Negative Predictive Value of Pigmented Lesion Evaluation by Multispectral Digital Skin Lesion Analysis in a Community Practice Setting

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ABSTRACT

Objective: To determine if the high negative predictive value of a multispectral digital skin lesion analysis that has been previously found in an academic-based trial would be similar in a community-based setting with its expected different distribution of pigmented lesions. **Design:** Data were collected from patients undergoing routine skin examinations over a one-year period at a community-based practice in Florida. All lesions that were selected for biopsy to rule out melanoma were also imaged with multispectral digital skin lesion analysis prior to biopsy. Histopathological diagnoses and multispectral digital skin lesion analysis results were reviewed and compared with findings from a prior primarily academic center-based multispectral digital skin lesion analysis trial. **Setting/participants:** Community-based clinical setting in Florida. **Measurements:** Negative predictive value, sensitivity, and specificity. **Results:** One hundred thirty-seven consecutive lesions were selected for biopsy and also analyzed via multispectral digital skin lesion analysis. All 21 cases with multispectral digital skin lesion analysis "Low Disorganization" readings were all histologically benign (100% negative predictive value, 95% lower confidence boundary = 96.9%). The negative predictive value and the sensitivity were not significantly different than what was found in the prior academic-based multispectral digital skin lesion analysis trial. Multispectral digital skin lesion analysis also correctly identified all high-risk lesions, which were subsequently confirmed via histology to be one invasive melanoma and 15 moderately dysplastic nevi (100% sensitivity). Specificity with multispectral digital skin lesion analysis was significantly higher than reported in the academic-based multispectral digital skin lesion analysis trial (18% vs. 10%, p=0.02). **Conclusion:** Because of the high negative predictive value achieved by multispectral digital skin lesion analysis, lesions with readings of "Low Disorganization" may be considered for observation versus biopsy. Similar to what was noted in the academic center setting, multispectral digital skin lesion analysis may help dermatologists reduce the number of unnecessary biopsies while improving diagnostic accuracy. (*J Clin Aesthet Dermatol.* 2015;8(3):20–22.)

The incidence of melanoma is rising by approximately three percent each year.[1] Dermatologists are faced with the challenge of diagnosing melanoma early as survival is indirectly proportional to time prior to intervention. Often, patients present with multiple suspicious pigmented lesions and differentiating which require biopsy from those that should be monitored complicates biopsy decision management for the clinician. In the evolving landscape of healthcare delivery in the United States, it is important to emphasize evidence-based practice that may increase biopsy efficiency. New technologies are emerging as tools for dermatologists to

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use in identifying suspicious lesions for biopsy and to enhance overall accuracy of biopsy decisions.[2]

A multispectral digital skin lesion analysis (MSDSLA) (MelaFind®; MELA Sciences, Inc.) device is a noninvasive objective instrument that can aid dermatologists in determining which suspicious pigmented skin lesions should be biopsied to rule out melanoma.[3] MSDSLA images and analyzes a pigmented skin lesion across 10 spectral bands of light (430–950nm) from the skin surface to 2.5mm in depth. Automated computerized analysis evaluates 75 unique features of pigment distribution within an atypical lesion to determine the level of morphological disorder and generate a classifier score (CS).[3] A CS greater than or equal to 0 is considered to have "high" disorganization and scores less than 0 have "low" disorganization.

The safety and effectiveness of MSDSLA were originally established from data analyzing 1,632 skin lesions collected by physicians at pigmented skin lesion centers of several major academic centers.[4] In this primarily university-based study, a low disorganization finding was associated with a 98 percent negative predictive value (NPV).[4] However, the frequency and distribution of pigmented lesions that are encountered at high-risk pigmented lesion clinics would be expected to be different than what is experienced in a community-based setting. The purpose of this study was to determine if the NPV using MSDSLA is similar in a community-based setting to what was described in the primarily academic pigmented lesion center study, thereby enabling the community-based clinician to choose to potentially follow versus biopsy those lesions identified as having low disorganization.

METHODS

Data were collected from patients undergoing routine skin examinations over a one-year period at a community-based practice in Florida. Dermatologists were instructed to identify suspicious or atypical pigmented lesions for which biopsy was necessary to rule out melanoma. All lesions were imaged with MSDSLA prior to biopsy and were required to meet the FDA-approved labeling of the device.[4] Pathology results for these lesions were reviewed and compared with the data provided by MSDSLA. Moderately and severely dysplastic nevi recommended for re-excision were considered "positive" lesions, along with malignant melanoma and atypical melanocytic proliferation. All lesions included in the study were selected for biopsy to rule out melanoma by the practitioner. Therefore, physician specificity and NPV based on clinical decisions alone could not be derived. Results were compared to the prior academic trial findings using chi square and standard error analysis.

RESULTS

One hundred thirty-seven consecutive lesions that were selected for biopsy were also analyzed via MSDSLA (Tables 1 and 2). All 21 cases with MSDSLA "Low Disorganization" readings (11 mildly dysplastic nevi, 9 seborrheic keratoses, 1 compound nevus) were histologically benign (100% NPV, 95% lower confidence boundary = 96.9%). The difference between NPVs achieved in both the present study (100%) and the academic-center trial (98%) was not statistically significant. MSDSLA correctly identified all high-risk lesions that were subsequently confirmed via histology to be one invasive melanoma and 15 moderately dysplastic nevi where complete excision was recommended (100% sensitivity). Specificity found with MSDSLA in this study was significantly higher than reported in the academic-based MSDSLA trial (18% vs. 10%, p=0.02). Overall biopsy accuracy was higher with MSDSLA than after clinician decisions alone (38% vs. 14%, p=0.002).

TABLE 1. Pigmented lesion biopsy decision data for MSDSLA vs. clinical evaluation alone

CLINICIAN PERFORMANCE	NO. CASES	MSDSLA PERFORMANCE	NO. CASES
FP	120	FP	99
FN	0	FN	0
TN	0	TN	21
TP	17	TP	17
Total	**137**	**Total**	**137**
CLINICIAN PERFORMANCE	**%**	**MSDSLA PERFORMANCE**	**%**
Sensitivity	100	Sensitivity	100
Specificity	n/a	Specificity	18
Biopsy accuracy	14	Biopsy accuracy	38
PPV	12	PPV	15
NPV	n/a	NPV	100

DISCUSSION

The ability of MSDSLA to potentially identify lower risk pigmented lesions in a community-based clinical practice had not been previously studied. Although the high NPV of MSDSLA for the detection of benign pigmented skin lesions was evaluated in a previous trial,[4] this study demonstrates similar efficacy identifying benign lesions in

TABLE 2. Biopsy results and MSDSLA analyses for study lesions

PATHOLOGY	MSDSLA DISORGANIZATION	
	HIGH	LOW
Melanoma	1	0
Atypical melanocytic proliferation	0	0
Dysplastic nevi Severe Moderate Mild	86 0 15 71	11 0 0 11
Benign nevi	12	1
Seborrheic keratoses	14	9
Actinic keratosis	1	0
Solar lentigines	2	0

the different pigmented lesion distribution found in the community-based setting. Specificity of MSDSLA from this study is also significantly higher than reported in the academic pigmented lesion centers' trial. This finding is consistent with another community-based MSDSLA study that found specificity to be higher than in the academic setting[5] and was attributable to the lower risk distribution of pigmented lesions encountered in the community-based environment. The similar pigmented lesion distribution noted in the current study may also explain the improved specificity that was found here.

CONCLUSION

Despite the differences in the distribution of pigmented lesions studied, the negative predictive value for MSDSLA previously reported in the academic center-based trial (98%) was similar to what was found in this study (100%). Because of the high NPV achieved by MSDSLA, lesions with readings of "Low Disorganization" in both community-based and academic centers may be considered for observation versus biopsy. Similar to what was noted in the academic-center setting, MSDSLA may help dermatologists reduce the number of potentially unneeded biopsies while improving diagnostic accuracy.

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