Pigmented Skin Lesion Biopsies After Computer-Aided Multispectral Digital Skin Lesion Analysis

Richard R. Winkelmann, DO; Natalie Tucker, BS; Richard White, MS; and Darrell S. Rigel, MD, MS

From the National Society for Cutaneous Medicine in New York, New York (Dr Winkelmann); MELA Sciences Inc in Irvington, New York (Ms Tucker); Iris Interactive Systems in Cody, Wyoming (Mr White); and the Department of Dermatology, New York University School of Medicine in New York (Dr Rigel). Dr Rigel holds a master's degree in management information science.

Financial Disclosures: Dr Winkelmann's clinical research fellowship is funded in part by MELA Sciences Inc; Ms Tucker is employed by MELA Sciences Inc; Mr White received compensation for the collection of audience response data; and Dr Rigel is a consultant for MELA Sciences Inc.

Support: This study was funded in part by a grant from MELA Sciences Inc.

Address correspondence to Richard R. Winkelmann, DO, 35 E 35th St, Suite 208, New York, NY 10016-3823.

E-mail: rrwink@gmail.com

Submitted May 1, 2015; revision received July 18, 2015; accepted August 3, 2015.

Background: The incidence of melanoma has been rising over the past century. With 37% of patients presenting to their primary care physician with at least 1 skin problem, primary care physicians and other nondermatologist practitioners have substantial opportunity to make an impact at the forefront of the disease process. New diagnostic aids have been developed to augment physician analysis of suspicious pigmented skin lesions (PSLs).

Objective: To determine the effects of computer-aided multispectral digital skin lesion analysis (MSDSLA) on dermatologists' and nondermatologist clinicians' decisions to biopsy suspicious PSLs after clinical and dermatoscopic evaluation.

Methods: Participants were shown 6 images of PSLs. For each PSL, participants were asked 3 times if they would biopsy the lesion: first after reviewing a clinical image of the PSL, again after reviewing a high-resolution dermatoscopic image, and again after reviewing MSDSLA probability findings. An answer was right if a melanoma or high-risk lesion was selected for biopsy or a low-risk lesion was not selected for biopsy. An answer was wrong if a melanoma or high-risk lesion was not selected for biopsy or a low-risk lesion was selected for biopsy. Clinicians' decisions to biopsy were evaluated using χ^2 analysis for proportions.

Results: Data were analyzed from a total of 212 participants, 177 of whom were dermatologists. Overall, sensitivity of clinical image review was 63%; dermatoscopic image review, 5%; and MSDSLA, 83%. Specificity of clinical image review was 59%; dermatoscopic image review, 40%; and MSDSLA, 76%. Biopsy decision accuracy was 61% after review of clinical images, 52% after review of dermatoscopic images, and 80% after review of MSDSLA findings. The number of lesions participants indicated that they would biopsy increased significantly, from 52% after reviewing clinical images to 63% after reviewing dermatoscopic images ($P<.001$). However, the overall number of specimens that participants indicated they would biopsy did not change significantly after they reviewed MSDSLA findings (53%).

Conclusion: Sensitivity, specificity, and biopsy decision accuracy increased after clinicians reviewed MSDSLA findings. The use of objective, computer-based diagnostic aids such as MSDSLA during clinical evaluations of ambiguous PSLs could aid clinicians' decisions to biopsy such lesions.

J Am Osteopath Assoc. 2015;115(11):666-669
doi:10.7556/jaoa.2015.137

The incidence of melanoma has been rising over the past century in the United States.[1,2] Among all dermatologic conditions, melanoma is the deadliest and most costly to patients as well as the health care system. The poor prognosis associated with advanced metastatic melanoma (<10% 5-year survival rate) necessitates efforts to improve early detection and management of this condition.[3] As the US health care system increasingly calls for efficient, evidence-based care, clinicians are challenged to optimize diagnoses while maintaining efficient expenditure of health care resources. The diagnosis and management of melanoma is not limited to dermatologists; approximately 37% of patients present to their primary care physician with at least 1 skin problem,[4] suggesting that primary care physicians and other nondermatologist practitioners have substantial opportunity to influence the forefront of the disease process.

Traditionally, physicians have evaluated suspicious pigmented skin lesions (PSLs) for clinical features of melanoma, commonly referred to as the "ABCDEs": asymmetry, border irregularity, color variegation, diameter greater than 6 mm, and recent evolution.[5,6] However, of approximately 1.5 million skin lesions biopsied in the United States each year, a small estimated percentage (7%) are found to be positive for melanoma.[7] Therefore, new diagnostic aids have been developed to augment physician analysis of suspicious PSLs.[8]

Dermatoscopy is one such diagnostic tool that has been recently adopted into routine practice, with usage rates among dermatologists increasing from 23% in 2001 (when dermatoscopy was a relatively new diagnostic tool) to 79% in 2015.[9] Dutch primary care physicians were found to be 1.25 times more likely to accurately diagnose malignant skin conditions with dermatoscopy than without it,[10] and use of this tool has also been shown to increase primary care physicians' confidence in referring suspicious PSLs to dermatologists.[11,12]

Imaging technologies that incorporate automated computerized analysis may further improve PSL evaluation and dermatologists' decisions to biopsy a lesion. These diagnostic aids are approved by the US Food and Drug Administration, and studies supporting their efficacy have been published.[12,13] Multispectral digital skin lesion analysis (MSDSLA) is one such technology that uses a noninvasive, hand-held medical device to provide rapid, objective clinical data characterizing PSL morphology. In turn, clinicians can use these data in their decision to biopsy a lesion. One study[13] demonstrated a sensitivity and specificity of 94% and 40%, respectively, for the detection of melanoma using MSDSLA.

The MSDSLA technology uses 10 bands of visible and near-infrared light (430-950 nm) to image and evaluate PSLs up to 2.5 mm beneath the skin's surface. Its 75 unique computerized analytical algorithms measure the degree of morphologic disorder of a PSL based on its distribution of melanin. By means of a logical regression model previously validated on a set of 1632 PSLs,[14] the probability of melanoma and the probability of the lesion being a melanoma, high-grade dysplastic nevus, or atypical melanocytic hyperplasia are calculated and provided to the clinician.

Although MSDSLA may be used by all clinicians in our practice, the US Food and Drug Administration currently only recommends MSDSLA use for dermatologists. In the present study, we assessed how MSDSLA findings affect dermatologists' and nondermatologist clinicians' decision to biopsy PSLs after clinical and dermatoscopic evaluation.

Methods

Clinicians (including physicians, physician assistants, and nurse practitioners) were recruited from program materials at a conference in Las Vegas, Nevada, in October 2014. Participation was voluntary, and participants did not receive compensation. Institutional review board approval was not required to conduct this study.

Participants were shown clinical (distant and close-up) and dermatoscopic images of 6 PSLs (2 melanomas

in situ, 1 invasive melanoma, 1 nevus, 1 low-grade dysplastic nevus, and 1 lentigo) previously analyzed by MSDSLA.[14] For each PSL, participants were asked 3 times whether they would biopsy the lesion: first after they were shown the clinical images, again after they were shown the high-resolution dermatoscopic images, and once more after they were shown the MSDSLA probability findings. An answer was right if a melanoma or high-risk lesion was selected for biopsy or a low-risk lesion was not selected for biopsy. An answer was wrong if a melanoma or high-risk lesion was not selected for biopsy or a low-risk lesion was selected for biopsy.

The study took approximately 1 hour to complete and took place in 1 continuous sitting. Practitioner type and biopsy decisions were collected anonymously using a wireless keypad. The correct answers were withheld from participants until all data had been collected to avoid bias. Biopsy decisions were evaluated using χ^2 analysis.

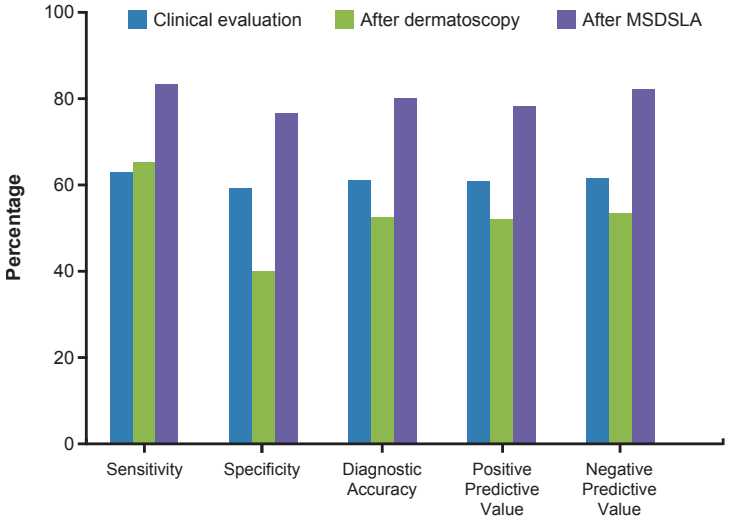

Figure.
Analysis of clinicians' decision to biopsy pigmented lesions after reviewing clinical images, dermatoscopic images, and multispectral digital skin lesion analysis (MSDSLA) findings.

Results

A total of 212 participants were included in the study: 177 dermatologists, 9 nondermatologist physicians, 14 physician assistants, 7 nurse practitioners, and 5 unidentified clinicians. Data from all participants were eligible for analysis (*Figure*). Overall, sensitivity was 63% after participants reviewed clinical images, 65% after they reviewed dermatoscopic images, and 83% after they reviewed MSDSLA findings ($P<.001$). Specificity was 59% after review of clinical images, 40% after review of dermatoscopic images, and 76% after review of MSDSLA findings ($P<.001$). Biopsy decision accuracy was 61% after review of clinical images, 52% after review of dermatoscopic images, and 80% after review of MSDSLA findings ($P<.001$). Positive predictive value was 61% after review of clinical images, 52% after review of dermatoscopic images, and 80% after review of MSDSLA findings ($P<.001$). Negative predictive value decreased from 61% after review of clinical images to 53% after review of dermatoscopic images and increased to 82% ($P<.001$) after review of MSDSLA findings. The number of lesions participants indicated that they would biopsy increased significantly from 52% after review of clinical images to 63% after review of dermatoscopic images ($P<.001$). However, the overall number of specimens participants indicated that they would biopsy did not change significantly after they reviewed MSDSLA findings.

Participants were also significantly less likely to perform biopsies on lesions that were not melanoma, high-grade dysplastic nevus, or atypical melanocytic hyperplasia after reviewing MSDSLA findings than after reviewing the clinical and dermatoscopic images. Therefore, although the total number of specimens selected for biopsy did not increase with MSDSLA findings, participants' biopsy decision accuracy improved, with more melanomas and fewer lower-risk PSLs being selected.

Discussion

In the present study, clinicians' decisions to biopsy PSLs were more sensitive and specific after reviewing MSDSLA findings. Participants were also less likely to decide to perform biopsies on nonmalignant specimens after reviewing these findings. Our results suggest that providing clinicians with data from a computer-based device can improve decision making when managing PLSs, which in turn can decrease the number of nonessential biopsies for nonmelanocytic lesions even after dermatoscopic evaluation. The demonstrated impact of MSDSLA corresponds to trends in a comparable study of 67 practitioners in which the sensitivity in determining biopsy increased from 65% after clinical examination to 92% after MSDSLA, and sensitivity increased from 44% after clinical examination to 57% using MSDSLA.[15]

Potential limitations of this study include the lack of opportunity for in vivo lesion evaluation, the relatively small number of participants, and the nonuniform dermatoscopic expertise. In addition, clinicians with a particular interest in skin cancer or technology may have self-selected themselves to take part in the study. Therefore, results of this study may not be generalized to the average level of expertise by practicing clinicians.

Conclusion

Our findings revealed cumulative increases in both sensitivity and specificity for dermatologists and nondermatologist clinicians after reviewing MSDLA findings of PSLs, without a concomitant increase in decision to biopsy. Objective clinical tools like MSDSLA could aid clinicians' decisions to biopsy ambiguous PSLs and thus could reduce the overall disease burden of melanoma in the future. Such tools may be particularly valuable as the US health care system increasingly focuses on efficient, evidence-based care.

Author Contributions

Dr Winkelmann, Ms Tucker, Mr White, and Dr Rigel provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; Dr Winkelmann and Dr Rigel drafted the article or revised it critically for important intellectual content; Dr Winkelmann, Ms Tucker, Mr White, and Dr Rigel gave final approval of the version of the article to be published; and Dr Winkelmann and Dr Rigel agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References

1. Siegel R, Ma J, Zou Z, Jemal A. Cancer statistics, 2014. *CA Cancer J Clin*. 2014;64(1):9-29.
2. Rigel DS, Russak J, Friedman R. The evolution of melanoma diagnosis: 25 years beyond the ABCDs [published online July 29, 2010]. *CA Cancer J Clin*. 2010;60(5):301-316. doi:10.3322/caac.20074.
3. *NCCN Clinical Practice Guidelines in Oncology: Melanoma*. 2015. Fort Washington, PA: National Comprehensive Cancer Network; 2015.
4. Lowell BA, Froelich CW, Federman DG, Kirsner RS. Dermatology in primary care: prevalence and patient disposition. *J Am Acad Dermatol*. 2001;45(2):250-255.
5. Abbasi NR, Shaw HM, Rigel DS, et al. Early diagnosis of cutaneous melanoma: revisiting the ABCD criteria. *JAMA*. 2004;292(22):2771-2776.
6. Rigel DS, Friedman RJ, Kopf AW, Polsky D. ABCDE—an evolving concept in the early detection of melanoma. *Arch Dermatol*. 2005;141(8):1032-1034.
7. Shoo BA, Sagebiel RW, Kashani-Sabet M. Discordance in the histopathologic diagnosis of melanoma at a melanoma referral center [published online March 19, 2010]. *J Am Acad Dermatol*. 2010;62(5):751-756. doi:10.1016/j.jaad.2009.09.043.
8. March J, Hand M, Grossman D. Practical application of new technologies for melanoma diagnosis: part I, noninvasive approaches. *J Am Acad Dermatol*. 2015;72(6):929-941. doi:10.1016/j.jaad.2015.02.1138.
9. Winkelmann RR, Rigel DS. Management of dysplastic nevi: a 14-year follow-up survey assessing practice trends among US dermatologists. *J Am Acad Dermatol*. In press.
10. Koelink CJ, Vermeulen KM, Kollen BJ, et al. Diagnostic accuracy and cost-effectiveness of dermoscopy in primary care: a cluster randomized clinical trial. *J Eur Acad Dermatol Venerol*. 2014;28(11):1442-1449.
11. Argenziano G, Puig S, Zalaudek I, et al. Dermoscopy improves accuracy of primary care physicians to triage lesions suggestive of skin cancer. *J Clin Oncol*. 2006;24:1877-1882.
12. Herschorn A. Dermoscopy for melanoma detection in family practice. *Cam Fam Physician*. 2012;58(7):740-745.
13. Rigel DS, Roy M, Yoo J, Cockerell CJ, Robinson JK, White R. Impact of guidance from a computer-aided multispectral digital skin lesion analysis device on decision to biopsy lesions clinically suggestive of melanoma [published online February 20, 2012]. *Arch Dermatol*. 2012;148:541-543. doi:10.1001/archdermatol.2011.3388.
14. Monheit G, Cognetta AB, Ferris L, et al. The performance of MelaFind: a prospective multicenter study [published online October 18, 2010]. *Arch Dermatol*. 2011;147(2):188-194.
15. Winkelmann RR, Yoo J, Tucker N, White R, Rigel DS. Impact of guidance provided by multispectral digital skin lesion analysis following dermoscopy on decisions to biopsy atypical melanocytic lesions. *J Clin Aesthet Dermatol*. 2015;8(9):21-24.