	26	82	26
Unknown level	1	0		1	—	2	—
Percentage of lesions that were non-invasive (95% confidence interval)	96.1% (94.8% to 97.5%)	98.2% (97.1% to 99.2%)	0.027	96.6% (95.9% to 97.3%)		95.8% (94.9% to 96.7%)	
Percentage of lesions that were neither invasive nor potentially malignant‡§ (95% confidence interval)	94.0% (92.3% to 95.7%)	93.6% (91.6% to 95.5%)	0.731	93.8% (92.8% to 94.8%)		88.8% (87.4% to 90.2%)	
Median (range) thickness of melanoma (mm)	0.40 (0.10-4.20)	0.60 (0.10-14.0)	0.344	0.60 (0.20-11.00)		0.50 (0.10-13.0)	

*Lesions for which there were missing data for particular variable excluded.

†Six monthly average for direct comparison of counts with baseline phase (expected values calculated based on baseline total).

‡Potentially malignant lesions include melanomas, Hutchinson's melanotic freckle, and dysplastic naevi.

§Percentage of total number of excised lesions.

TABLE III—Reason given for excision of lesions and perceived pressure from patient on excising physician. Data for period after intervention. Figures are numbers (percentages)

Detail	Control city	Intervention city	P value for difference between cities
Reason for excision given by excising doctor:			
To exclude malignancy	1871 (78)	1241 (72)	<0.0001
Discomfort	237 (10)	247 (14)	
Cosmetic	188 (8)	157 (9)	
Other	110 (5)	72 (4)	
Patient pressure to excise perceived by excising doctor†:			
1	532 (22)	399 (24)	0.88*
2	426 (18)	311 (19)	
3	655 (27)	391 (23)	
4	474 (20)	299 (18)	
5	314 (13)	275 (16)	

*Test for trend.

†On a five point scale in which 1=no pressure from patient and 5=excision fully due to pressure from patient.

TABLE IV—Responses of 64 doctors to questions about perceived accuracy of photographs in recording characteristics of pigmented skin lesions

Detail	No (%) of clinicians recording satisfaction
Characteristic:	
Size	51 (85)
Overall colour	27 (45)
Colour variation	30 (51)
Characteristics of edge	46 (78)
Surface features	19 (33)
Overall usefulness:	
In documenting changes	45 (76)
With more accurate follow up	44 (76)
In reassuring patients	52 (90)
In reducing unnecessary excisions	31 (52)

reported in the two study cities, of which 1995 (45%) were excised in the intervention city, the same proportion as at baseline (table I). Junior hospital medical staff submitted only a small proportion (3.2%) of the lesions. Compared with the number of lesions excised during the six month period before intervention the number of lesions excised six monthly (on average) in both cities decreased by 242 (135 (18%) in the control city; 107 (18%) in the intervention city) after the intervention was introduced. The percentage of excised lesions that were neither malignant nor potentially malignant, however, fell from 93.6% at baseline to 88.8% in the intervention city (table II), a difference of 4.8% (95% confidence interval 2.4% to 7.2%). This difference between cities in the changes from baseline to after intervention (adjusted for patient's sex, age, and site of lesion) was highly significant ($P < 0.001$). The percentage of benign lesions excised during the baseline period (94.0%) in the control city changed only slightly (to 93.8%) after the intervention. Over the same period the percentage of melanomas excised in the intervention city rose from 2.5% to 5.7% while in the control city they remained essentially constant (4.3% baseline and 4.6% after intervention) with little difference between experience in the first and second year.

In contrast with the similar sex and age distributions in both cities at baseline, lesions were excised from proportionately more male patients in the intervention community ($P = 0.017$), and the ages of patients were now significantly higher in the intervention community than in the control community ($P = 0.0004$; table I). The median number (2.5% and 97.5% percentiles) of excisions per doctor differed at 4 (1, 30) and 9 (1, 39) for the intervention and control cities,

respectively. The distributions of sites of the excised lesions, however, remained similar for both cities ($P = 0.318$).

Significantly fewer doctors in the intervention community than in the control community offered exclusion of malignancy as the reason for excision ($P < 0.0001$; table III). Also they perceived significantly less pressure from patients to excise melanocytic lesions than doctors in the control community ($P < 0.005$), although similar proportions of lesions were excised as a direct result of pressure from patients.

USE OF CAMERA AND ACCEPTABILITY OF INTERVENTION

All but two of the doctors (62 out of 64 who initially agreed to participate) in the intervention city reported using the camera in their practice. The modal frequency of use was once every week. Two doctors indicated that they used the camera infrequently (one lost the camera after a year; and the other used the camera for other than managing naevi). The camera was kept in a treatment room by 37 doctors, and in another room outside their own consulting room by 24. Difficulties were apparently few; 52 (84%) doctors experienced none; six had some difficulties loading new film; four complained about the quality of the pictures. Fifty three stored the photograph with the patient's main clinical record; six used a secondary patient file; and three used a special storage file for photographs. Fifty doctors (81%) usually photographed only one lesion per patient. Most did not provide patients with pictures of their own lesions routinely, although six did so at least occasionally. Thirty six doctors thought that patients attended for follow up. Photographs were reported as being more helpful in recording changes in characteristics of size and outline than in recording colour and surface features (table IV). Responses to overall usefulness indicated that most doctors found the cameras worth while for objectively documenting changes or achieving more accurate follow up of lesions and useful for reassuring patients. Thirty one doctors (60% who answered) thought that they had reduced the incidence of unnecessary excisions as a result of using the camera.

Discussion

We found that offering doctors a diagnostic algorithm and providing them with a camera seemed to reduce the relative proportion of benign naevi they removed especially from women and young patients, in

whom relative rates of excisions of benign pigmented lesions are known to be high.⁸ The effectiveness of the intervention protocol was shown by the differences in changes in the excision patterns between the intervention city and the control city. Neither the proportion nor the absolute number of melanomas decreased; rather they doubled in the intervention city relative to the control city even though there was a decrease in the background incidence of excisions seen in both cities. That is, the rate of false positive diagnoses seems to have been reduced, and there was no indication that the rate of false negative diagnoses had risen. Our conclusions regarding the importance of the changes after the intervention must be tentative, however, given the sample size of one city in each arm. Ideally several cities would have been randomised to each arm of the trial, but logistic and financial considerations constrained the size of the present study.

The simple algorithm provided a structured approach to the management of pigmented lesions. With the algorithm clinicians could systematically sort those which were obviously benign and did not require excision; those whose excision was clearly indicated on the basis of clinical appearance or the patient's history; and those lesions for which the diagnosis of melanoma could not be definitely excluded. For the latter lesions a doctor can elect to follow up the patient rather than excise the lesion immediately because detectable change in its appearance over a relatively short period increases the probability that it is a malignant melanoma.¹¹ We provided a camera as an aid to increasing the certainty that a change in appearance of the lesion in doubt had occurred, hypothesising that diagnostic specificity would be increased if the clinician had an accurate and objective record of the appearance of the pigmented lesion on initial presentation. A Polaroid photograph attached to a patient's records thus provided a valid baseline against which to compare the clinical appearance of the pigmented lesion on follow up.

Other aids to improving the differential diagnosis of melanoma do not entail monitoring the change in appearance of suspicious pigmented lesions. Techniques such as computer image analysis² and epiluminescence microscopy¹³ rely on the clinical appearance of a suspicious pigmented lesion at the time of initial presentation. The aim of computer image analysis is to refine the physician's assessment of critical diagnostic features of early melanoma—namely, area, colour variegation, regularity of outline—whereas epiluminescence microscopy attempts to grade the patterns of epidermal and dermal pigmentary structures not visible to the naked eye. Appropriate computer hardware and software are required for the former technique and considerable skill to interpret the pigmentary patterns observed is required for the latter. Such

diagnostic adjuncts cannot be absorbed simply into clinical practice, unlike a Polaroid camera which requires no special training to use proficiently. Moreover, the camera is relatively cheap and within reach of most clinicians.

It is difficult to speculate what cost-benefits might accrue from the widespread use of these adjuncts to diagnosis, and they would be greater the higher the prevalence of pigmented lesions in the community. In the present study the total number of lesions saved from excision was about four (out of eight) for each general practitioner a year or about 200 lesions annually in a community served by 50 general practitioners. The cost of operations entails not only the price of the surgical excision (about \$A50-100) but also the cost of the histology (about double the cost of excisions), the cost of visits for care of wounds, and, in a proportion of patients, the additional costs of any complications such as infection that may occur after operations. Other costs to patients, such as the discomfort and unsightliness of surgical scars, are also a consideration. Against these must be weighed the costs of more follow up visits (of those not incorporated into other forms of episodic care) at about \$A25 each visit, the camera itself (about the cost of a good stethoscope), and the film (about \$A2 per photograph).

Information on acceptability and perceived usefulness of the intervention protocol obtained from the doctors in the intervention city indicated that the camera was a feasible addition to the normal apparatus of a medical practice. Most doctors were satisfied that the photographs helped not only by improving accuracy of follow up but also in reassuring patients.

Despite the large variation in clinical circumstances surrounding the diagnosis of pigmented skin lesions, careful photographic follow up of suspicious lesions about whose malignant state a clinician harbours genuine doubt seems to be an immediately accessible and effective adjunct to clinical diagnosis. Furthermore, if further research confirmed that this strategy helps to decrease the high incidence of excision of benign pigmented lesions⁸ its cost effectiveness would be substantial, especially among white populations whose background incidence of melanoma is high.

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Key messages

- Early cutaneous melanoma may be indistinguishable from banal melanocytic naevi
- To avoid missing a diagnosis of melanoma many benign pigmented skin lesions are excised
- Unless obviously malignant initially a lesion for which malignancy cannot be excluded may be watched if its size and appearance can be accurately recorded so that any change is detected with follow up
- An instant camera and a simple algorithm may reduce false positive excisions without increasing false negative diagnoses in populations susceptible to malignant melanoma
- Use of an instant camera and an algorithm is relatively easy to incorporate into usual clinical practice

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