Diagnostic accuracy in skin cancer clinics: the Australian experience

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Abstract

Background Australia, with the world's highest incidence of skin cancer, has witnessed the emergence of "open access" skin cancer clinics during the past decade. These clinics are becoming increasingly popular destinations for the diagnosis and treatment of skin cancers, yet little is known about the diagnostic performance of practitioners in this setting. We sought to measure the accuracy of clinical diagnosis in this setting.

Methods Clinical and histological data were obtained from 199 consecutive patients undergoing biopsy or excision for 287 skin lesions. We measured the sensitivity, specificity and predictive value of the clinical diagnoses compared with histological diagnoses.

Results Of 287 biopsied or excised lesions, the most common were benign nevi (24%) and basal cell carcinomas (22%), followed by actinic keratoses (11%), dysplastic nevi (11%) and squamous cell carcinomas (7%). Sensitivity was highest for diagnosing BCC (0.89, 95%CI 0.78–0.95) and dysplastic nevi (0.80, 95%CI 0.61–0.93), and lowest for actinic keratoses and the group of benign lesions. Specificity was greater than 0.93 for all diagnoses except BCC (0.76, 95%CI 0.70–0.81). Treating clinicians perceived moderate to strong pressure to excise 49% of lesions overall, but in particular for benign nevi (73%).

Conclusions Australian family practitioners in open access skin cancer clinics diagnose a wide range of skin lesions with high specificity and moderate to high sensitivity. Benign nevi are accurately diagnosed and often excised because of patient pressure.

Introduction

Cancers of the skin are the most commonly occurring malignancies in fair-skinned populations, associated with substantial costs for their diagnosis and treatment.¹ The American Cancer Society estimated that in 1996, more than 800 000 new cases of squamous cell carcinoma (SCC) and basal cell carcinoma (BCC) were diagnosed in the US population.² More than 45,000 Americans are diagnosed with melanoma each year.³ The highest rates for cancers of the skin are observed in Australia, where over 420,000 histologically confirmed skin cancers (BCC, SCC, melanomas and others) are excised each year in a population of only 20 million. The costs of diagnosing and treating nonmelanoma skin cancer account for 12% of Australia's annual expenditure for cancer, more than is spent treating any other cancer in that population.⁴

The burden of skin cancer in fair-skinned populations poses a challenge to health planners seeking to devise the most efficient system for preventing mortality and reducing morbidity. Under Australia's medical system, almost all patients with skin cancer initially consult a family practitioner, with referral to

surgeons or dermatologists typically reserved for difficult diagnoses or specialized treatment.⁵ A new development during the past decade has been the establishment of "open access" clinics, staffed by family practitioners providing consultations solely for diagnosing and treating skin cancers and suspicious skin lesions.

While skin cancer screening clinics have been available to the public in the US,⁶ Canada,⁷ and Italy,⁸ they differ from the emerging Australian experience in that those clinics have been organized by professional medical societies or cancer advocacy organizations, usually for a limited duration, and have been staffed by dermatologists. The new variety of skin cancer clinics in Australia are privately owned medical practices staffed by family practitioners offering ongoing clinical follow up and referral to dermatological care.

Because such clinics may offer a model for skin cancer management in other countries with a moderate to high incidence of skin cancer, we undertook a preliminary study to determine the diagnostic performance of the practitioners in that setting, specifically with respect to lesions undergoing biopsy or surgical excision.

Methods

Setting

We collected data from all patients undergoing excision, biopsy or curettage of a skin lesion during a 6-week period in March and April, 2003 at a busy skin cancer clinic in Queensland, Australia. We included all lesions sent for histological confirmation in this study, comprising 287 lesions from 199 patients. Of these, 163 (57%) were shave biopsy specimens, 110 (39%) were excisional biopsies, 11 (4%) were punch biopsies and three (1%) were curettage specimens.

Data collection

Before biopsy or excision, the clinical details of each skin lesion were recorded on a case report form. A provisional clinical diagnosis was recorded for each lesion, and the practitioner recorded their degree of certainty for the diagnosis on a visual analog scale ranging from 0% to 100%. Three general descriptors were placed immediately below the scale, describing ranges of certainty for the clinical diagnosis ["low (0–39%)", "moderate (40–79%) and "high (80–100%)"]. The forms also included an item to score the degree of patient pressure to excise the skin tumor perceived by the treating clinician, rated on an ordinal scale from 1 (no patient pressure) to 5 (strong patient pressure).⁹

Data cleaning and analysis

The mix of skin lesions biopsied or excised during this study generated 49 clinical diagnoses and 51 histopathological diagnoses. Each diagnosis was assigned to one of eight broad categories for analysis: (1) melanoma; (2) SCC; (3) BCC; (4) actinic keratosis; (5) dysplastic nevus; (6) benign nevus; (7) other benign pigmented lesion (such as ephelides, lentigines and seborrheic keratoses); and (8) other benign lesion (such as cysts and dermatofibromas). For specimens incurring multiple histological diagnoses, a diagnosis of malignancy took precedence over diagnoses of precursors or benign lesions.

Statistical analysis

We used SPSS for Windows (SPSS Inc., Chicago, IL, USA) to first examine the frequency distributions of the clinical diagnoses. Analysis was necessarily restricted to those skin lesions for which there was both a clinical and histological diagnosis, as lesions diagnosed clinically with no surgical management were not included in this study. We calculated indices of diagnostic accuracy for each of the eight categories of skin lesions separately using the accepted approach.^{10,11} Thus for SCCs, we defined "true positives" as those lesions for which the clinical diagnosis of SCC was confirmed by the histological diagnosis, whereas "false positives" were those lesions clinically diagnosed as SCC, but not confirmed by histology. "False negatives" were lesions that the clinician had diagnosed as being other than SCC, but that were histologically confirmed as being SCC. "True negatives" were lesions which were clinically diagnosed and histologically confirmed as not being

SCC. Using these values, we calculated the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) according to standard formulae.¹² We cross-tabulated the clinical diagnoses against the histological diagnoses (the "gold standard" for this study) to calculate the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) according to standard formulae.¹² Exact 95% confidence intervals for each of these measures were calculated in EpiInfo 6.0 (CDC, Atlanta, GA).

Approval to undertake the study was obtained from the Human Research Ethics Committees of the Queensland Institute of Medical Research and University of Queensland.

Results

During the 6-week ascertainment period, 287 lesions were excised at an average of almost 24 excisions per week per practitioner. Of these excised lesions, benign nevi and BCCs were the most common, representing 24% and 22% of all lesions, respectively (Table 1). Actinic keratoses and dysplastic nevi each accounted for approximately 11% of all lesions undergoing biopsy or excision, while non-nevus pigmented lesions and SCCs comprised 8% and 7% of lesions, respectively. The remaining skin samples were from other benign lesions (18%) and one melanoma. Taken together, keratinocytic lesions (BCC, SCC and actinic keratoses) were significantly more common among men, whereas melanocytic lesions (benign and dysplastic nevi) were more common among women ($P = 0.02$).

Sensitivity and specificity of clinical diagnosis

Practitioners made a clinical diagnosis of BCC (38%) more frequently than any other lesion type, followed by dysplastic nevi (15%) and benign nevi (15%). Overall, 57% (95%CI 51–63%) of clinical diagnoses precisely matched the histological diagnosis (Table 2).

Excluding melanoma, for which only one confirmed case occurred, sensitivity was highest for BCC and dysplastic nevi (Table 3). Greater than 80% of these lesions were correctly diagnosed by family practitioners. SCCs were diagnosed with less sensitivity; however, all but one of the histologically confirmed SCCs ($n = 19$) were clinically diagnosed as a skin cancer (BCC or SCC). Grouping BCCs and SCCs together as "keratinocyte cancers" yielded a sensitivity of 0.94 (95%CI 0.86–0.98). The specificity of clinical diagnosis was greater than 0.90 for all categories of lesions except for BCC (0.76, 95%CI 0.70–0.81).

Predictive value of clinical diagnosis

Overall, clinical diagnoses for benign lesions were more likely to be confirmed by histology than were clinical diagnoses for dysplastic and malignant lesions (Table 2). Ninety-three per cent (95%CI 81–99%) of lesions diagnosed as benign nevi

Table 1 Clinical vs. histological diagnosis of 287 excised skin lesions

Clinical diagnosis	Histological diagnosis								Totals
	Melanoma	Dysplastic nevus	Benign nevus	SCC	BCC	Actinic keratosis	Other pigmented lesion	Other non-pigmented lesion	
Melanoma	1	5	3	0	1	0	2	1	13
Dysplastic nevus	0	24	16	0	1	0	2	0	43
Benign nevus	0	1	40	0	0	0	0	2	43
SCC	0	0	0	8	3	9	2	5	27
BCC	0	0	8	10	55	16	4	15	108
Actinic keratosis	0	0	0	0	0	3	0	1	4
Other pigmented lesion	0	0	2	1	2	3	13	8	29
Other nonpigmented lesion	0	0	0	0	0	0	1	19	20
Total	1	30	69	19	62	31	24	51	287

Table 2 Diagnostic accuracy of clinical diagnoses for 287 skin lesions compared with histology

Clinical diagnosis	Sensitivity	95%CI*	Specificity	95%CI	PPV†	95%CI	NPV‡	95%CI
Melanoma	1.00	0.03–1.00	0.96	0.93–0.98	0.08	0.00–0.37	1.00	0.99–1.00
Dysplastic nevus	0.80	0.61–0.93	0.93	0.89–0.95	0.56	0.40–0.71	0.98	0.95–0.99
Benign nevus	0.58	0.45–0.70	0.99	0.96–1.00	0.93	0.81–0.99	0.88	0.83–0.92
SCC	0.42	0.20–0.66	0.93	0.89–0.96	0.30	0.14–0.50	0.96	0.93–0.98
BCC	0.89	0.78–0.95	0.76	0.70–0.81	0.51	0.41–0.61	0.96	0.92–0.98
Actinic keratosis	0.10	0.02–0.26	1.00	0.98–1.00	0.75	0.19–0.99	0.90	0.86–0.93
Other pigmented lesions	0.54	0.33–0.74	0.94	0.90–0.96	0.45	0.26–0.64	0.96	0.92–0.98
Other nonpigmented lesions	0.37	0.24–0.52	1.00	0.98–1.00	0.95	0.75–1.00	0.88	0.84–0.92

*95% confidence interval; †positive predictive value; ‡negative predictive value.

Table 3 Indication for surgical intervention, by histologic grouping

Histological grouping	Total	Indication for biopsy or excision*			
		Exclude malignancy	Discomfort	Cosmesis	Other
Melanoma	1	1 (100%)	0	0	0
Dysplastic nevus	30	30 (100%)	0	0	0
Benign nevus	69	40 (58%)	14 (20%)	17 (25%)	0
SCC	18	18 (100%)	1 (6%)	0	0
BCC	62	62 (100%)	2 (3%)	0	0
Actinic keratosis	31	29 (94%)	3 (10%)	0	0
Other pigmented lesion	24	18 (75%)	3 (13%)	2 (8%)	0
Other nonpigmented lesion	51	34 (67%)	16 (31%)	2 (4%)	1 (2%)
Total	285	232 (81%)	39 (14%)	21 (7%)	1 (0%)

*Practitioners were permitted to assign more than one reason for undertaking a biopsy or excision.

and 95% (95%CI 75–100%) of lesions diagnosed as “other benign lesions” were confirmed by histology. A clinical diagnosis of dysplastic nevus was confirmed by histology more than half of the time; the remainder of lesions diagnosed clinically as “dysplastic nevi” were typically benign nevi.

Positive predictive values for SCC and BCC were 0.30 and 0.51, respectively, owing largely to the considerable overlap

in diagnoses for these keratinocytic tumors. Of 13 suspected melanomas, one was confirmed by histology, five were histologically confirmed as dysplastic nevi, and one was a BCC.

We re-analyzed these data after stratifying the lesions according to the degree of diagnostic certainty recorded by practitioners when making their clinical diagnosis. Across the spectrum of skin lesions, those diagnosed by the clinicians with

a high level of certainty (52%) were associated with higher diagnostic sensitivity and specificity than those diagnosed with medium and low levels of certainty (48%) (not shown).

Indication and patient pressure to excise a skin lesion

Treating clinicians recorded their reason for biopsy or excision on the case report form before surgery for 285 (99%) of the 287 eligible lesions (Table 3). All malignant skin tumors (melanoma, SCC, BCC) had been biopsied or excised to exclude malignancy. Similarly, all of the dysplastic nevi had undergone surgical management to exclude malignancy.

Clinicians perceived no pressure to treat 146 (51%) lesions, whereas moderate pressure was perceived for 103 (36%) lesions, and strong patient pressure to excise was perceived for 36 (13%) lesions. Practitioners reported pressure to excise benign nevi (73%), dysplastic nevi (57%) and other benign lesions (52%) more often than other types of lesions. Benign nevi were often excised for reasons of discomfort (20%) and cosmesis (25%). Lesions excised from female patients were more commonly associated with perceived pressure (57%) than lesions from male patients (41%). This sex difference was attributable to the fact that females were more likely than males to request excision of melanocytic lesions, and these lesions were more common among females.

Discussion

Recent emergence of open access clinics dedicated to diagnosing and treating skin cancer heralds a change in the way these conditions are being managed in Australia, yet very little is known about the performance characteristics of practitioners working in this setting. We undertook a prospective study to measure the diagnostic performance of family practitioners in this setting.

Skin lesions most commonly undergoing excision or biopsy were BCCs and common acquired nevi, together accounting for almost half of all specimens. Actinic keratoses, dysplastic nevi and SCCs together comprised almost one third of lesions. The remaining lesions were pigmented and nonpigmented lesions of various histological types.

We have no reason to believe that the clinic reviewed here differed from other skin cancer clinics in terms of patient population and lesion frequency. Like other Australian clinics of this type, the practice was "open access" in that patients did not require a referral to see a doctor, and patients incurred no out-of-pocket expenses as all charges were billed directly to the universal health insurance scheme. Moreover, reports from traditional Australian family practice settings broadly agree with the proportional distribution of lesions observed here;^{13,14} however, the absolute number of skin lesions excised by family practitioners in the setting of an open access skin cancer clinic was considerably higher than figures reported in traditional family practice settings. A prospective survey

in north Queensland (an area of very high SCC and BCC incidence¹⁵) found that greater than 60% of family practitioners excised skin lesions less often than once per week, and less than 10% of practitioners excised five or more skin lesions each week,¹⁴ compared with the 24 excisions per week observed for family practitioners in this study.

The family practitioners in this study achieved comparable diagnostic accuracy to those reported in other population-based studies for dermatologists and surgeons for diagnosing BCC and SCC.^{11,16} Positive predictive values were very high for benign nevi and other benign lesions, but were lower for dysplastic and malignant lesions. These data suggest that family practitioners were usually able to correctly diagnose benign lesions, but tended to err towards a diagnosis of cancer when confronted with suspicious lesions.¹⁷

As for previous studies that have measured the accuracy of clinical diagnosis of skin cancer against the "gold standard" histological diagnosis,^{10,11} we were unable to measure the accuracy of the treating practitioners for diagnosing skin lesions that they decided not to biopsy or excise. Potentially, this is an important limitation, and could introduce error if, for example, a proportion of clinically diagnosed "benign lesions" were, in fact, cancers. While certainly possible, we have grounds for believing that the impact of such a bias is likely to be very small in this setting. First, this study obtained measures of diagnostic accuracy for all excised lesions, benign as well as malignant. We therefore know that the positive predictive value for diagnosing benign lesions (such as nevi and actinic keratoses) was very high, and was indeed considerably higher than for malignant lesions. This indicates that the clinicians were able to accurately diagnose benign lesions. Second, we also measured each practitioner's certainty at the time of clinical diagnosis for every lesion. We found that objective measures of diagnostic accuracy were uniformly higher for lesions that practitioners were more certain about. In other words, when practitioners were confident in their diagnosis, then their diagnosis was more likely to be confirmed by histology.

Given these findings, we consider it extremely unlikely that the positive predictive values for benign lesions not biopsied (i.e. those for which the practitioner was very confident were not malignant) would be lower than the positive predictive value for benign lesions that were biopsied (i.e. those for which the practitioner could not exclude a diagnosis of malignancy). Of course, this inference cannot be proven without biopsying every skin lesion on every patient, especially those lesions that the practitioner is certain are benign; however, such a proposition is ethically unacceptable. Nevertheless, it is our view that the measures of diagnostic accuracy reported here are likely to be underestimates of the "true" diagnostic accuracy with respect to the clinically important question of diagnosing cancer.

Studying only one center does limit the generalizability of our findings somewhat; however, this must be balanced

against the absence of published data in this newly emerging area of medical practice. We contend that these first data provide a basis for future comparisons and may also offer a stimulus for further research. Given the burden of skin cancer in the Australian community, it is likely that increasing numbers of open access clinics will offer exclusive services in the area of skin cancer diagnosis and management. Despite concerns about the ability of nondermatologists to accurately diagnose skin cancers,³ our data suggest that family practitioners in the setting of a specialized skin cancer clinic are able to perform this role with moderate-to-high levels of sensitivity. Whether skin cancer can be managed most effectively through open access clinics remains the focus of further research.

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