STUDY

Diagnostic Accuracy of Patients in Performing Skin Self-examination and the Impact of Photography

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Objective: To determine the sensitivity and specificity of skin self-examination (SSE) to detect new and changing moles with and without the aid of baseline digital photographs in patients with dysplastic nevi.

Design and Intervention: Patients had baseline digital photography and mole counts of their back, chest, and abdomen and were instructed to perform a baseline SSE. Print copies of the images were provided to the patient. Following the baseline examination, the appearance of existing moles was altered and new moles were created using cosmetic eyeliner. The number of moles altered and/or created totaled approximately 10% of each patients' absolute mole count.

Setting and Patients: Fifty patients with 5 or more dysplastic nevi from the outpatient clinic at Memorial Sloan-Kettering Cancer Center, New York, NY.

Main Outcome Measure: Skin self-examinations with and without access to the baseline photographs to identify the number of new and altered moles.

Results: The sensitivity and specificity of SSE for detection of both altered and new moles without photography were 60.2% and 96.2%, respectively. Skin self-examination with photography yielded a sensitivity and specificity of 72.4% and 98.4%, respectively. The findings were similar when stratified by site (back vs chest or abdomen). The sensitivity and specificity for new moles were higher compared with altered moles.

Conclusions: Access to baseline photography improved the diagnostic accuracy of SSE on the back and chest or abdomen and improved detection of changing and new moles. Our results suggest that baseline digital photography in tandem with SSE may be effective in improving the diagnostic accuracy of patients performing SSE.

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LESION THICKNESS (BRESLOW depth) has been identified as the most important prognostic factor for primary cutaneous melanoma, with survival inversely related to lesion thickness.[1-4] There is a direct relationship between survival of patients with melanoma and early detection. The 5-year survival rate for patients with melanoma smaller than 1 mm thick is 94% compared with 50% for melanomas larger than 3 mm thick.[5] This finding suggests that the identification and excision of thin lesions may be important in reducing mortality from melanoma.

The American Academy of Dermatology has recommended that individuals practice skin self-examination (SSE) to detect new and/or changing lesions.[6] Self-screening is important because self-detection by patients, spouses, and families is the most common way skin cancer is currently detected, even though SSE may not be performed routinely or thoroughly.[7-9] Results suggest that SSE is associated with a reduced risk of melanoma, and it is a moderately effective tool for detecting changes in mole size.[10-12]

During the past decades, atypical nevi (dysplastic nevi) have been identified as the strongest indicators of melanoma risk.[13-18] The presence of large numbers of clinically atypical nevi hinders self-examination and professional evaluation. Because the wholesale excision of these lesions is impractical, the present standard of care for individuals with dysplastic nevi is close observation and excision of changing lesions.[19-21] In individuals with large numbers of moles and/or dysplastic nevi, attempts to recognize new or changing lesions are aided by comparison of the clinical examination to pictures of the individual's skin at an earlier point in time.[19,22-24] Providing patients with photographs offers a baseline measure and may encourage the patient to carefully watch lesions.[25] It has been suggested that

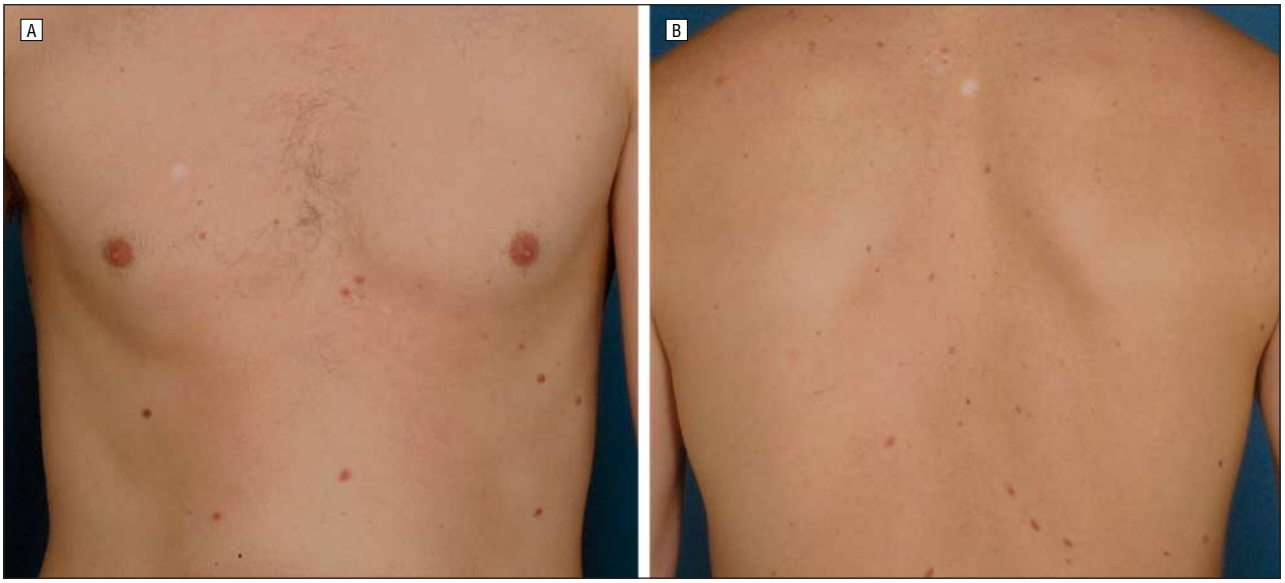

Figure 1. Body areas for digital photography and mole counts.

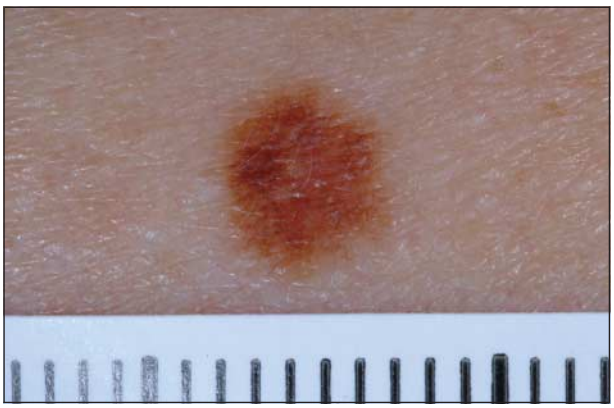

Figure 2. Unaltered mole.

patients may be able to better detect changes in their lesions if they have an opportunity to repeatedly view the original lesion with photographs.[26] In addition, through the application of computerized image analysis, digital imaging may offer an opportunity to identify new lesions or changes in lesions earlier and more accurately than standard photographically assisted follow-up.

The purpose of this study was to determine the sensitivity and specificity of SSE to detect new and changing moles in patients with dysplastic nevi. New and changing moles were artificially created with the use of cosmetic makeup. We also assessed the impact of making personal baseline digital photographs available to these patients at the time of SSE on diagnostic accuracy (ie, sensitivity and specificity).

METHODS

STUDY PARTICIPANTS

The study was conducted in the outpatient setting of the Pigmented Lesion Clinic of the Dermatology Service at Memorial Sloan-Kettering Cancer Center (New York, NY). Fifty patients 18 years or older with 5 or more clinical dysplastic nevi who were willing to have digital whole-body photography were recruited and informed consent obtained. Patients who were visually or physically impaired were not eligible for the study.

CONDUCT OF THE STUDY AND DATA COLLECTION

Baseline Examination

Information was obtained from each participant at baseline using an in-person interview conducted and recorded by a research fellow (D.C.). Specifically, information was collected on age, sex, race/ethnicity, hair color at the age of 18 years, eye color, skin tone, tendency to burn, ability to tan, self-reported mole count, personal and family history of skin cancer, and SSE practices. As part of the baseline data collection, patients were asked to perform SSE with the aid of a full-length (35×127 cm) and hand-held mirror (16×19 cm). Patients who wore corrective glasses were instructed to wear them while performing their SSE. Digital photography and mole counts of the chest, abdomen, and back were performed on each patient by a research fellow (**Figure 1**).[22] Print copies of the images were provided to the patient.

Procedures to Create and Alter Moles

This was an intervention study design whereby patients received the intervention (alteration or creation of moles) and served as their own comparison group. Following the baseline examination, the appearance of existing moles was altered and new moles were created using cosmetic eyeliner that was water soluble and nontoxic. Four different color shades of eyeliner were available, and the shade closest in color to the patient's typical nevi was used to minimize any color discrimination by the patient. Each patient had approximately 10% of their moles altered and/or created on their back and chest or abdomen. To alter the size and shape of moles, a template was used to convert existing 5-mm moles to slightly more irregularly shaped 7-mm moles. To assess the ability of patients to identify focal changes in the color of moles, a 2-mm, dark brown mark was made in the confines of existing 5-mm moles. A template was used to create new 4-mm moles (**Figures 2**, **3**, **4**, and **5**). Blindfolding of patients and sham drawing on multiple sites were used to ensure that the patients were unaware of the location of cosmetically altered

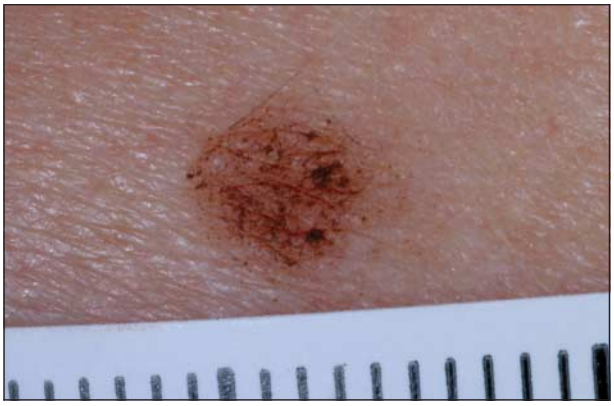

Figure 3. New 4-mm mole.

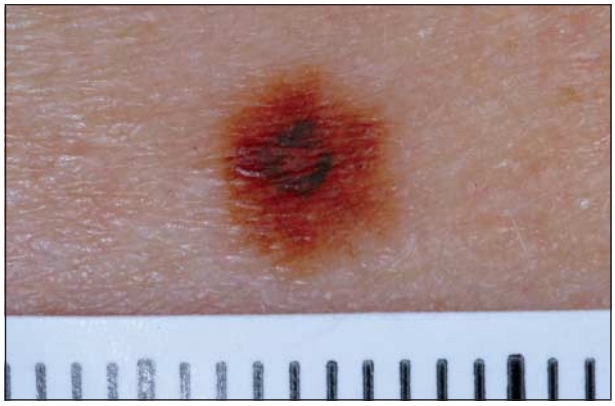

Figure 4. A 2-mm, dark brown mark within the existing 5-mm mole.

moles and to preclude tactile recall of the sites of the altered and created moles.

Patient Assessment of New and Altered Moles

Patients had the blindfolds removed and were then asked to perform SSE (with full-length and hand-held mirror) first without the aid of baseline digital photographs and subsequently with access to their personal photographs. The research fellow recorded the number and types (new vs altered mole) of changes correctly and incorrectly identified by the patient.

Statistical Analysis

Descriptive statistics were used to characterize the study population. Sensitivity, specificity, κ statistic, 95% confidence intervals, and *P* values derived from the κ statistic are presented. Using the mole as the unit of analysis, the sensitivity and specificity of SSE to detect new and changing moles were calculated for SSE with and without the aid of baseline digital photographs. The reference standard was the lesion count and recorded number of moles changed and/or created.

The κ statistic was used to evaluate the diagnostic accuracy (sensitivity and specificity) of each SSE modality (eg, with and without baseline photography). In this context, κ is a weighted statistic that expresses the desirable properties of the test (eg, low probability of false results). The comparison of the κ statistic between each SSE modality and the resultant *P* value are based on an approach for the comparison of 2 diagnostic tests, each evaluated against the same gold standard (eg, actual number of moles physically altered and/or created) in the same study sample.[27] The positive predictive values (PPVs) and negative predictive value (NPVs) of SSE, with and without the aid of baseline digital photography, were also calculated using the Bayes theorem.[28]

The diagnostic accuracy of SSE can be affected by numerous factors. Stratified analyses were performed by age, sex, history of melanoma, melanoma risk factors, and SSE practices. We explored the potential effects on SSE accuracy of mole location (back vs chest or abdomen), type of mole detected (newly created moles vs altered existing moles), and total number of moles altered and/or created on the patient (dichotomized at median; ≤5 moles altered or created vs >5 moles altered or created) by conducting stratified analyses.

RESULTS

The participation rate for this study was 93% (50/54). Characteristics of the 50 patients who were recruited and completed the study are presented in **Table 1**. There was

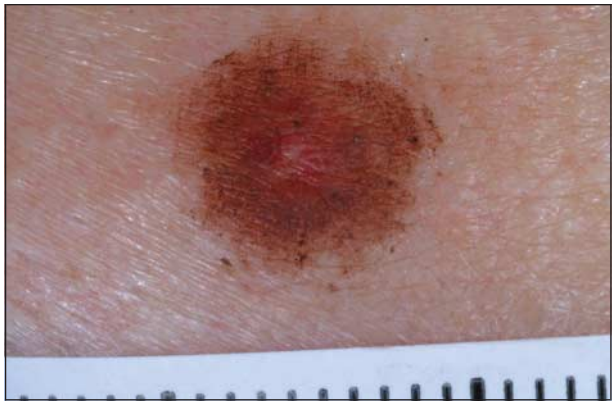

Figure 5. A 5-mm mole changed to an irregularly shaped, 7-mm mole.

a total of 3167 moles (median, 50; mean, 63) that contributed to the analyses; 108 moles were altered and 211 new moles were created. The number of altered or created moles per patient ranged from 2 to 27 based on the criteria of altering 10% of each patients' moles. Fifty-two percent of the patients had 5 or fewer moles altered or created, and 48% of the patients had more than 5 moles altered or created. The sensitivity and specificity of SSE for detection of both new and altered moles without photography were 60.2% and 96.2%, respectively, whereas SSE with photography yielded a sensitivity and specificity of 72.4% and 98.4%, respectively (**Table 2**).

Sex differences were apparent, with men performing better than women without the aid of photographs (**Table 3**). However, women had a higher sensitivity and specificity of SSE with the use of photographs compared with men. Results showed that patients with more than 5 moles altered or created had significant improvements in diagnostic accuracy with the aid of baseline photographs, although patients with 5 or fewer moles altered or created still gained some benefit from access to photography (**Table 4**). The stratified analyses suggested that patients with fairer complexions (eg, light skin, eye, and hair color, tendency to burn, and ability to tan) had higher sensitivities both with (76.6%, 82.8%, 79.8%, 76.0%, and 78.7%, respectively) and without (59.9%, 70.5%, 67.5%, 60.5%, and 61.9%, respectively) the aid of photographs compared with patients who did not have these risk factors (with photography: 62.9%, 66.0%, 68.3%, 54.7%, and 66.5%, respectively; without photog-

Table 1. Patient Characteristics

Characteristic	Patients, No. (%) (N = 50)*
Sex	
Male	20 (40)
Female	30 (60)
Age, y	
≤30	13 (26)
31-40	18 (36)
41-50	12 (24)
≥51	3 (6)
White race	50 (100)
Tendency to burn	
Easily or some	43 (86)
Rarely or never	7 (14)
Tendency to tan	
Deep or moderate	25 (50)
Mild or none	25 (50)
Eye color	
Blue or green	20 (40)
Hazel or brown	30 (60)
Hair color at age 18 y	
Blond or red	20 (40)
Brunette or black	30 (60)
Skin tone	
Very fair or fair	35 (70)
Medium or dark	15 (30)
Personal history of melanoma	
Yes	22 (44)
No	28 (56)
Family history of melanoma	
Yes	14 (28)
No	25 (50)
Family history of basal cell carcinoma	
Yes	18 (36)
No	21 (42)
Family history of squamous cell carcinoma	
Yes	4 (8)
No	29 (58)
No. of skin self-examinations in last 4 mo	
0	17 (34)
1-4	33 (66)
No. of moles altered and/or created for study protocol	
≤5 (range, 2-5; mean, 4; median, 4)	26 (52)
>5 (range, 6-27; mean, 9; median, 7)	24 (48)

*Some percentages do not total 100% because of missing responses.

raphy: 60.8%, 53.8%, 56.1%, 58.4%, and 58.5%, respectively). There were no similar trends in the analyses stratified by family history of skin cancer or SSE practices. However, patients with a personal history of melanoma had higher sensitivities both with (80.0%) and without (65.8%) the aid of photography compared with patients with no such personal history (with photography: 67.8%; without photography: 56.8%).

We calculated the PPV and NPV for SSE with and without the aid of baseline photography. The stratified estimates for PPV and NPV for SSE with photography ranged from 70% to 90% and 97% to 99%, respectively. For SSE without the aid of baseline photography, the stratified estimates for PPV and NPV for SSE ranged from 54% to 67% and 96% to 98%, respectively. However, these estimates are highly dependent on the prior selected prevalence of altered or created moles and should therefore be interpreted with caution. The PPV and NPV results could differ in a population with a different prevalence of new and changing moles; in our study, we fixed the prevalence at 10%, since we created the new and changing moles.

COMMENT

This pilot study determined the sensitivity and specificity of SSE to detect new and changing moles in patients with dysplastic nevi and also assessed the impact of making personal baseline digital photographs available to these patients at the time of initial self-examination. The sensitivity of SSE to detect both new and altered moles was 60.2% without photography and increased substantially to 72.4% with the aid of digital photographs. The results suggest that patients had high specificity (few false-positive results) both with and without access to photographs. The specificity was 96.2% without photographs and increased slightly to 98.4% with the aid of photographs.

Berwick et al[10] reported that SSE is associated with a reduced risk of melanoma, with the potential for a 63% reduction in mortality. A prospective study of the effectiveness of SSE is needed; however, the logistic constraints in conducting such a study are obvious. In a preliminary study by Muhn et al,[11] the efficacy of SSE to detect changes in mole size has been investigated in high-risk patients.[11] The specificity of SSE was 62% and the sensitivities of detecting 2-mm and 4-mm changes were 58% and 75%, respectively. In a recent study by Dawid et al,[12] the ability of patients to identify real changes in melanocytic nevi was evaluated in 251 patients with 1431 melanocytic nevi. The sensitivity to detect enlarging nevi was low (10.9%), whereas the specificity was 99.2%. In a study by Edmondson et al,[25] the effect of instant photography as a method for screening melanoma during routine health examinations was assessed. Copies of the prints were given to patients for observation of any changes in the lesions of interest. Although the objective was not to study the effect of providing photographs to patients, the results showed that the possession of a photograph by the patient led to a diagnosis of melanoma in 2 instances.

Although the ultimate end point of interest in a screening study of this type would be melanoma, we defined new lesions and lesion change as intermediate outcomes because we believe these are the most important and relevant for self-directed prescreening and early detection. Limitations of the study are that SSE was not formally taught to the patients and the study was not restricted to patients who could adequately perform SSE. Patients who are taught SSE may receive more benefit. We only assessed the diagnostic accuracy of SSE performed on the back and chest or abdomen, and the results may not be generalizable to different sites on the body. Also, there can be other subtle changes related to margins, thickness, and texture that are not captured with this simplistic approach of creating new moles and altering existing moles using cosmetic eyeliner.

The design of the intervention for this study differs from the intervention design that would be observed in routine follow-up examination because the study popu-

Table 2. Sensitivity and Specificity of Skin Self-examination for Identification of Altered (A) and New (N) Moles

Mole Category*	Without Photography, % (95% CI)		With Photography, % (95% CI)		*P* Value†
	Sensitivity	Specificity	Sensitivity	Specificity	
All A/N moles	60.2 (54.6-65.6)	96.2 (95.4-96.8)	72.4 (67.1-77.2)	98.4 (97.9-98.8)	<.001
Back A/N moles	57.5 (50.3-64.4)	97.0 (96.1-97.7)	68.5 (61.5-74.8)	98.3 (97.6-98.8)	<.001
Chest or abdomen A/N moles	64.7 (55.4-73.1)	94.8 (93.3-96.0)	79.0 (70.4-85.7)	98.5 (97.6-99.1)	<.001
All new moles	63.0 (56.1-69.5)	97.8 (97.3-98.3)	75.8 (69.4-81.3)	99.4 (99.1-99.6)	<.001
All altered moles	54.6 (44.8-64.1)	98.3 (97.8-98.7)	65.7 (55.9-74.4)	99.0 (98.6-99.3)	<.001
Moles altered in size‡	56.0 (41.4-69.7)	. . .	74.0 (59.4-84.9)	. . .	.01
Moles altered in color‡	53.4 (40.0-66.5)	. . .	58.6 (45.0-71.1)	. . .	.58

Abbreviation: CI, confidence interval.
*N = 50 patients. All A/N moles, n = 319; back A/N moles, n = 200; chest or abdomen A/N moles, n = 119; new moles, n = 211; all altered moles, n = 108; moles altered in size, n = 50; moles altered in color, n = 58; all unaltered moles, n = 3059; back unaltered moles, n = 1922; and chest or abdomen unaltered moles, n = 1137.
†*P* value for paired comparison of skin self-examination diagnostic accuracy with and without the aid of baseline photography.
‡Patients were not asked if an identified altered mole was specifically altered with respect to size or color. As a result, the specificity of moles altered in size or color could not be calculated.

Table 3. Sensitivity of Skin Self-examination for Identification of Altered (A) and New (N) Moles According to Sex

Mole Category*	Men (n = 20)			Women (n = 30)		
	Sensitivity, % (95% CI)			Sensitivity, % (95% CI)		
	Without Photography	With Photography	*P* Value†	Without Photography	With Photography	*P* Value†
All A/N moles	63.8 (55.4-71.4)	67.8 (59.6-75.1)	.01	57.1 (49.3-64.5)	76.5 (69.2-82.5)	<.001
Back A/N moles	61.3 (50.6-71.1)	65.6 (54.9-74.9)	.32	54.2 (44.3-63.8)	71.0 (61.3-79.2)	<.001
Chest or abdomen A/N moles	67.9 (53.9-79.4)	71.4 (57.6-82.3)	.001	61.9 (48.8-73.6)	85.7 (74.1-92.9)	<.001
All new moles	67.8 (57.0-77.0)	68.9 (58.1-78.0)	.09	59.5 (50.2-68.2)	81.0 (72.6-87.3)	<.001
All altered moles	57.6 (44.1-70.2)	66.1 (52.5-77.6)	.04	51.0 (36.5-65.4)	65.3 (50.3-77.9)	.002
Moles altered in size	64.3 (44.1-80.7)	82.1 (62.4-93.2)	.13	45.5 (25.1-67.3)	63.6 (40.8-82.0)	.13
Moles altered in color	51.6 (33.4-69.4)	51.6 (33.4-69.4)	>.99	55.6 (35.6-74.0)	66.7 (46.0-82.8)	.38

Abbreviation: CI, confidence interval.
*Men: all A/N moles, n = 149; back A/N moles, n = 93; chest or abdomen A/N moles, n = 56; all new moles, n = 90; all altered moles, n = 59; moles altered in size, n = 28; and moles altered in color, n = 31. Women: all A/N moles, n = 170; back A/N moles, n = 107; chest or abdomen A/N moles, n = 63; all new moles, n = 121; all altered moles, n = 49; moles altered in size, n = 22; and moles altered in color, n = 27.
†*P* value for paired comparison of skin self-examination diagnostic accuracy with and without the aid of baseline photography.

Table 4. Sensitivity of Skin Self-examination for Identification of Altered (A) and New (N) Moles According to Number of Moles

Mole Category*	≤5 A/N Moles (n = 26)			>5 A/N Moles (n = 24)		
	Sensitivity, % (95% CI)			Sensitivity, % (95% CI)		
	Without Photography	With Photography	*P* Value†	Without Photography	With Photography	*P* Value†
All A/N moles	66.0 (56.0-74.9)	70.9 (61.0-79.2)	<.001	57.4 (50.5-64.0)	73.1 (66.6-78.8)	<.001
Back A/N moles	61.7 (48.2-73.7)	65.0 (51.5-76.6)	.05	55.7 (47.1-64.0)	70.0 (61.6-77.3)	<.001
Chest or abdomen A/N moles	72.1 (56.1-84.2)	79.1 (63.5-89.4)	<.001	60.5 (48.6-71.4)	78.9 (67.8-87.1)	<.001
All new moles	60.0 (48.0-70.9)	70.7 (58.9-80.3)	<.001	64.7 (56.0-72.6)	78.7 (70.7-85.0)	<.001
All altered moles	82.1 (62.4-93.2)	71.4 (51.1-86.1)	.58	45.0 (34.0-56.5)	63.8 (52.2-74.0)	<.001
Moles altered in size	80.0 (51.4-94.7)	80.0 (51.4-94.7)	>.99	45.7 (29.2-63.1)	71.4 (53.5-84.8)	.01
Moles altered in color	84.6 (53.7-97.3)	61.5 (32.3-84.9)	.25	44.4 (30.0-59.9)	57.8 (42.2-72.0)	.11

Abbreviation: CI, confidence interval.
*Five or fewer A/N moles: all A/N moles, n = 103; back A/N moles, n = 60; chest or abdomen A/N moles, n = 43; all new moles, n = 75; all altered moles, n = 28; moles altered in size, n = 15; moles altered in color, n = 13. More than 5 A/N moles: all A/N moles, n = 216; back A/N moles, n = 140; chest or abdomen A/N moles, n = 76; all new moles, n = 136; all altered moles, n = 80; moles altered in size, n = 35; and moles altered in color, n = 45.
†*P* value for paired comparison of skin self-examination diagnostic accuracy with and without the aid of baseline photography.

lation was a select, highly motivated group composed of patients at high risk for melanoma based on the presence of 5 or more dysplastic nevi. These patients expected an artificial alteration in a lesion, and the alteration and SSE to detect change were performed at the same appointment. Because the assessment of diagnostic accuracy of SSE occurred shortly after the baseline SSE, patients were relying on immediate rather than long-term

recall of the location and characteristics of their moles, and there is the potential for an overestimate of the diagnostic accuracy. The research fellow who interviewed the patients and altered the patients' moles was also responsible for recording the patients' ascertainment of altered moles. Hence, there may be the potential for bias related to accuracy ascertainment. However, the research fellow was instructed to simply record the patients' responses with respect to ascertainment. Due to logistical constraints, it was not feasible to use a separate research fellow for accuracy ascertainment.

This study was conducted in an experimental, highly controlled situation and may not represent what would occur in a population-based setting. Sham-altered nevi may not represent what would occur in a real-world setting; however, this was designed as a pilot study. A prospective study is being planned, and the results will allow us to draw firm conclusions about the impact of digital photography on accuracy of SSE in high-risk patients.

The patient population was also highly motivated, with a high prevalence of dysplastic nevi (100%), history of malignant melanoma (65.8%), and previous performance of SSE (66.0%). These preliminary results likely represent the best case scenario, since our study population was highly motivated and had the advantage of an immediately antecedent baseline SSE.

The availability of baseline digital photographs improved the sensitivity and specificity to detect new and altered moles. Our results suggest that baseline digital photography as an adjunct to SSE improves the diagnostic accuracy of patients performing SSE. Providing patients with photographs may encourage patients to more carefully monitor their lesions and may enable patients to better detect suspicious changes in their lesions.

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