RESEARCH LETTERS

Caring for Melanoma Survivors with Self-detected Concerning Moles During COVID-19 Restricted Physician Access: A Cohort Study

June K. Robinson, MD[1], Burkhard Jansen, MD[2]

[1]Department of Dermatology, Northwestern University Feinberg School of Medicine, Chicago, IL
[2]DermTech. Inc., La Jolla, CA

ABSTRACT

Background: Physician appointments for non-essential care ceased during COVID-19.

Objective: To pilot test a telehealth solution for patients to rule out melanomas and need for surgical biopsies based on genomic analyses of pigmented lesion samples obtained via adhesive patches.

Methods: Surveys assessed SSE anxiety. Under remote clinician guidance, patients or partners obtained samples using adhesive patches (DermTech, La Jolla, CA).

Results: SSE anxiety increased. Guided self-sampling led to molecular risk factor analyses in 7/7 (100%) of cases compared to 9/10 (90%) randomly selected physician-sampled control cases.

Conclusions: Adhesive patch self-sampling under remote physician guidance is a viable specimen collection option.

INTRODUCTION

Self-management of melanoma detection with skin self-examination (SSE) by melanoma survivors and other patients at-risk to develop melanoma depends on ready access to dermatologists when a concerning mole is detected.[1] With the March 2020 Illinois stay at home order (COVID-19) in-person physician appointments for non-essential care ceased. Additionally, there is uncertainty about when regularly scheduled health care would resume. Dermatologists currently provide care under expanded telehealth benefits using electronic health record (EHR) portals for synchronous e-visits.[2] Despite the limited quality of store-forward images,[3] physicians attempted to interpret patient's photographs and videos of concerning moles; however, improvements and objective assessments beyond image interpretation appear highly desirable.

The cohort study of melanoma survivors presented here assessed SSE anxiety prior to and during restricted physician access. It furthermore evaluated a telehealth support solution that enables patients to rule out melanomas and the need for surgical

biopsies based on genomic analyses of pigmented lesion samples obtained non-invasively via adhesive patches. Patients applied adhesive patches to confirmed skin lesions suspicious for melanoma under remote guidance by their dermatologist (JKR).[4] (DermTech, Inc. La Jolla, CA.)

METHODS

Melanoma survivors were trained to perform partner assisted SSE and completed periodic online surveys assessing SSE performance, identification of concerning moles, physician visits for moles, and biopsies of moles.[5] SSE anxiety and benefit were assessed (Table 1).

In March 2020, melanoma survivors submitted photographs of concerning moles that had changed or had moles reviewed via FaceTime by their dermatologist, who determined if the mole was clinically suspicious for melanoma. For confirmed concerning moles, the dermatologist ordered adhesive patch skin sample collection kits (DermTech, La Jolla, CA) to be couriered to patients. Patients or their skin check partners obtained the samples under remote clinician guidance. Samples were returned by courier to DermTech for LINC00518 and PRAME genomic risk factor analyses via DermTech's Pigmented Lesion Assay (PLA).[4] The dermatologist communicated test results and next steps to patients remotely. Subjects were interviewed about their mole self-sampling experience. The Institutional Review Board of Northwestern University approved the research. Melanoma survivors received $20 for each survey and those who submitted a specimen received $50.

RESULTS

There were 211 respondents among 258 eligible melanoma survivors (81.7%). In the

Table 1. Skin self-examination induced anxiety^

SSE Anxiety In recent months, …	Prior to COVID-19 Mean (SD) (n=258)	During COVID-19 Mean (SD) (n= 211)
Checking for moles caused me some distress.	1.2 (0.3)	3.1 (0.2)*
Checking for moles made me very concerned about having a melanoma.	1.9 (0.4)	4.3 (0.6)*
I felt fearful when I checked my skin.	1.3 (0.2)	2.1 (0.9)
I found it hard to focus on anything else other than my anxiety when I checked my skin.	1.1 (0.1)	1.8 (0.1)
My worries overwhelmed me when I checked my skin.	1.2 (0.2)	1.3 (0.2)
I felt uneasy when I checked my skin.	1.4 (0.3)	3.4 (1.5)*
SSE benefit: decision to seek health care		
I feel that checking my moles has helped me to better be able to decide if a mole needs to be checked by a doctor.	4.6 (0.7)	4.8 (0.2)

*χ^2 $p < .05$
^Likert scale 1= strongly disagree, 3= neutral, 5 = strongly agree. Adapted from PROMIS Anxiety measures. Cella D, Choi SW, Condon DM, Schalet B, Hays RD, Rothrock NE, et al. PROMIS adult health profiles: efficient short-form measures of seven health domains. Value Health 2019; 22(5):537-544.

9 months preceding March 2020, 166 performed three SSEs. Subjects were 54.5% female (115 of 211), had a mean age of 55 years, and 78.7% (166) had regularly scheduled appointments for skin examinations. All studied melanoma SSE anxiety topics increased during COVID -19 and there was a statistically significant difference in SSE anxiety for 3 self-reported responses prior to and during COVID-19 (Table 1).

Table 2. Comparison of mole self-sampling specimens with physician provided samples

A) PLA patient self-sampling under the remote supervision of a licensed healthcare professional						
Sample #	Sex	Lesion Size (mm)	Lesion Location	LINC	PRAME	PLA
Sample 1	M	5 x 5	Hip	ND	ND	N
Sample 2*	F	5 x 5	Shoulder	ND	ND	N
Sample 3§	M	7 x 9	Leg	ND	ND	N
Sample 4§	M	7 x 7	Scalp	ND	ND	N
Sample 5	F	7 x 8	Back	ND	ND	N
Sample 6	F	6 x 11	Back	ND	ND	N
Sample 7*	F	7 x 7	Back	ND	ND	N
B) Randomly selected physician collected PLA control samples received during the same time period^						
Sample #	Sex	Lesion Size (mm)	Lesion Location	LINC	PRAME	PLA
Control 1	M	10 x 10	Back	ND	ND	N
Control 2	F	9 x 10	Ankle	QNS	QNS	QNS
Control 3	F	10 x 7	Back	ND	D	P
Control 4	F	6 x 7	Leg	ND	ND	N
Control 5	F	11 x 12	Back	ND	ND	N
Control 6	F	11 x 13	Buttock	ND	ND	N
Control 7	M	6 x 4	Flank	D	ND	P
Control 8	F	6 x 5	Breast	ND	D	P
Control 9	F	12 x 11	Back	ND	ND	N
Control 10	M	13 x 11	Back	ND	ND	N

Abbreviations: Pigmented Lesion Assay (PLA), Long Intergenic Non-Coding RNA 518 / LINC00518 (LINC), Preferentially Expressed Antigen in Melanoma (PRAME), Male (M), Female (F), Quantity Not Sufficient (QNS), Detected (D), Not Detected (ND), Positive (P), Negative (N), Same Patient. *§
^ Samples collected in states without restricted physician access.

After COVID-19, five subjects noted change in a mole. Subjects related that lack of physician access influenced subjects' decision to do mole self-sampling. Guided self-sampling led to successful molecular risk factor analyses by PLA in 7/7 (100%) of cases compared to 9/10 (90%) randomly selected physician-sampled control cases received during the same timeframe (Table 2).

DISCUSSION

In this study, increased SSE anxiety may be partially attributed to generalized health anxiety; however, lack of physician access to provide skin examinations for melanoma survivors with self-identified concerning moles was an important factor in patients' desire for high-quality alternatives. A limitation was lack of general anxiety assessment. This research demonstrates

that adhesive patch self-sampling under physician guidance is a viable specimen collection option. Remote collection can expand access to assessment by PLA, a gene expression – based melanoma rule-out test with a negative predictive value above 99%, that reduces avoidable surgical biopsies of pigmented lesions clinically suspicious for melanoma by over 90% as demonstrated in a recent registry study of 3,418 cases.[6]

CONCLUSION

This proof-of-concept research demonstrates that patients are able to reliably perform self-sampling of concerning moles under remote physician supervision. Patient-obtained skin sample collection using adhesive patches was successful in 100% of cases enabling actionable molecular pathology PLA test reports to rule-out melanoma in all cases. The offered teledermatology solution provided pigmented lesion management with a negative predictive value of over 99% and reduced patient anxiety while avoiding office visits during a period when office visits are limited by COVID-19 to essential care. Adhesive patch self-sampling under remote clinician guidance is a viable specimen collection option.

Acknowledgment: Supported by R01 CA154908 to June K. Robinson, MD, from the United States National Cancer Institute. Pigmented lesion assay testing provided by DermTech Inc. (La Jolla, CA). Mary Kwasny, PhD, Department of Preventive Medicine, Northwestern University, Feinberg School of Medicine, Chicago, IL, provided statistical analysis and received compensation for her role.

Conflict of Interest Disclosures: Dr. Jansen is an employee of DermTech, Inc. Dr. Robinson has no conflicts of interest.

Clinical Trials registration: NCT02854657

Corresponding Author:
June K. Robinson, MD
Department of Dermatology
Northwestern University Feinberg School of Medicine
645 N Michigan Ave, Suite 1050
Chicago, IL, 60611 USA
Email: june-robinson@northwestern.edu

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