Research Article

Cancer Epidemiology, Biomarkers & Prevention

Correspondence between Pigmented Lesions Identified by Melanoma Patients Trained to Perform Partner-Assisted Skin Self-Examination and Dermatological Examination

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Abstract

Background: Skin self-examination (SSE) training interventions can increase understanding of melanoma early detection criteria and promote SSE. However, there remains a need to evaluate whether intervention participants can apply such early detection skills to accurately identify concerning, or potentially malignant, pigmented lesions during full body SSE.

Methods: We assessed SSE accuracy using data from a randomized control trial of a SSE skills training intervention designed to promote partner-assisted SSE among melanoma patients. In the trial, patient–partner pairs were administered the training intervention and performed monthly SSE to identify, evaluate, and track concerning pigmented skin lesions. Patients received a total body skin examination by a dermatologist approximately 4-months postintervention. SSE accuracy was assessed as the correspondence between the specific concerning pigmented lesions identified by 274 study pairs during SSE with those identified during dermatological examination. We also examined whether lesions that were biopsied during the study were identified prior to biopsy during SSE.

Results: Approximately three in four of the concerning lesions identified by pairs during SSE were also identified during the dermatological exam. There were 81 biopsies performed during the study and pairs had identified 73% of the corresponding lesions during SSE. Of the five melanoma detected, three were identified during SSE.

Conclusion: Melanoma patients and partner taught to do SSE using an evidence-based program developed a high degree of correspondence with the study dermatologist in identifying concerning lesions.

Impact: This study provides novel evidence that supports the accuracy of full-body SSE for the patient identification of concerning lesions. *Cancer Epidemiol Biomarkers Prev; 24(8); 1247–53. ©2015 AACR.*

Introduction

There is promising evidence that melanoma patients may benefit from skin self-examination (SSE). A majority of newly diagnosed melanomas are found by patients or their partner (1, 2) and 47% to 68% of melanoma patients find another melanoma during the intervals between doctor follow-up visits (3–5). Early-stage melanoma is highly treatable but thicker later-stage disease rapidly progresses to the advanced stage with metastasis to internal organs and poor survival prognosis. Patients who perform SSE have significantly thinner melanomas compared to those who do not (6) and melanomas identified during SSE are thinner than those found incidentally (7). Most importantly, there is evidence of lower rates of lethal melanoma among patients who perform SSE (8) or monitor their skin (9).

A variety of patient training programs have been developed to encourage SSE and teach simple visual inspection techniques for early detection of melanoma (10). Many SSE programs utilize the ABCDE criteria (11, 12) to provide patients with objective and succinct rules for identifying concerning pigmented lesions (PL) by comparing features of PLs found during SSE to features typically observed in melanoma. Concerning PLs are defined as those that may be melanoma or should be watched for change to assure that the lesion has not evolved to become a melanoma. Several SSE programs have demonstrated efficacy in increasing melanoma patients' SSE knowledge and attitudes, ability to identify features of melanoma on training evaluations, and SSE frequency (10). Program efficacy may be further enhanced by the inclusion of a SSE partner during training (13–15) or SSE aids to assist patients with identifying, tracking, and detecting changes in PLs (16–19).

Several prominent professional health organizations advocate for routine SSE (20, 21) but others, including the United States Preventive Services Task Force, have not supported routine SSE due to a perceived lack of sufficient evidence regarding the efficacy of SSE (22). Although SSE training intervention participants show improved ability to identify concerning PLs on training evaluations (23–26), researchers have not examined whether participants are able to apply such skills in the context of full body SSE (27). In other words, it is unclear whether participants are able

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doi: 10.1158/1055-9965.EPI-15-0218

to utilize learned melanoma early detection criteria during SSE to accurately identify concerning PLs. A related concern is that SSE training may lead to unnecessary physician visits and healthcare burden if patients inaccurately apply detection criteria during SSE by identifying benign PLs as concerning PLs that require immediate medical attention.

The aim of this study was to examine the accuracy of patient SSE following a SSE skills training intervention. We used data from a randomized control trial of an SSE intervention designed to teach proper techniques for identifying PLs during SSE to melanoma patients and their partners. Following the intervention, the patient and partner pairs identified concerning PLs during monthly SSE and patients received a total body skin examination (TBSE) by the study dermatologist 4 months later. SSE accuracy was evaluated by comparing the specific concerning PLs identified by pairs during SSE with the PLs identified by the dermatologist TBSE. We also examined whether skin lesions that were biopsied during the study were identified as concerning PLs during SSE prior to biopsy. Our research questions were as follows: (i) What is the correspondence rate between the specific PLs identified during SSE and those identified during TBSE? (ii) Is there an influence of patient characteristics, including demographic variables, phenotypic characteristics, and SSE experience prior to the intervention, on PL correspondence? (iii) What is the likelihood that biopsied lesions were identified as concerning PLs during SSE? (iv) How many of the physicians visits that occurred during the study were due to unwarranted concern about PLs identified during SSE that proved to be benign?

Materials and Methods

Melanoma patients and their partners were recruited to the SSE training intervention randomized control trial from June 2011 to April 2013. Detailed methods of subject recruitment and data collection are available in prior publications (28–30). Briefly, patients had a history of Stage 0 to IIB melanoma, were able to see sufficiently well enough to read a newspaper, spoke English, were between 21 and 80 years old, and had a person willing to participate as a SSE partner (e.g., a spouse, partner, close relative, or close friend). Pairs were recruited with three methods: in-person during a follow-up clinic visit, an electronic medical record search, or a newspaper advertisement. The Institutional Review Board of Northwestern University approved the study and all participants provided written informed consent.

Study design

Each enrolled pair was randomized to a customary care control condition or one of three SSE skills training interventions. All patients completed a baseline survey assessment. Intervention pairs were encouraged to perform monthly SSE following the intervention and to track their results using a provided body map and scorecard (19). Patients were scheduled to receive a TBSE from the study dermatologist (June K. Robinson) 4 months following intervention delivery.

SSE training interventions. The three skills training interventions included an in-person PowerPoint presentation delivered by a trained research assistant, a self-guided paper workbook, or an electronic interactive intervention delivered on a tablet computer. The in-person intervention consists of a presentation of melanoma detection rules, an SSE skills demonstration of using a magnifying glass to examine illustrated examples, and skills quizzes with performance feedback (13). The 39-page workbook was designed to replicate the information and illustrative examples of the presentation (14). The tablet-delivered Internet intervention adapted the information presented in the other formats while also allowing for narrated video presentations and animated graphics (28–30). Each intervention was delivered during an in-person office visit following recruitment into the study. Our prior work comparing these intervention approaches has found similar efficacy in promoting SSE (14, 30).

Each intervention differs in format but they all provide standardized consistent rules evaluated in our prior research to guide the identification and assessment of concerning PLs during SSE (19, 26). Specifically, because partners have had difficulty with identifying asymmetry in moles in our prior work (19), we modified the ABCDE rule as Assess moles for Border, Color, Diameter and Evolution. Each aspect of the ABCDE rule was explained with color picture examples. Pairs were instructed to apply these identification rules to identify and score moles during monthly SSE. Pairs also learned about two benign lesions commonly found on skin, seborrheic keratosis, and cherry angiomas, and how to differentiate them from moles that may be suspicious.

SSE aids: Body map and scorecard. Intervention pairs received an SSE Enabling Kit consisting of a laminated card with a summary of the intervention ABCDE assessment rules, a lighted magnifying glass, a ruler, and body maps. The body maps consisted of line drawings of distinct body regions and a scorecard for recording and tracking monthly SSE results (19). Pairs used the scorecard to record the body location of each PL, provide ratings on the border, color, and diameter criteria, and assess the PL for change. Pairs were asked to bring the body map to the 4-month TBSE so they could review their chosen PLs with the doctor following the TBSE. Although pairs were not instructed to identify and score every PL on their body, some of the first 20 pairs enrolled in the study pilot phase did so and felt that it was too burdensome. Subsequent pairs were instructed to select 5 to 10 PLs to score and watch for change over the initial four months. A total of nine of these initial 20 pairs were in an intervention condition and were excluded from the data analyses given the differences in SSE instructions.

Clinical examination. The 4-month visual TBSE performed by the study dermatologist (June K. Robinson) was designed to assess whether the patient had concerning PLs that should be monitored for change or biopsied. During the TBSE, the doctor identified and scored PLs using the body map and scorecard in the same manner as pairs were instructed to do in the SSE program. A research assistant was present during the TBSE and recorded each of the dermatologist's evaluations onto a blank body map. The research assistant and dermatologist were blinded as to patients' intervention condition and to the SSE results recorded on their body map scorecard. Following the TBSE, the research assistant reviewed the pairs' SSE body map scorecard and compared the results to the TBSE scorecard to determine whether each pair's identified PLs were scored during the TBSE. If the research assistant was unsure if a specific PL identified during SSE matched a TBSE PL, both the dermatologist and the research assistant returned to the pair to determine if the spot identified during TBSE was the one they selected. The research assistant created a new scorecard that

became the basis for the analysis by merging the information from the SSE and TBSE PL scorecards.

Measures

Body map scorecard. Pairs used the scorecard during SSE to record the body location of each PL and provided a rating on the border, color, and diameter based on the criteria described in the program (rating options were 1 = *normal*, 2 = *not sure*, and 3 = *abnormal*). Following the first SSE, pairs rated whether each PL met the Evolution criterion in any of the BCD criteria, defined as a change from a prior score of *normal* to a score of *abnormal*. Pairs also provided an evaluation of each PL as either *benign* (if the PL had *normal* scores on all 3 criteria), *watch* (for change during subsequent SSE) (if the PL had a score other than *normal* on any of the criteria), or *serious* (if the PL had a score of *abnormal* on all three criteria or met the Evolution criterion). Pairs were instructed that PLs judged to be *serious* should be examined by a doctor within 2 weeks. The scoring (i.e., 1, 2, 3 ratings) was similarly used by the study dermatologist during TBSE.

Patient characteristics. Select patient characteristic variables were measured in a baseline assessment. Demographic characteristics included patients' gender, age, education, and time since melanoma diagnosis. Phenotypic variables included patients' tendency to freckle easily as a child (response option = *no, somewhat, yes*) and skin type as assessed by skin sunburn tendency of untanned skin (response options = *never sunburn, rarely, sometimes, usually, always*). Patients also indicated if prior to the SSE program (i) a doctor or health care worker had ever recommended they perform SSE, (ii) a doctor or health care worker had ever taught them to perform SSE, or (iii) they currently examined their skin for new or changing moles.

Data analyses

PL correspondence. SSE accuracy was assessed by examining the correspondence rate between PLs scored by pairs during SSE with those identified by the dermatologist during TBSE. We used the scorecard created by the RA following the TBSE to create a PL correspondence variable that was coded for each PL as either 0 = *no PL agreement* if the PL was identified on the SSE scorecard but not the TBSE scorecard or 1 = *PL agreement* if the PL was identified during both SSE and TBSE. The overall PL correspondence rate was calculated with a random intercept-only mixed logistic regression model using the mixed generalized linear model option in SPSS statistical software (Version 21; IBM Corp, 2014). The mixed model properly accounts for correlated error within pairs that occurs due to the nesting of PL data points nested within. Each patient characteristic variable was examined as a level 2 fixed effect in separate, bivariate mixed logistic regression models to assess the influence of baseline patient characteristics on PL correspondence.

Biopsy. Study patients received dermatologist care during the 4-month TBSE and were also instructed to continue with regularly scheduled follow-up visits with their customary care dermatologist during the study. Some pairs also initiated nonscheduled visits to have a dermatologist or other physician evaluate a concerning PL (see following paragraph). We present information about number of biopsies resulting from these dermatologist visits, the biopsies findings, and whether biopsied lesions were identified by patients as a concerning PL during SSE or were the result of a dermatological examination.

Ad hoc visits. Patients could request an immediate visit, referred to as an *ad hoc* visit, to see the study dermatologist or their customary care dermatologist to evaluate a PL they found to be seriously concerning during SSE. Prior to the 4-month TBSE, patients reported on whether they had visited their customary care dermatologist or other physician for an *ad hoc* visit. We computed the total number of patients who requested *ad hoc* visits during the study.

Results

Participants

Of the 395 participants enrolled in an intervention conditions in the efficacy study, 106 patients were excluded from analyses for the following reasons: early study termination (n = 35), no body map provided or did not attend the 4-month follow TBSE (n = 62), among the intervention participants who received differing SSE instructions during the pilot (see Materials and Methods; n = 9). An additional 15 participants who requested an *ad hoc* visit with a dermatologist to evaluate a concerning PL were also excluded from the accuracy analysis as such a visit may have biased their subsequent SSE behavior. Demographic information is presented for the remaining 274 patients who scored at least one PL on their body map and received the 4-month TBSE (Table 1).

PL correspondence

PL correspondence rate. The mean number of PLs identified by the 274 pairs on the SSE body maps was 9.66 (SD = 5.47, range 1–34, mode = 10, median = 9). A total of 2,646 PLs were identified during SSE and 1,836 of these PLs were also identified during

Table 1. Demographic characteristics of the sample of melanoma patients (n = 274)

	Sample, %
Gender	
Female	51.8
Male	48.2
Age (years)	
39 or younger	13.1
40 to 49	14.6
50 to 59	27.8
60 to 69	31.7
70 or older	12.8
Race	
Caucasian/white	98.9
Black or African American	0.4
Other	0.7
Ethnicity	
Hispanic	1.1
Non-Hispanic	98.9
Education	
High school graduate or lower	5.9
Some post-high school education	13.6
College graduate	39.2
Graduate degree	41.4
Annual household income	
$34,999 or less	6.3
$35,000 to $50,999	5.2
$51,000 to $100,000	30.5
Over $100,000	58.0

TBSE. Table 2 presents results from the mixed logistic regression models. We included the estimated marginal means, which represent the least squared means estimated from the fitted model. Means can be interpreted as the average rate of the dichotomously coded PL correspondence variable for each model parameter. For example, the parameter labeled PL correspondence between SSE and TBSE in the first row of Table 2 results represents the estimated marginal mean of PL correspondence (0.74) derived from the intercept parameter from a random intercept-only mixed logistic regression model. This mean can be interpreted as: nearly three in four of the PLs identified by pairs during SSE were also identified by the dermatologist during TBSE. The random error variance was significant for the model ($\sigma = 2.39$, $P < 0.001$), which suggests there was significant within-pair variance in PL correspondence.

A total of 810 PLs identified by pairs during SSE were not identified during TBSE. Following the TBSE, the dermatologist immediately reexamined each of these pair-identified PLs and classified them as follows: benign seborrheic keratosis (64%), benign mole (11%), cherry angioma (7%), lentigo (3%), dermatofibroma (2%), scar tissue (2%), other (9%), or no judgment provided (2%).

Patient characteristics as correlates of PL correspondence. There were nonsignificant differences in mean rates of PL correspondence when comparing pairs in the tablet intervention to the workbook ($P = 0.384$) or in-person format ($P = 0.875$; Table 2). Male patients had significantly lower rates of PL correspondence (0.68) compared to female patients (0.80; $P < 0.001$). The mean PL correspondence rate for the patients 39 years old or younger did not differ from those aged 40 to 49 ($P = 0.798$) but was significantly higher when compared to the three older groups (all $P \leq 0.001$). Nonsignificant effects were observed for education, time since diagnosis, freckling tendency, or sunburn tendency. Patients who had a received a recommendation to conduct SSE prior to the program had significantly higher PL correspondence (0.76) compared to those without a recommendation (0.57; $P = 0.016$). PL correspondence was also higher among patients who had been taught to do SSE in the past (0.80) compared to others (0.70; $P = 0.013$). However, prior SSE was marginally associated with higher PL correspondence rates ($P = 0.072$). In a multivariate analysis with all correlates in a single model, only age was significantly associated with PL correspondence (results not presented).

Biopsy results

There were a total of 81 skin lesion biopsies performed by either the study dermatologist ($n = 20$) or customary care dermatologist ($n = 61$). The majority of biopsies were performed during regularly scheduled dermatologist visits (65%) with the remaining occurring following the 4-month TBSE (23%) or an *ad hoc* visit (11%). Of the 81 biopsied lesions, 73% were listed on the pairs' SSE scorecard and were evaluated as follows: serious or having evolution (17%), needing to be watched (37%), or benign (19%). A total of five melanomas were identified by biopsy. Two of the melanoma biopsies were performed as a result of a patient ad hoc visit (and one melanoma biopsy was identified as evolving by the pair during SSE. The body location and histologic subtype of these

Table 2. Correspondence of pigmented lesions identified during pairs' SSE with lesions identified during dermatologic total body skin examination

Variable	Parameter	Estimated means[a] (95% CI)	β	*P*
PL correspondence	PL correspondence between SSE and TBSE	0.74 (0.69–0.78)	1.036	<0.001
Intervention condition	Ref (Tablet)	0.72 (0.61–0.81)	—	—
	Workbook	0.77 (0.71–0.83)	0.270	0.384
	In-person	0.71 (0.64–0.78)	−0.048	0.875
Gender	Ref (female)	0.80 (0.75–0.85)	—	—
	Male	0.68 (0.58–0.72)[b]	−0.761	<0.001
Age in years	Ref (39 or younger)	0.92 (0.86–0.95)	—	
	40 to 49	0.91 (0.84–0.95)	−0.133	0.798
	50 to 59	0.76 (0.69–0.82)[b]	−1.248	<0.001
	60 to 69	0.60 (0.52–0.67)[b]	−2.006	<0.001
	70 or older	0.44 (0.32–0.58)[b]	−2.621	<0.001
Education	Ref (graduate degree)	0.73 (0.62–0.82)	—	—
	Less than college	0.68 (0.61–0.75)	−0.217	0.479
	College degree	0.80 (0.73–0.85)	0.370	0.236
Time since diagnosis	Ref (1 year or greater)	0.74 (0.69–0.79)	—	—
	Less than 1 year	0.72 (0.64–0.79)	−0.122	0.609
Freckling	Ref (No)	0.69 (0.61–0.76)	—	—
	Somewhat	0.74 (0.64–0.82)	0.257	0.398
	Yes	0.77 (0.71–0.82)	0.402	0.110
Sunburn tendency	Ref (Never/rarely)	0.71 (0.53–0.83)	—	—
	Sometimes	0.79 (0.71–0.86)	0.489	0.268
	Usually	0.71 (0.62–0.79)	0.058	0.894
	Always	0.72 (0.65–0.79)	0.103	0.804
SSE recommended	Ref (Yes)	0.76 (0.71–0.80)	—	—
	No	0.57 (0.41–0.72)[b]	−0.852	0.016
SSE taught	Ref (Yes)	0.80 (0.74–0.85)	—	—
	No	0.70 (0.64–0.75)[b]	−0.560	0.013
Engaged in SSE prior to intervention	Ref (Yes)	0.76 (0.71–0.80)	—	—
	No	0.66 (0.55–0.75)	−0.478	0.072

Abbreviation: CI, confidence interval.

[a]Estimated marginal means represent least squares means estimated from the fitted model. The means represent the average rate of PL correspondence for each level of the correlates.

[b]Significant difference between parameter and the reference category code.

three melanomas were: left ala nasi, *in situ*; left hand, third digit, stage 1A; right chest, stage 1A). Pairs did not identify the two remaining melanomas (left upper back, *in situ*; right upper back, *in situ*).

Ad hoc visits

In the four months between the intervention and TBSE appointment, 7 patients were seen as an *ad hoc* visit by the study dermatologist and 8 patients reported scheduling an *ad hoc* visit with the customary care dermatologist or other physician to evaluate a lesion judged to be serious by the pair. These 15 patients represent less than 4% of the 395 total patients who received the educational training.

Discussion

This study shows that melanoma patient and partner pairs developed a high degree of correspondence with a dermatologist in identifying concerning PLs following an SSE training intervention. PL correspondence was highest among female patients, younger patients, and patients who had received a SSE recommendation or training prior to the program. Pairs identified the majority of biopsied PLs during SSE including three of the five found melanomas. Less than 4% of participants requested immediate doctor visits to evaluate concerning PLs found during SSE.

Nearly three in four of the PLs identified during SSE were also identified during dermatologist TBSE. This suggests pairs were able to accurately apply the early clinical detection rules taught in the intervention during SSE. Prior studies of the accuracy of SSE and early detection training have relied on testing participants' ability to detect artificially produced changes in photographs of existing moles (23, 24) or improvements in their evaluation of illustrated examples of PLs (25, 26). Other SSE accuracy studies have examined the participants and doctor correspondence in total body nevi counts (31–34). This is the first study to assess SSE accuracy through tracking and comparing specific PLs identified by melanoma patients and partner pairs during SSE with those identified during TBSE by a dermatologist, who was blinded to the choices made by the pairs. Furthermore, three of the five melanoma identified by biopsy were identified as either serious or in need of monitoring for change during SSE. These findings represent novel evidence that patients can apply the visual inspection and diagnostic skills taught in the SSE intervention during real-world SSE. In addition, the data from the detailed body map scorecard data and biopsy results goes beyond existing SSE intervention efficacy studies that show increases in SSE using global and retrospective measures (22).

The analysis of patient characteristics as correlates of PL correspondence also adds to our understanding of SSE. PL correspondence did not differ between the three different SSE program delivery methods, which is consistent with our recent study that showed comparable beneficial effects of the three methods (28, 30). We observed a higher PL correspondence among women patients and this findings is consistent with research that shows women have a higher ability to detect skin lesions compared to men when provided with a detection aid, in the form of mole photographs (23). However, it is important to note that there is little consistent evidence of gender differences in nevi-counting studies (31–34). There are several documented difficulties associated with performing SSE and distinguishing concerning PLs among older individuals (35). These difficulties may account for the low PL correspondence among for patients 60 years old or older. Patients who had received a recommendation to conduct SSE or an SSE demonstration prior to the program had higher PL correspondence. It is difficult to tell whether the beneficial effects of such experiences on SSE accuracy were a result of increased SSE motivation and buy-in due to these prior experiences or whether these participants had a preintervention understanding of SSE that led to a greater learning of SSE skills. Regardless of the reason for the benefit, the findings suggest that simply recommending SSE or providing a brief demonstration may be beneficial to melanoma patients.

Heightened awareness of PLs among the pairs performing SSE did not result in a burdensome number of unscheduled dermatologist visits. The body map and scorecard require the layperson to commit to a decision regarding the presence of a concerning PL and provide a diary to document the scores that likely serves to actively reinforce the decision rules during SSE. The ability of the melanoma survivors to accurately apply these rules to distinguish benign from potentially malignant lesions may have contributed to their not requiring additional visits. Prior work has shown that melanoma patients were typically overconcerned with common moles but their ability to distinguish between benign and malignant lesions increases following brief training with the ABCDE criteria (25). This training intervention has been shown to increase patient SSE self-efficacy (13) and the empowerment provided by such confidence may mitigate the anxiety associated with their risk of developing another melanoma and decrease the number of physician visits.

This study has limitations. Findings were assessed over a relatively short follow-up period. Future work with a longer follow-up is needed to determine whether the observed SSE benefits are sustainable. Patient and partner pairs recruited to the study may have a high motivation to engage in SSE compared to those who did not volunteer. The frequency and thoroughness of the pairs' SSE may have been influenced by their knowledge of being enrolled in a study that tested a SSE training intervention or their expected interaction with the study dermatologist during the TBSE. Study generalizability is negatively affected by the exclusion of 25% of the sample due to early study termination or nonadherence to study procedures. In addition, patients were recruited from a single area and reported average incomes that are higher than average U.S. income levels. The extent to which the findings can be extrapolated to other high-risk melanoma populations and settings remains to be determined. Finally, the study dermatologist performed a comprehensive TBSE but pairs were not asked to identify all of their concerning PLs during a comprehensive SSE. Given that pairs were not instructed to record every concerning PL during a comprehensive SSE, PLs identified during TBSE but missed SSE cannot be considered a false negative result because it is not possible to know whether the pairs examined the PL and made the decision not to score it. Thus, this study design precludes a true test of the specificity and sensitivity of SSE.

Partner-assisted SSE training intervention approaches for melanoma patients have produced increases in SSE confidence, knowledge, skills, and SSE frequency (13, 14, 19, 26, 28, 30). This study provides further support by demonstrating the interventions result in a high degree of accuracy in identifying concerning PL during SSE. Scientific organizations have found

insufficient evidence to support the recommendation of SSE due to a lack of evidence that participants can apply taught SSE skills during subsequent SSE (22, 27). This study provides novel preliminary evidence that the patients can perform SSE in a manner that is consistent with TBSE. In addition, more than half of biopsied PLs and subsequent melanoma diagnoses were either brought to a doctor's attention by the patient or identified in need of further evaluation. It needs to be emphasized that the demonstration that pairs can accurately apply decision aid rules during SSE does not suggest that SSE alone is an adequate replacement for TBSE by a physician. However, because patients and their families bear the ultimate burden of failure to diagnose melanoma promptly, the study provides encouraging evidence that teaching SSE skills can assist patients and their partners in making responsible decisions about early self-detection of melanoma.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Disclaimer

The study sponsor did not have a role in study design, the collection, analysis, and interpretation of data, the writing the report, or the decision to submit the report for publication. Manuscript content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): J.L. Stapleton, R. Turrisi, J.K. Robinson
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Administrative, technical, or material support (i.e., reporting or organizing data, constructing databases): J.L. Stapleton, R. Turrisi, J.K. Robinson

Acknowledgments

Trial registration ID: NCT01432860.

Grant Support

All authors received support through a grant from the NIH, National Cancer Institute (R01 CA154908, PI: J.K. Robinson).

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Received March 3, 2015; revised May 9, 2015; accepted May 25, 2015; published OnlineFirst June 10, 2015.

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