Received: 6 December 2022 | Accepted: 13 January 2023

DOI: 10.1111/srt.13286

INVITED REVIEW

WILEY

Detection of cutaneous malignant melanoma by tape stripping of pigmented skin lesions – A systematic review

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Systematic review registration: PROSPERO CRD42022312716

Abstract

Background: Cutaneous malignant melanoma (MM) is potentially aggressive, and numerous clinically suspicious pigmented skin lesions are excised, causing unnecessary mutilation for patients at high healthcare costs, but without histopathological evidence of MM. The high number of excisions may be lowered by using more accurate diagnostics. Tape stripping (TS) of clinically suspicious lesions is a non-invasive diagnostic test of MM that can potentially lower the number needed to biopsy/excise.

Materials and methods: The aim is to determine the diagnostic accuracy of TS in detecting MM in clinically suspicious pigmented skin lesions. This systematic review following PRISMA guidelines searched PubMed, Web of Science, and Embase (September 2022) using melanoma combined with tape stripping, adhesive patch(es), pigmented lesion assay, or epidermal genetic information retrieval.

Results: Ten studies were included. Sensitivity ranged from 68.8% (95% confidence interval [CI] 51.5, 82.1) to 100% (95% CI 91.0, 100). Specificity ranged from 69.1% (95% CI 63.8, 74.0) to 100% (95% CI 78.5, 100). A pooled analysis of five studies testing the RNA markers LINC00518 and PRAME found a sensitivity of 86.9% (95% CI 81.7, 90.8) and a specificity of 82.4% (95% CI 80.8, 83.9).

Conclusion: Overall quality of studies was low, and the reliability of sensitivity and specificity is questionable. However, TS may supplement well-established diagnostic methods as pooled analysis of five studies indicates a moderate sensitivity. Future studies are needed to obtain more reliable data as independent studies with no conflict of interest.

KEYWORDS
adhesive patch, diagnostic accuracy, epidermal genetic information retrieval, malignant melanoma, nevus, pigmented lesion assay, skin cancer, tape stripping

1 | INTRODUCTION

Cutaneous malignant melanoma (MM) is one of the most aggressive skin cancers. In 2020, more than 300,000 people were diagnosed with melanoma globally, and more than 50 000 patients died of MM globally.[1] Early detection of melanoma makes a vast difference in overall survival.[2] Therefore, a quick and accurate diagnosis and fast, efficient treatment of MM are imperative for overall survival.

A suspicious lesion is diagnosed by excision and subsequent histopathology examination; this constitutes the reference standard for MM diagnosis.[3] In a study by Malvehy et al., 2014, diagnostic efficacy was studied in MM.[4] The observed sensitivity was 70.6% and specificity was 81.4% in a group of dermatologists, including visual- and dermoscopic assessment. A high number of clinically suspicious pigmented skin lesions are therefore excised annually, where histopathological examination demonstrates no signs of MM. There is no medical need to remove these lesions, and the unnecessary removal burdens dermatologists, surgeons, lab workers and pathologists.

The tape stripping (TS) method has been used in other skin diseases such as atopic dermatitis and psoriasis.[5] TS of pigmented lesions is a novel non-invasive diagnostic test for MM. Several potential biomarkers exist, such as RNA, cells and lipids. MM expresses a different RNA profile on the surface than normal skin and nevi, which can be used diagnostically.[6] An adhesive patch is placed on the pigmented lesion. After delineation of the lesion by a surgical marker pen or a standard dark colour pen, the patch is immediately removed, and cells from the stratum corneum are left on the patch to be analysed. TS can be repeated with a new patch on the same lesion multiple times. If the method detects, for example, specific RNA markers at a certain threshold, the TS test is positive (TS+). Likewise, if the method does not detect RNA markers at a certain threshold, the TS test is negative (TS-). Some RNA markers are downregulated in MM, and the TS method will detect the lack of these specific RNA markers and the test will be positive (TS+). A disadvantage of TS is that the adhesive patch does not necessarily work on mucous membranes, palms, soles, and nails or if there is bleeding or serous exudation.[7] A commercially available test that can examine pigmented lesions is referred to as pigmented lesion assay (PLA).

Exfoliative cytology is a non-invasive method that uses skin cells from the stratum corneum to identify disease by examining the structure and characteristics of these cells.[8] Typically, the examiner scrapes the skin cells using a scalpel or curette and then smears the cells on a glass slide. Another way of collecting the skin cells is to use double-stick tape; one side sticks to the glass slide and the other sticks to the skin. After the cells are smeared or taped onto the glass slide, the cells can be stained with various stain types, for example, toluidine blue and then examined under a microscope.

Numbers needed to biopsy/excise (NNB) is a metric used to assess the accuracy and cost-effectiveness of MM diagnostics. A systematic review from 2019 included 46 articles and found an NNB ranging from 2.2 to 287. The weighted mean NNB was 15.6.[9] The NNB partly depends on the prevalence of MM in the patient population and on the performers' ability to distinguish MM from other skin conditions. Theoretically, when TS is introduced in MM diagnostics, this may lower the NNB.

2 | MATERIAL AND METHODS

This study aims to determine the diagnostic accuracy of TS for detecting MM in clinically suspicious pigmented lesions. A meta-analysis was made to examine the test's accuracy by comparing the existing studies. The primary outcomes are sensitivity and specificity for the index test TS. This systematic review based on PRISMA guidelines is registered through PROSPERO (CRD42022312716).

The inclusion criteria of this study were the index test "TS" and analysis of the tissue on tape. The reference standard was skin biopsy and histopathological examination. The target disease was MM. Studies were on patients with pigmented lesions or lesions clinically suspicious of MM and included details on true positives, true negatives, false positives, and false negatives. Articles were in Danish, English or German. The exclusion criteria of this study were animal and ex vivo studies and articles in other languages.

On 14 September 2022, literature searches were performed on PubMed, Web of Science and Embase to retrieve studies on TS and MM. Reference lists were manually searched for additional studies to include. The search was performed according to PRISMA guidelines.[10] The MeSH and Emtree terms "melanoma" and the word "melanoma" were combined with the terms: TS, adhesive patch(es), PLA or epidermal genetic information retrieval (EGIR). Two authors (Ida Marie Nedergaard Thomsen and Mette Mogensen) screened the articles and agreed on which articles should be included in this review.

The following data from the included studies were extracted: information on lesions, index test, reference standard, true positive, true negative, false positive, false negative, population characteristics, study details and setting. Two authors (Ida Marie Nedergaard Thomsen and Ida M. Heerfordt) independently extracted data from the included studies, registering all data in Microsoft Excel ver. 16.66.1 (22101101).

Only data on the true negative, true positive, false negative and false positive were used in the review to guarantee sensitivity, specificity and 95% confidence interval (95% CI) were identically calculated. Sensitivity, specificity and 95% CI were calculated in the statistical software "R Studio" (ver. 1.4.11.06). The calculations from R studio are shown in Supplementary 1.

QUADAS-2 tool was used to judge the Risk of Bias and Applicability. Two authors (Ida Marie Nedergaard Thomsen and Ida M. Heerfordt) independently performed the judgement and if disagreement between reviewers, they would discuss the different evaluations. A summary was made to visualise the Risk of Bias and Applicability judgement.[11]

3 | RESULTS

Figure 1 shows a PRISMA flow diagram of the search results. Fifty-two articles met the inclusion/exclusion criteria. Fourteen hits were meeting, or conference abstracts and no articles were found. Sixteen

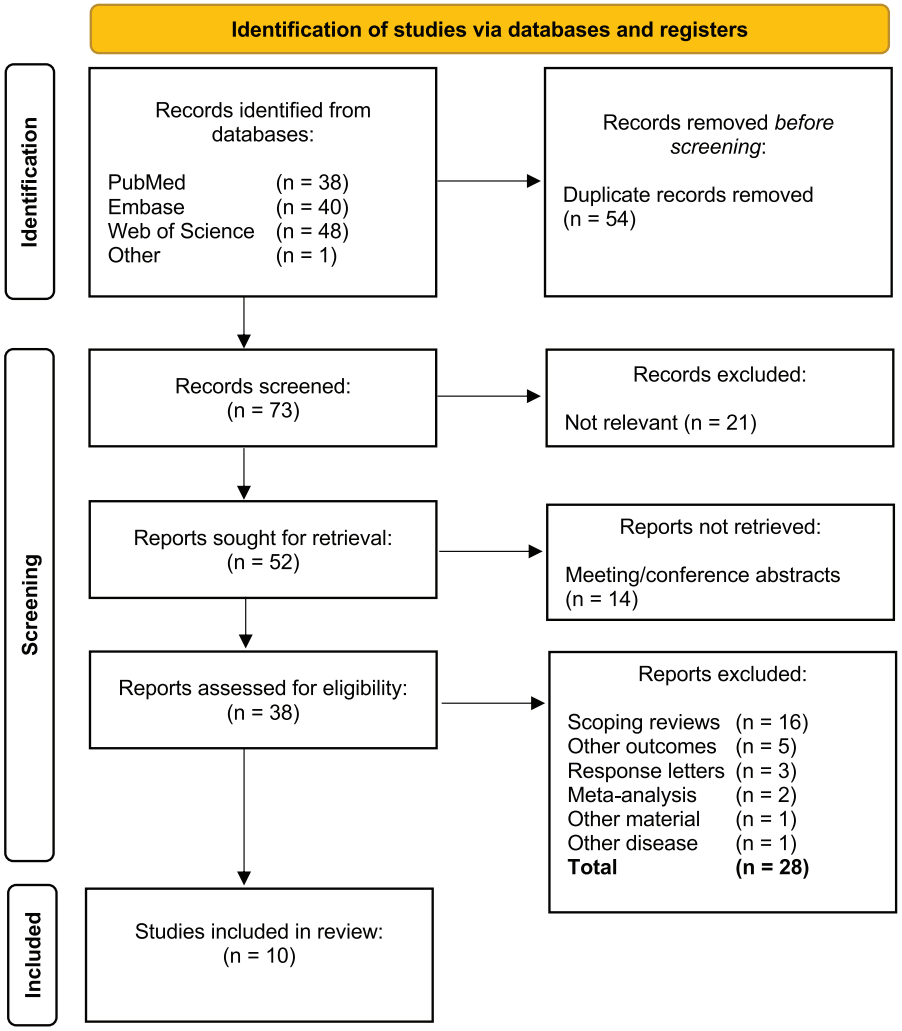

FIGURE 1 PRISMA Flow diagram.

hits were scoping reviews, and TS of MM was only mentioned in short.[5,7,12–25] Five articles had other outcomes where sensitivity and specificity were not examined.[26–30] Three articles were "response letters" to other articles with no relevant data.[31–33] One article used formalin-fixed paraffin-embedded tissue block samples instead of in vivo skin on patients,[34] and one article examined melasma instead of MM.[35] The last two articles consisted of an article which analysed another article's data,[36] and an article which was "A Health Technology Assessment".[37] In total, 28 articles were excluded, and ten articles were included in this review.

The extracted data were combined into five categories, as shown in Table 1. One study separated their data and had two datasets: TS+ and TS-.[38] These two datasets were combined in the review to calculate sensitivity and specificity. Four studies showed results from when they made the index test and when they validated the index test.[6,39–41] The results used in this review are the results from the test validations.

All ten studies included data on the true negative, true positive, false negative, and false positive.[6,38–46] Sensitivity ranged from the lowest 68.8% (95% CI 51.5, 82.1)[46] to the highest 100% (95% CI 91.0, 100).[6] Two other studies also had a sensitivity of 100% but with a wider 95% CI.[42,45] Specificity ranged from the lowest 69.1% (95% CI 63.8, 74.0)[40] to the highest 100% (95% CI 78.5, 100).[42] All included studies tested the lesions with tape strips,[6,38–46] and the results are shown in Table 1. Nine studies examined RNA markers,[6,38–45] and one examined the cells using exfoliative cytology.[46] One study tested for 17 MM RNA markers to determine if the suspected lesions were melanoma.[6] Another study tested the lesions for two RNA markers: overexpression of LINC00518 and downregulation of CMIP.[39] A third study made a test that tested for overexpression of two RNA markers: LINC00518 and PRAME.[41] The same two RNA markers were used in the remaining six studies.[38,40,42–45] One study called their test EGIR).[6] and another study called their test "Adhesive patch method".[39] Seven studies all called their test Pigmented lesion Assay "PLA".[38,40–45] In all nine RNA marker studies, the tests were analysed at the same American company, and all used four patches per lesion for the analysis.[6,38–42,44,45] The exfoliative cytology study called their test "TS toluidine blue". They used one tape strip per lesion and analysed the tests in their own lab.[46]

Skelsey et al. included the most (1546 lesions),[38] and Shah et al. included the least (20 lesions).[42] Gerami et al. performed biopsies on

TABLE 1 Extracted data and results.

		Skelsey et al., 2021		Shah et al., 2019	Hornberger et al., 2018	Ferris et al., 2018	Ferris et al., 2017[a]	Gerami et al., 2017	Yao et al., 2016	Gerami et al., 2014	Wachsman et al., 2011	Berardi et al., 1992
Index test	**Genes tested**	2		2	2	2	2	2	2	2	17	0
	Name of genes	LINC00518 + PRAME		LINC00518 + PRAME	LINC00518 + PRAME	LINC00518 + PRAME	LINC00518 + PRAME	LINC00518 + PRAME	LINC00518 + PRAME	LINC00518 + CMIP	LINC00518, CMIP, PRAME + 14 genes	-
	Name of method	PLA		PLA	PLA	PLA	PLA	PLA	PLA	Adhesive patch method	EGIR	TSTB
	Location of analysis	USA[b]		USA[b]	USA[b]	USA[b]	USA[b]	USA[b]	USA[b]	USA[b]	USA[b]	Italy
	Patch pr. lesion	4		4	N/A	4	4	4	4	4	4	1
Reference standard and lesions	**Total lesions**	**TS- 1233**	**TS+ 313**	**20**	**319**	**381**	**60[a]**	**398**	**73**	**64**	**128**	**150**
	Assummed non-melanoma[c]	1223	-	14	288[d]	329[e]	-	-	42[f]	-	-	-
	Total biopsies	10	313	6	42	55	60[a]	398	73	64	128	150
	Histopathologic melanoma	10	59	6	15	20	8[a]	87	31	42	39	32
	Histopathologic nevus	N/A	213	N/A	14	28	44[a]	253	N/A	21	89	98
	Other histopathological diagnosis	N/A	41 (keratoses and scars after biopsy)	N/A	2	4 seborrheic or actinic keratoses	8 (5 lentigines, 3 keratoses)[a]	58 (seborrheic keratosis, lentigo simplex BBC and fibrosis)	N/A	1	0	20 (1 lentigo simplex, 7 seborrhoeic keratosis, 5 BCC, 7 other)
	Location on body	N/A	N/A	N/A	N/A	N/A	N/A	Info	N/A	Info	Info[b]	N/A

(Continues)

TABLE 1 (Continued)

		Skelsey et al., 2021		Shah et al., 2019	Hornberger et al., 2018	Ferris et al., 2018	Ferris et al., 2017[a]	Gerami et al., 2017	Yao et al., 2016	Gerami et al., 2014	Wachsman et al., 2011	Berardi et al., 1992
Accuracy	**True positive**	59		6	14	19	8	79	22	41	39	22
	True negative	1223		14	279	329	46	215	37	16	76	115[g]
	False negative	10		0	1	1	0	8	9	1	0	10[h]
	False positive	254		0	25	32	6	96	5	6	13	3
	Sensitivity (95% CI)	85.5 (75.3; 91.9)		100 (61.0; 100)	93.3 (70.1; 98.8)	95.0 (76.4; 99.1)	100 (67.6; 100)	90.8 (82.9; 95.3)	71.0 (53.4; 83.9)	97.6 (87.6; 99.6)	100 (91.0; 100)	68.8 (51.5; 82.1)
	Specificity (95% CI)	82.8 (80.8; 84.6)		100 (78.5; 100)	91.8 (88.2; 94.4)	91.1 (87.7; 93.6)	88.5 (77.1; 94.6)	69.1 (63.8; 74.0)	88.1 (75.0; 94.8)	72.7 (51.8; 86.8)	85.4 (76.6; 91.3)	97.5 (92.9; 99.2)
Study details and Setting	**Type of study**	Cohort study	CSS	Case report	Registry study (CSS)	Registry study (CSS)	CSS	CSS	CSS	CSS	CSS	CSS
	Eligibility criteria	N/A	N/A	N/A	N/A	N/A	N/A	Info	N/A	Info	Info	N/A
	Follow-up time (if no biopsy)	36 months	-	3-6 months	3-6 months	3-6 months	-	-	-	-	-	-
	Samples collected	Aug 2017 - Aug 2018	July 2018 - June 2019	N/A	N/A	May 2016 - June 2017 PLA(+)	N/A	N/A	N/A	2004 - 2010 DermTech	N/A	Sep 1990 - Sep 1991
	Conflic of interest	Yes	Yes	No	Yes[i]	Yes[i]	Yes	Yes[i]	Yes[i]	Yes[i]	Yes[i]	N/A
	Samples collected	5 clinical sites (USA)	53 practices (USA)	Pigmented lesion clinic (USA)	2 derm. sites (USA)	4 derm. sites (USA)	N/A[a]	28 derm. sites (USA, Europe and Australia)	N/A	Derm. sites (USA 18, Europe 2 and Australia 1)	USA	Italy (Dept. of Dermatology)

(Continues)

TABLE 1 (Continued)

		Skelsey et al., 2021		Shah et al., 2019	Hornberger et al., 2018	Ferris et al., 2018	Ferris et al., 2017[a]	Gerami et al., 2017	Yao et al., 2016	Gerami et al., 2014	Wachsman et al., 2011	Berardi et al., 1992
Population characteristics	**Total patients**	1233	N/A	1	N/A	381	N/A	398[j]	N/A	64	N/A	142
	Median/mean age (year)	N/A	Median: 48	64	N/A	N/A	N/A	Median: 49	N/A	Mean: 48.4%[k]	Mean: 52.9[l]	Mean: 29
	Age range (year)	N/A	N/A	-	N/A	N/A	N/A	19-97	N/A	18-83	19-95[l]	(2-91)
	Male/Female	N/A	39.2%/60.8%	1/0	N/A	N/A	N/A	218/179	N/A	42/22	42%/58%[l]	49/93

[a]Lesions from the same pool of patients as Gerami et al., 2017.
[b]Test analysed at the same American company.
[c]Assummed non-melanoma if no biopsy was performed at follow-up.
[d]11 lesions had a histopathological diagnosis "non-melanoma".
[e]Three lesions had a histopathological diagnosis "non-melanoma".
[f]42 lesions had a histopathological diagnosis "non-melanoma".
[g]27 non-significant, 78 true-negative.
[h]Seven non-significant, three true-negative.
[i]Funded/partly funded by the same American company.
[j]One patient with no male/female information.
[k]Calculated using multiple means.
[l]Info both validation set and training set.
Abbreviations: BCC, basal cell carcinoma; CSS, cross-sectional study; derm, dermatology; EGIR, epidermal genetic information retrieval; N/A, not available; PLA, pigmented lesion assay; TSTB, tape stripping toluidine blue.

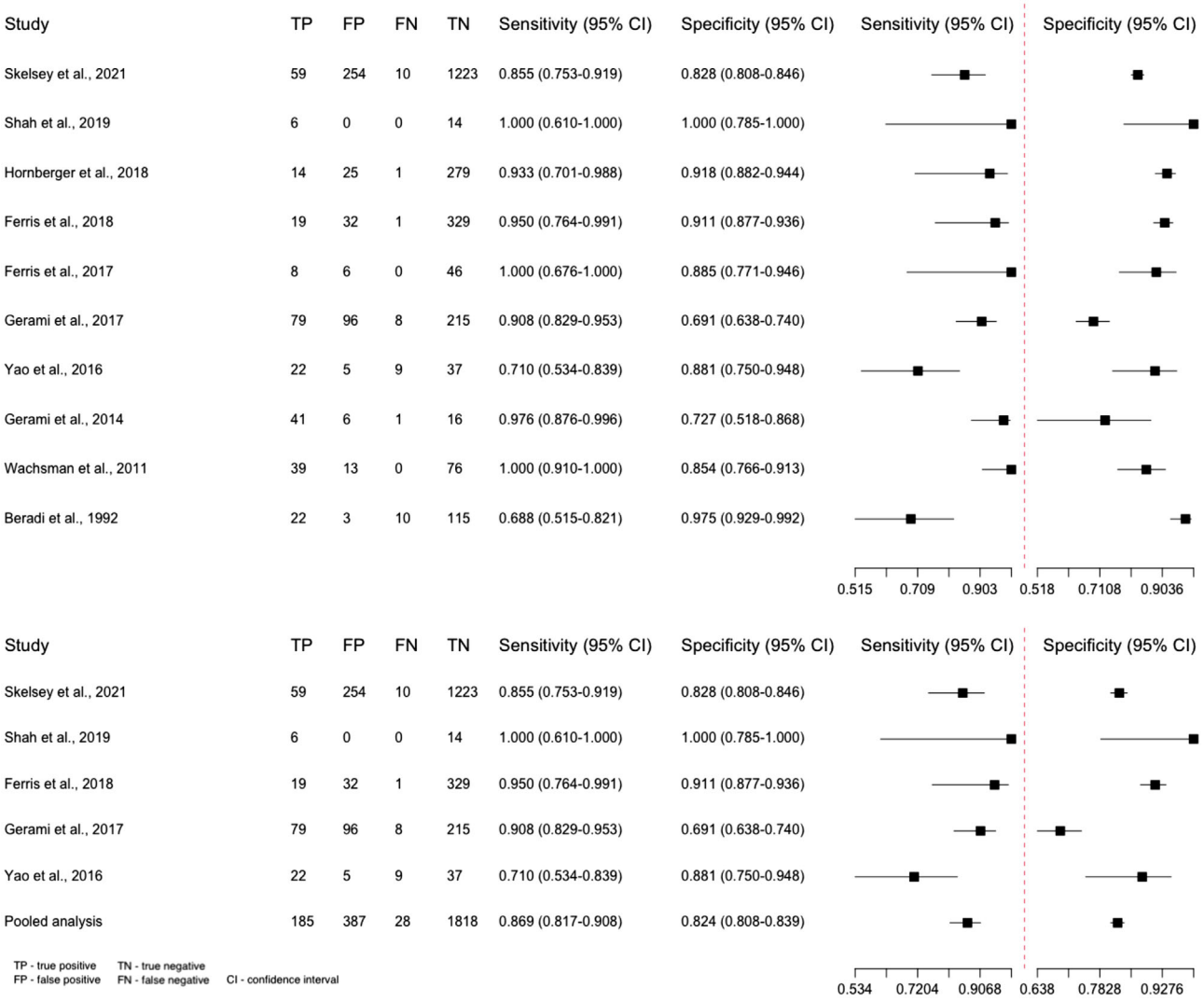

FIGURE 2 Forest plots of tape stripping—all included studies and a pooled analysis.

398 lesions and was the study with the most biopsied lesions.[40] All studies had information on how many melanomas were biopsied.[6,38–46] Eight studies demonstrated data on how many nevi and other skin lesions were biopsied,[6,38–40,43–46] including actinic keratoses, seborrheic keratoses, fibrosis, basal cell carcinoma and lentigo simplex. Only three studies had information on the tested lesions' location on the body.[6,39,40]

All ten studies examined the accuracy of TS. Nine articles did a cross-sectional study,[6,38–41,43–46] and one article did a case report.[42] Three studies had information on inclusion and exclusion criteria[6,39,40] and are shown in Supplementary 2.

Nine studies had data on the country of sample retrieval. In one study, the samples were from Italy.[46] Five studies had samples from The United States.[6,38,42–44] Three studies had samples from Australia, The United States, and Europe.[39,40,45] Eight studies had information on the place of the test: a dermatology site.[38–40,43–46] Only one study wrote that dermatologists chose the lesions.[40] No studies had data on who did the TS, for example, doctors or trained staff. Four articles had information on when samples were collected.[38,39,44,46] The collection time for the four studies did not overlap. Three studies did not biopsy all lesions tested. Instead, TS-lesion patients had follow-up appointments.[38,42–44] Three studies had a follow-up period of 3–6 months,[42–44] and one study had a follow-up period of 36 months.[38]

Eight studies have a potential conflict of interest (COI) as they are all associated with the same American company.[6,38–41,43–45]

Six studies had information on the patient's age and sex.[6,38–40,42,46] One study only had data on TS+ patients.[38] In three of these six studies, most patients were female,[6,38,46] and in the three other studies, the majority were male.[39,40,42] The mean age of the included patients ranged from 29[46] to 52.9 years.[6] The case report included one patient, who was 64 years old.[42] In two studies, the median ages were 48[38] and 49 years,[40] respectively. In one study, patients under 18 years were included.[46]

A meta-analysis of two forest plots shows the sensitivity and specificity of all the included studies and pooled analysis of five included studies (Figure 2). The pooled analysis includes studies that used the

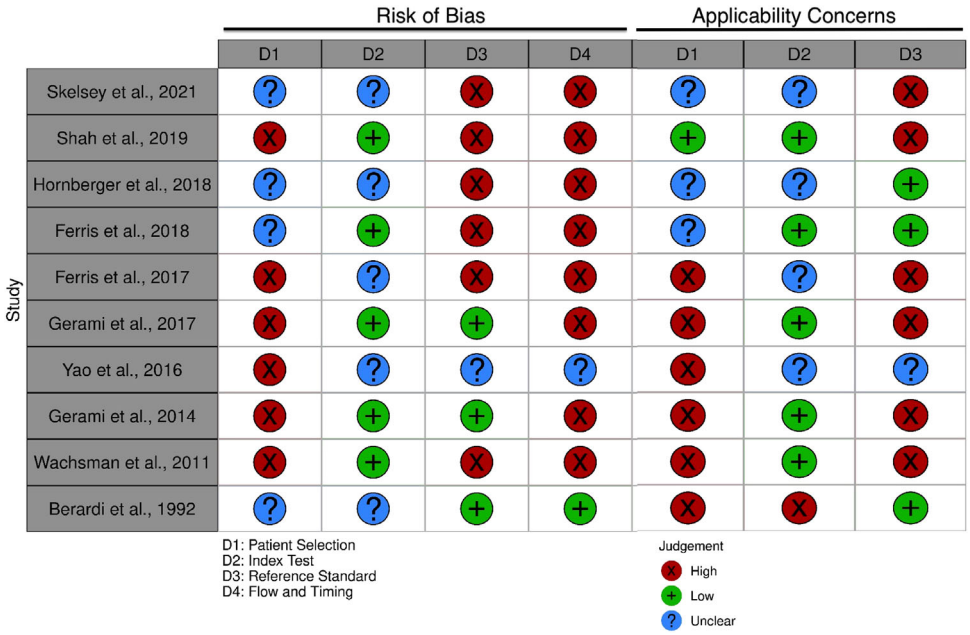

FIGURE 3 Risk of bias and applicability concerns summary.

RNA markers LINC00518 and PRAME.[38,40–42,44] Two studies were not included in the analysis because there was a risk of the same lesions being included twice.[43,45] The pooled analysis found a sensitivity of 86.9% (95% CI 81.7, 90.8) and specificity of 82.4% (95% CI 80.8, 83.9).

The Risk of Bias and Applicability results are demonstrated in Figure 3. If lesions were not randomly selected, the standard reference was not the same for every lesion and all patients were not included in the analysis, the studies scored high.

4 | DISCUSSION

We examined the diagnostic accuracy of TS to detect MM. The meta-analysis suggests moderate sensitivity and specificity and the Risk of Bias and Applicability results display low quality of the included studies, especially on patient selection, reference standard and "flow and timing".

TS must have high sensitivity to ensure the test diagnoses all MM. At the same time, it is crucial that TS also obtains high specificity to avoid unnecessary biopsies and excisions. The pooled analysis of the "PLA" test had a sensitivity of 86.9% (95% CI 81.7, 90.8) and a specificity of 82.4 % (95% CI 80.8, 83.9). In contrast, the "EGIR" test had a sensitivity of 100 (95% CI 91.0, 100) and a specificity of 85.4% (95% CI 76.6, 91.3).[6] As the PLA test is commercially available, it is essential to encourage independent studies exploring which RNA markers have the highest diagnostic accuracy for the diagnosis of MM.

Only one study of TS and exfoliative cytology is included in the review. Even though the method can distinguish MM from nevi, the demonstrated RNA analysis is more accurate.

The studies lacked information, especially on population characteristics and settings. An example was the number of patients; four papers did not write how many patients were included in their studies.[6,41,43,45] The RNA markers may vary from patient to patient; therefore, some patients' melanoma and skin types may be better to test with TS than others. Of the six papers that did have information on the number of included patients,[38–40,42,44,46] one paper only had partial information on the number of patients included. Four studies had the same number of lesions as patients.[38–40,44] One study had one patient and 20 lesions[42] and one study had 142 patients and 150 lesions, which suggests some patients had more than one lesion tape-stripped.[46]

Shah et al. included the lowest number of patients, as it was a case report with one patient[42] and Skelsey et al. included the highest number of patients, with at least 1233 patients.[38]

Six studies had a reference standard (histopathological examination) for every included lesion.[6,39–41,45,46] A limitation of the four most recent studies is the lack of histopathological examination for TS-lesions. Instead, they did a follow-up after 3–36 months and assumed that TS-lesions not biopsied at follow-up were true negatives.[38,42–44] When studies do not have the same standard reference, the studies get a high risk of bias.

Details on who performed the TS were missing in all the included studies, and only one study specifically stated the lesions were selected by a dermatologist.[40]

There is a potential risk of overlap of patients. One study[45] used lesions from the same pool of patients as another study.[40] Two studies are registry studies.[43,44] Both studies had one lesion that tested TS- and was biopsied the same day. This was not the typical procedure for their studies when a lesion tested negative. It could be the same lesion and perhaps an overlap in patients in the studies. There is an additional risk of patient overlap as two studies are registry studies, and six studies do not have information on when patients were included.

As the quality of the included studies is low, the reliability of sensitivity and specificity is questionable. Some of the studies show high sensitivity.[6,39,42,45] However, the pooled analysis indicates moderate sensitivity. New studies with no COI and transparent population selection, characteristics and settings are required. All included lesions should undergo a biopsy to find a more reliable sensitivity and specificity in future studies.

Most of the studies included are conducted in the United States, with only a few patients from Europe and Australia. Australia and New Zealand (NZ) in 2020 had the most diagnosed MM pr. 100 000 citizens worldwide, followed by western Europe.[47] A new prospective cohort study from Denmark is being conducted, but more studies are needed in Europe and Australia/NZ to assess regional differences and ensure the test works on European and Australian/NZ skin.[48]

No randomised control trials have yet been made to find the difference between TS and no TS and how it affects the patient's prognosis, which would be very relevant.

Included papers present TS as a supplement to the already established evaluation of clinically suspicious lesions (visual inspection, dermoscopy and clinical photography).[42] The test should be used for the "clinically ambiguous lesions" and not "definitive melanomas".[38] The proportion of diagnosed TS+ lesions should therefore be in situ or pT1a MM. One of the included papers studied how dermatologists' mean biopsy sensitivity and specificity improved when TS was incorporated into their decision on when or when not to biopsy. Mean biopsy sensitivity improved from 95.0% to 98.6% ($p = 0.01$) and specificity increased from 32.1% to 56.9% ($p < 0.001$).[45] As the histopathological examination is still the golden standard, TS will not likely replace MM's standard diagnostics. Another non-invasive method to combine with TS would be reflectance confocal microscopy which offers bedside in vivo microscopy of suspicious lesions with moderate to high diagnostic accuracy and a reduction of numbers needed to excise by 43% shown in a randomized diagnostic trial of more than 3000 patients.[49]

5 | CONCLUSION

As the overall quality of the included studies is low, the reliability of sensitivity and specificity is questionable. Some of the studies show high sensitivity and specificity. The pooled analysis indicates moderate sensitivity and specificity. The pooled analysis examines RNA markers LINC00518 and PRAME and found a sensitivity of 86.9% (95% CI 81.7, 90.8) and specificity of 82.4% (95% CI 80.8, 83.9). TS with RNA markers is more accurate than exfoliative cytology. Lastly, TS should be done by a person with knowledge of skin cancers to only test lesions where MM is suspected.

CONFLICT OF INTEREST

None declared.

FUNDING INFORMATION

The authors received no financial support for the research, authorship, and/or publication of this article.

DATA AVAILABILITY STATEMENT

All the data for this study will be made available upon reasonable request to the corresponding author.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Thomsen IMN, Heerfordt IM, Karmisholt KE, Mogensen M. Detection of cutaneous malignant melanoma by tape stripping of pigmented skin lesions – A systematic review. *Skin Res Technol*. 2023;29:e13286. https://doi.org/10.1111/srt.13286