

Impact of dermoscopy and short-term sequential digital dermoscopy imaging for the management of pigmented lesions in primary care: a sequential intervention trial

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Summary

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At the commencement of the trial S.W.M. was a paid consultant for the manufacturer of the SDDI device, Polartechnics Ltd.

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Background Studies have shown the benign to malignant ratio of excised pigmented skin lesions is suboptimal in primary care.

Objectives To assess the impact of dermoscopy and short-term sequential digital dermoscopy imaging (SDDI) on the management of suspicious pigmented skin lesions by primary care physicians.

Methods A total of 63 primary care physicians were trained in the use of dermoscopy and SDDI (interventions) and then recruited pigmented lesions requiring biopsy or referral in routine care by naked eye examination. They were then given a dermatoscope and the option of a SDDI instrument, and change of diagnosis and management was assessed.

Results Following the use of the interventions on 374 lesions a total of 163 lesions (43.6%) were excised or referred, representing a reduction of 56.4%. Of the 323 lesions confirmed to be benign, 118 (36.5%) were excised or referred, leading to a reduction of 63.5% ($P < 0.0005$) in those requiring excision or referral. The baseline naked eye examination benign to melanoma ratio was 9.5 : 1 which decreased to 3.5 : 1 after the diagnostic interventions ($P < 0.0005$). Of the 42 malignant lesions included in the study (34 melanoma, six pigmented basal cell carcinoma and two Bowen disease) only one in situ melanoma was incorrectly managed (patient to return if changes occur) resulting in the correct management of 97.6% and 97.1% of malignant pigmented lesions and melanoma, respectively.

Conclusions In a primary care setting the combination of dermoscopy and short-term SDDI reduces the excision or referral of benign pigmented lesions by more than half while nearly doubling the sensitivity for the diagnosis of melanoma.

The age-standardized incidence rate of primary melanoma of the skin continues to rise in most countries. Associated with the increased incidence has been the increase in the cost to the healthcare system of excising skin lesions; in Australia these costs increased threefold between 1984 and 1995.^{1,2} Diagnostic efficiency can be measured in terms of the ratio of

benign to malignant lesions that are removed. Based on Australian 1995 Medicare data this ratio was 1.2 : 1 for non-melanoma skin cancer, while for pigmented lesions (melanoma and its benign differential diagnoses including moles and seborrhoeic keratoses) it was 34 : 1.² A large prospective randomized trial in Australia in 2002 reported that 468

general practitioners (GPs) in Perth, the capital of Western Australia, had a ratio of baseline benign pigmented lesions (BPL) to melanoma of 20 : 1.³

Dermoscopy (surface microscopy, oil epiluminescence microscopy, dermatoscopy) is a technique that uses a hand-held magnifying device combined with either the application of a liquid between the transparent plate of the device and the skin, or the use of cross-polarized light. This technique allows the visualization of diagnostic features of pigmented skin lesions that are not seen with the naked eye.^{4,5} Meta-analyses performed on studies in a variety of clinical and experimental settings have shown that dermoscopy improves diagnostic accuracy for melanoma.^{6–8} Two studies in a specialist setting showed reduced rates of excision of benign lesions using dermoscopy (reduced benign to malignant ratio of excised lesions and reduction of patients referred to biopsy) and provide indirect evidence for improved specificity.^{9,10} While there are few studies on dermoscopy in general practice, all three that were undertaken show a consistently improved sensitivity for the diagnosis of melanoma or the identification of suspicious lesions requiring biopsy.^{11–13} However, in these studies, there was no evidence of an improvement of diagnostic specificity^{11,12} or improved management (reduced referral or biopsy) of benign lesions.¹³

Sequential digital dermoscopy imaging (SDDI) involves the capture and assessment of successive dermoscopic images of melanocytic lesions (moles or melanoma), separated by an interval of time to detect suspicious change. This is performed in two settings: short-term SDDI over a period of 3 months (range 1.5–4.5 months) for suspicious melanocytic lesions, and long-term monitoring for standard surveillance (usually at intervals of 6–12 months).¹⁴ Studies conducted in a specialist setting consistently show that SDDI allows the detection of melanomas that lack dermoscopic evidence of malignancy.^{14–19} In one prospective study of melanomas diagnosed by a variety of clinical means, 34% were detected using the changes detected by SDDI exclusively and were without dermoscopic features of melanoma.¹⁷ Long-term SDDI is generally used in the surveillance of high-risk patients, usually with multiple dysplastic naevi. In contrast, short-term SDDI of individual suspicious moles can be used in any patient setting.

We hypothesized that the combination of dermoscopy and short-term SDDI would significantly reduce the excision or referrals of pigmented lesions in a primary care setting. As dermoscopy has been shown to improve the diagnostic sensitivity for melanoma in general practice, and SDDI allows detection of dermoscopic featureless melanoma, we also hypothesized that the reduction of excision or referrals of pigmented lesions would occur without a detrimental effect on the detection of melanoma.

Materials and methods

Design overview

The study was a sequential intervention trial using within-lesion controls (allowing a paired analysis) in patients seen

in routine care from general practices in metropolitan Perth, Western Australia. The trial was managed from the coordinating centre at the Discipline of General Practice, School of Primary, Aboriginal and Rural Health Care, University of Western Australia. Ethics approval for this study was obtained from the University of Western Australia Human Research Ethics Committee. The trial was registered at the Australian Clinical Trials Register ACTRNO12605000031662.

Patient recruitment ran from December 2005 to August 2006. Following informed written consent from the patient, the GP recorded the site of the lesion and the initial diagnosis, confidence of diagnosis (scale 1 to 10; 1 not at all confident and 10 extremely confident), certainty of melanoma (scale 0 to 100%; 0 definitely not melanoma and 100 definitely melanoma) and management (biopsy, referral). This data sheet was then placed in a sealed envelope before proceeding to dermoscopy examination. In most cases separation of clinical decision-making was further enforced by placing the dermatoscope and SDDI device in a separate consulting room.

Dermoscopy examination was performed with a hand-held oil immersion glass plate device (Delta 10 Dermatoscope; Heine Ltd, Herrsching, Germany). GP diagnosis and management were then recorded on a separate data sheet. Triage management options included: biopsy due to clinician concern; biopsy due to patient concern; referral due to clinician concern; referral due to patient concern; short-term SDDI; and patient to return if changes occur. All lesions were then photographed with the dermoscopy imaging device (Sentry™ pilot; Polartechnics Ltd, Sydney, Australia). This incorporated a higher resolution megapixel camera which could be used for telemedicine diagnosis and for colour-calibrated SDDI as previously described for the lower-resolution device (Solar-Scan™; Polartechnics Ltd).¹⁵

For melanocytic lesions that did not have dermoscopic evidence of melanoma but were still considered to be suspicious (suspicious pigmented lesions, SPLs), short-term SDDI using the Sentry device was performed. Patients were advised to return for a follow-up image of the lesion at 3 months. GPs were advised that any morphological change in the lesion at 3 months should result in either biopsy or referral.^{14,15,19} For monitored lesions GPs completed a third data sheet recording the diagnosis and management after SDDI.

Setting and participants

GP recruitment

GPs were recruited from practices in metropolitan Perth with a minimum of three doctors. Inclusion criteria for the GPs and practices were: a history of excision or referral of at least 10 pigmented skin lesions over the previous 12-month period for each doctor, and available space for the SDDI device. Clinicians were excluded if they already used dermoscopy or SDDI in their routine practice.

Patient recruitment

Consecutive patients were eligible for recruitment if they had a pigmented lesion (some brown, grey, blue or black colour within some part of the lesion) which, after routine naked eye examination by the GP, would have been biopsied or referred, i.e. a SPL.

Interventions

Training in dermoscopy and sequential digital dermoscopy imaging

During the pretrial period all GPs underwent a training programme in the use of dermoscopy and SDDI. This included reading a textbook in dermoscopic diagnosis and the use of SDDI,⁴ and a tutorial on a CD-rom showing examples of changed and unchanged monitored lesions. In addition, GPs attended a 2-h workshop on the use of the diagnostic devices and recruitment procedures. The training was assessed through an online pre- and posteducation intervention test of 245 lesions not seen in the textbook or the CD-rom. Answers were provided during the post-test as a component of the educational intervention.

Before formal patient recruitment began, GPs assessed at least one pretrial lesion to determine the quality of imaging with the SDDI instrument and undertake completion of trial paperwork. GPs were allowed to practise using the dermoscopy device during this pretrial phase. The pretrial phase of education and run-in period occurred from May 2005 to January 2006.

Outcomes and follow-up

The primary outcomes were the proportion of lesions biopsied or referred following the combined interventions of dermoscopy and SDDI, and the impact these diagnostic tools had on the BPL : melanoma ratio. Secondary outcomes were: the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for the diagnosis of all malignant lesions and melanoma; GPs' certainty of diagnosis for true melanoma and true nonmelanoma; their confidence of diagnosis for all lesions; and the proportion of correctly managed malignant lesions and melanoma and correctly managed benign lesions.

Statistical analysis

Sample size estimates for addressing the primary aim were based on detecting a reduction of at least 20% in the number of lesions excised or referred with 95% power and a one-sided significance of $P < 0.05$. A total of 46 lesions was required given that eligible lesions were those that would have been excised or referred on initial naked eye examination. To assess all of the secondary aims the trial was designed to have an 80% power at a two-sided significance of $P < 0.05$. The largest sample size needed was to address the secondary aim

pertaining to the combined intervention of dermoscopy and SDDI. This required 199 lesions to undergo SDDI to show a reduction in excisions or referrals from 90% after dermoscopy to 80% after SDDI.

Reference diagnosis

A reference standard final diagnosis was recorded for all lesions recruited into the trial. This was defined by the hierarchical diagnosis order of (i) histopathology, (ii) unchanged lesions after SDDI indicating a benign diagnosis,¹⁹ (iii) specialist opinion following referral and (iv) dermoscopy telemedicine. All SDDI and dermoscopy telemedicine images of nonexcised lesions (including the lesions 'observed for change') were reviewed by an expert in dermoscopy and SDDI (S.W.M.) and a diagnosis recorded. If the diagnosis of the referred specialist differed from the telemedicine diagnosis then the diagnosis was regarded as unknown. Histopathological and specialist examination occurred according to standard practice and was not necessarily blinded to the GP's diagnosis. Dermoscopy telemedicine was blinded to the GP's diagnosis.

Sensitivity and specificity for the interim diagnoses and management decisions were determined for the dermoscopy, SDDI and for the final recorded diagnosis by the GP with respect to the reference standard diagnosis. To explore any potential clustering effect, the intraclass correlation (ICC) was assessed using methods for binary outcome data.²⁰ The ICC was not significantly different from zero for any of the analyses; results are therefore presented using confidence intervals derived from the usual formulae for binomial proportions. All analyses were performed using Stata 10, 2007 (Stata Corporation, College Station, TX, U.S.A.).

Results

Primary outcomes and the effect of the interventions on management

One hundred and two GPs were initially recruited; 74 (72.5%) of these completed the educational intervention and online assessment of learning. Sixty-three clinicians (61.8% of those initially recruited) from 19 practices assessed 374 lesions. The median number of lesions per GP was six (mean 5.9, SD 3.0). Figure 1 describes the management of the lesions after each examination and their final diagnosis.

The 374 SPL included in this study were all assessed as requiring excision or referral, based on clinical assessment with the naked eye. The use of dermoscopy alone reduced the number of SPL requiring immediate excision or referral by 72 lesions, a reduction of 19.3% [95% confidence interval (CI) 15.4–23.6%] (Fig. 1).

Without the availability of SDDI it is likely that most of the 192 SPL triaged to SDDI (Fig. 1) would have been immediately excised or referred. Therefore the availability of both dermoscopy and SDDI to the GP reduced the immediate excision or referral of SPL from 374 to 110, a 70.6% reduction.

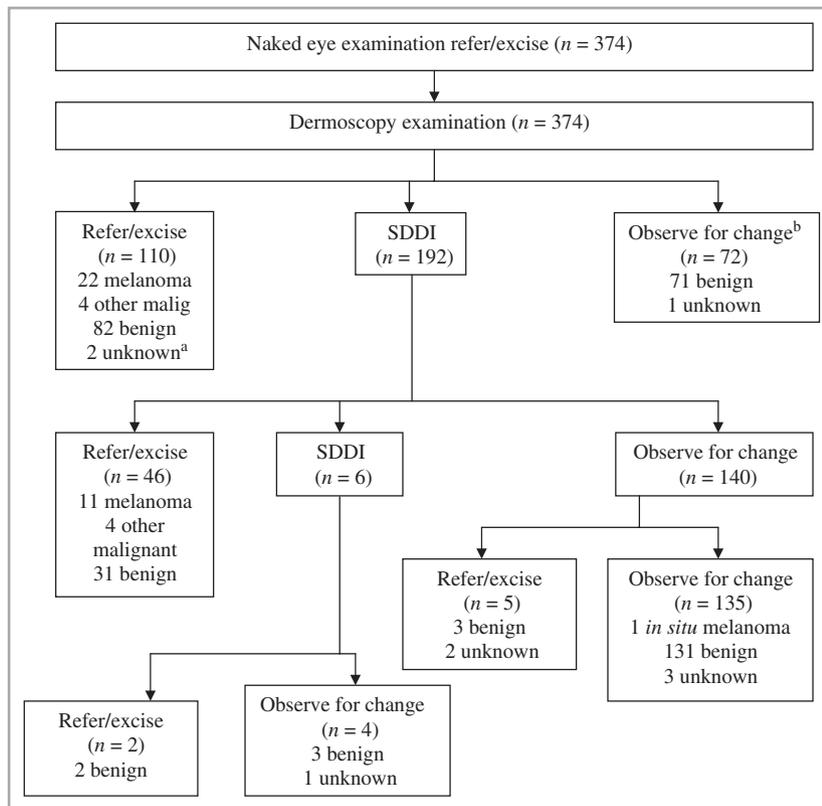


Fig 1. Trial profile. A total of 374 lesions were assessed for referral or excision. Following the diagnostic interventions only 163 (110 + 46 + 5 + 2) lesions (43.6%) were referred or excised, with 211 (72 + 135 + 4) lesions (56.4%) observed. The median Breslow thickness of all melanoma was in situ (range: in situ to 7 mm). There was no significant difference between the median Breslow thickness of melanoma undergoing sequential digital dermoscopy imaging (SDDI) (median 0.10 mm; range in situ to 0.65 mm) compared with those excised/referred (median in situ, range in situ to 7 mm) ($P = 0.45$). The final diagnosis was made according to the 'reference diagnosis' procedure (see Materials and methods). ^aUnknown diagnoses: four cases with no pathology results received following excision and five cases of uncertain diagnosis with telemedicine (poor quality images; patient failed to attend for follow-up imaging). ^bThe patient was told to observe the lesion for change and no further follow-up arranged.

Following the use of both intervention instruments (dermoscopy with or without SDDI) a total of 163 SPL (43.6%) of the 374 lesions were eventually excised or referred, representing a reduction of 56.4% (95% CI 51.2–61.5%) in SPL requiring excision or referral (Fig. 1).

Of the 323 lesions confirmed to be benign (excluding the 42 malignant lesions and nine lesions with unknown diagnosis), 118 (36.5%) were excised or referred, leading to a reduction of 63.5% (95% CI 58.0–68.7%) in those requiring excision or referral ($P < 0.0005$). Of the 42 malignant lesions (34 melanoma, six pigmented basal cell carcinoma and two Bowen disease), there was one in situ melanoma incorrectly managed (observation to return if changes noted). Therefore 97.6% of malignant pigmented lesions (95% CI 87.7–99.9%) and 97.1% of melanoma (95% CI 84.7–99.9%) were correctly managed, and the triage action of 'observation to return if changes noted' for presumed benign lesions worked as planned. There were no significant differences between correctly managed malignant lesions ($P = 0.35$) or melanoma ($P = 0.32$) compared with naked eye examination.

The BPL : melanoma ratio for naked eye examination was 323 : 34 or 9.5 : 1 (Fig. 1). Use of dermoscopy alone identified 110 SPL that required immediate excision or referral, resulting in a BPL : melanoma ratio of 82 : 22 (3.7 : 1) for these SPL ($P = 0.001$) (Fig. 1), a 2.6-fold reduction in this ratio compared with the naked eye assessment. SDDI eventually identified 48 SPL that required excision or referral, including one-third of detected melanomas (Fig. 1), resulting in a BPL : melanoma ratio of 33 : 11 (3.3 : 1) for these SPL, an

almost threefold reduction in this ratio compared with the naked eye assessment ($P = 0.002$).

In total, the BPL : melanoma ratio for excised/referred lesions was 323 : 34 (9.5 : 1) at baseline recruitment compared with 115 : 33 (3.5 : 1) following excision or referral consequent on dermoscopy and SDDI ($P < 0.0005$).

Other secondary outcomes

When comparing the initial naked eye diagnosis with the final diagnosis (using dermoscopy with or without SDDI) there was a near doubling in sensitivity for the diagnosis of melanoma (37.5% vs. 71.9%), a significant 16% increase in confidence of diagnosis and a significant increase in the certainty of melanoma for the true melanoma lesions (Table 1).

While there was no significant difference in specificity for the diagnosis of melanoma following the diagnostic interventions there was a significant improvement in the certainty of nonmelanoma and a significant 21% increase in the confidence of diagnosis in the true nonmelanoma skin lesions (Table 1).

When comparing the initial naked eye diagnosis with the dermoscopy diagnosis, there were nonsignificant improvements in the sensitivity (42% increase) and specificity for the diagnosis of melanoma (Table 1). However, there was a significant improvement in the confidence of diagnosis of both true melanoma (17% increase) and true nonmelanoma (16% increase) (Table 1).

When comparing the naked eye diagnosis with the SDDI diagnosis (for only those lesions that subsequently underwent

Table 1 The effect of the combination of dermoscopy alone and dermoscopy with or without sequential digital dermoscopy imaging (final outcome) on correct diagnosis and confidence of diagnosis of pigmented lesions compared with naked eye examination

Outcome	Naked eye	Dermoscopy	Final outcome
Diagnosis, % (95% CI)			
All malignant (n = 339)			
Sensitivity	40.0 (24.9–56.7)	55.0 (38.5–70.7) (P = 0.179)	67.5 (50.9–81.4) (P = 0.014)
Specificity	84.6 (80.0–88.5)	89.0 (84.9–92.3) (P = 0.116)	86.6 (82.2–90.3) (P = 0.484)
PPV	25.8 (15.5–38.5)	40.0 (27.0–54.1) (P = 0.090)	40.3 (28.5–53.0) (P = 0.071)
NPV	91.3 (87.4–94.4)	93.7 (90.2–96.2) (P = 0.209)	95.2 (92.0–97.4) (P = 0.070)
Melanoma ^a (n = 331)			
Sensitivity	37.5 (21.1–56.3)	53.1 (34.7–70.9) (P = 0.295)	71.9 (53.3–86.3) (P = 0.006)
Specificity	84.6 (80.0–88.5)	89.0 (84.9–92.3) (P = 0.116)	86.6 (82.2–90.3) (P = 0.484)
PPV	20.7 (11.2–33.4)	34.0 (21.2–48.8) (P = 0.120)	36.4 (24.7–49.6) (P = 0.055)
NPV	92.7 (88.9–95.65)	94.7 (91.3–97.0) (P = 0.336)	96.6 (93.7–95.4) (P = 0.041)
Certainty of melanoma, % (95% CI)			
True melanoma (n = 32)	34.5 (25.3–43.8)	45.9 (34.4–57.4) (P = 0.12)	51.7 (40.9–62.54) (P = 0.02)
True nonmelanoma (n = 317)	17.6 (15.3–19.6)	15.1 (12.7–17.5) (P = 0.12)	14.1 (11.1–16.2) (P = 0.02)
Confidence of diagnosis, mean (95% CI)			
All lesions (n = 352)	6.3 (6.1–6.5)	7.2 (7.0–7.4) (P < 0.0005)	7.5 (7.3–7.7) (P < 0.0005)
True melanoma (n = 33)	5.8 (5.2–6.4)	6.8 (6.2–7.4) (P = 0.002)	6.7 (6.0–7.3) (P = 0.049)
True nonmelanoma (including BCCs and BD) (n = 319)	6.3 (6.1–6.5)	7.3 (7.0–7.5) (P < 0.0005)	7.6 (7.4–7.8) (P < 0.0005)

Nine lesions with unknown diagnoses were removed from this analysis. To ensure comparability between measures for the diagnostic outcomes only lesions with a diagnosis recorded at each examination have been included.

^aLesions with a final diagnosis of basal cell carcinoma (BCC) or Bowen disease (BD) were excluded from this analysis.

CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

SDDI) the sensitivity for the diagnosis of melanoma increased by 300% without significant difference in specificity (Table 2). There was also a significant improvement in the certainty of diagnosis for true melanoma and nonmelanoma, and a 27% improvement in the confidence of diagnosis of true non-melanoma without any difference in confidence for the diagnosis of melanoma.

Discussion

Following the use of the combined diagnostic interventions of dermoscopy, with or without short-term SDDI, a 63% decrease in excision or referral of benign pigmented skin lesions was achieved. This resulted in a reduction of the BPL : melanoma excision/referral ratio from 9.5 : 1 to 3.5 : 1.

There are a number of strengths and weaknesses to the study. This study was performed in patients undergoing routine care in general practice with a very low attrition rate and

should therefore generalize to the wider clinical arena. Eligible GPs were those who excised or referred at least 10 lesions per year as these were the ones most likely to benefit from the intervention and lead to greater cost savings. Almost two-thirds (62.5%) of GPs initially recruited for the study completed the education and participated in the study, suggesting that GPs who treat one or more SPL each month are likely to be interested in this approach. The education intervention of a written text and online quiz was deliberately designed to allow potentially widespread implementation at low cost with minimal logistic constraints. However, the online education took between 10 and 20 h for most GPs in this study. This may limit the acceptability of the education intervention and capacity to train a large proportion of the total primary care workforce in these techniques.

The study design assumes that GPs applied inclusion criteria appropriately in that only those lesions that on the basis of routine clinical assessment required biopsy or referral were

Outcome	Naked eye ^a	SDDI
Diagnosis, % (95% CI)		
All malignant (n = 151)		
Sensitivity	23.1 (5.0–53.8)	69.2 (38.6–90.9) (P = 0.018)
Specificity	90.6 (84.5–94.9)	92.8 (87.1–96.5) (P = 0.514)
PPV	18.8 (4.1–45.6)	47.4 (24.4–71.1) (P = 0.076)
NPV	92.6 (85.9–95.4)	97.0 (92.4–99.2) (P = 0.109)
Melanoma ^b (n = 149)		
Sensitivity	18.2 (2.3–51.8)	72.7 (39.0–94.0) (P = 0.010)
Specificity	90.6 (84.4–94.9)	92.8 (87.1–96.5) (P = 0.514)
PPV	13.3 (1.7–40.5)	44.4 (21.5–69.2) (P = 0.053)
NPV	93.3 (87.6–96.9)	97.9 (93.5–99.5) (P = 0.083)
Certainty of melanoma		
True melanoma (n = 11)	20.0 (7.0–33.0)	40.5 (23.2–57.7) (P = 0.04)
True nonmelanoma (n = 148)	15.6 (13.0–17.9)	7.4 (4.9–10.0) (P < 0.0005)
Confidence in diagnosis, mean (95% CI)		
All lesions (n = 160)	6.2 (5.9–6.5)	7.8 (7.5–8.1) (P < 0.0005)
True melanoma (n = 10)	5.7 (4.6–6.8)	5.9 (4.2–7.6) (P = 0.82)
True nonmelanoma (including BCC and BD) (n = 150)	6.2 (5.9–6.5)	7.9 (7.6–8.2) (P < 0.0005)

^aNaked eye diagnosis was performed only with those lesions that eventually had SDDI performed. The nine lesions with an unknown diagnosis were excluded from the analysis. To ensure comparability between measures for the diagnostic outcomes only lesions with a diagnosis recorded at each examination have been included. ^bAll basal cell carcinomas (BCC) excluded from analysis.

CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value; BD, Bowen disease.

Table 2 The effect of sequential digital dermoscopy imaging (SDDI) on the diagnosis and confidence of diagnosis of pigmented lesions

included. This was confirmed by forcing GPs to record a management decision after the naked eye assessment. Furthermore, the relatively low baseline BPL : melanoma ratio would suggest GPs were not including lesions that would not have been referred or biopsied. However, a randomized controlled trial of dermoscopy, with or without SDDI, could assess whether the reduction of excision/referrals would also coincide with an improvement in the detection of melanoma. Such a trial would need to be much larger to obtain adequate power.

While the majority of melanomas are pigmented, we excluded amelanotic lesions. However, completely amelanotic melanomas are uncommon, less than 2% in the largest reported series.²¹ As it would be unethical to excise all lesions in the study, we relied on a hierarchy of clinical diagnostic procedures as a reference standard diagnosis for many lesions. While this approach is expected to be accurate, it cannot ensure the absolute sensitivity of histopathological examination.

No other study has assessed the combination of dermoscopy and SDDI in a primary care setting. Indeed only three studies have been performed in relation to dermoscopy in general practice. Two of these^{11,12} used photographic quizzes in a nonclinical setting, confirming the results of our pretrial quiz of an improvement in sensitivity but not specificity for the diagnosis of melanoma (data not shown). Only one randomized trial comparing routine naked eye examination vs. dermoscopy has been performed in primary care.¹³ This showed a significant 46% improvement in the identification of suspicious lesions in the dermoscopy arm, without any difference

in the referral of benign lesions. Our study complements this trial through the addition of short-term SDDI, which had an important effect on the correct management of benign lesions.

Only one study has assessed the combination of dermoscopy and SDDI in a specialist setting.⁹ In that study patients were randomized to either routine naked eye examination, or additional dermoscopy examination with or without access to SDDI. Dermoscopy examination led to a significant 42% reduction in patients referred for biopsy but there was no significant difference in the number of patients referred for biopsy in the dermoscopy vs. dermoscopy with SDDI arms. However, no structured education was given to the clinicians using SDDI in that trial. In contrast strict criteria for assessing short-term SDDI¹⁵ were adopted in our trial supported by recent evidence that 99.2% of suspicious melanocytic lesions which are unchanged at 3 months are benign.¹⁹

This trial is unique in that it demonstrates a large positive effect on the correct management of BPLs in primary care. Other interventions have proved disappointing. In a randomized trial of regional body photography in Australian men aged over 50 years, there was no difference in the excision rates of pigmented lesions between photographs vs. routine examination.²² In another randomized trial in Australia using a clinical diagnostic algorithm with the aid of an instant camera there was no impact on the benign to malignant ratio of excised pigmented skin lesions.³

Recently an audit of GPs undergoing an education programme which included understanding the role of dermo-

scopy for the diagnosis of pigmented lesions showed an improvement in the benign to malignant ratio of melanocytic lesions following the intervention (15 : 1 prior vs. 6 : 1 post-education).²³ In our trial the GPs had a baseline benign to melanoma ratio of 9.5 : 1 which decreased to 3.5 : 1 following the diagnostic interventions.

While the combination of dermoscopy and SDDI nearly doubled the sensitivity for the diagnosis of melanoma compared with naked eye examination, there was no significant change in specificity. However, both GPs' confidence in their diagnosis and certainty that the lesion was nonmelanoma improved following these interventions for true nonmelanoma lesions. We believe this led to the large reduction of referral and biopsy of true benign lesions.

The large improvement in sensitivity for diagnosis and management of melanoma using dermoscopy alone but no change in specificity is consistent with previous studies in primary care.^{11–13} While the diagnosis of benign lesions was not significantly different between naked eye examination and dermoscopy, again GPs' confidence in their diagnosis for these lesions was significantly increased. We believe increased confidence in benign diagnoses with dermoscopy enabled GPs to choose the alternative management strategies of observation or SDDI.

The addition of SDDI as an alternative management strategy for lesions about which GPs remain uncertain after dermoscopy was critical in reducing excision and referral rates of benign lesions. Just over half of all lesions initially included for excision or referral underwent SDDI. Of these, 82% of benign lesions were correctly managed following short-term SDDI. This is consistent with previous observations that approximately 84% of suspicious benign lesions remain unchanged following short-term SDDI.^{15,19} Furthermore, in our trial, the sensitivity for the diagnosis of melanoma increased from 53% following dermoscopy examination to 72% following the use of both interventions (i.e. the final outcome). Indeed one-third of melanomas were detected by SDDI. While short-term SDDI requires a delay in diagnosis of 3 months, this technique has been shown to be safe. In our study the maximum Breslow thickness of melanomas undergoing SDDI was 0.65 mm. This is consistent with larger studies performed in a specialist setting. In a study of 91 melanomas detected by SDDI (both short- and long-term monitoring) the median Breslow thickness was in situ melanoma, with all invasive melanoma less than 1 mm thick.¹⁴ More recently an analysis of 81 melanoma exclusively detected by short-term SDDI showed similar results (median in situ, maximum thickness 0.8 mm).¹⁹

With the current design it is unclear whether dermoscopy alone would have reduced the excision or referral of pigmented lesions much beyond the 19% seen in this trial. We suggest that SDDI was fundamental to achieving the final 63% reduction of excision/referral of benign lesions but only a two-armed trial could confirm this. A much larger two-armed randomized trial of the combined interventions vs. routine management would test whether a reduction of excision/referrals coincided with improved detection of melanoma. We

believe such a trial is not justified. As confirmed in our trial, dermoscopy increases the sensitivity for the diagnosis of melanoma compared with naked eye examination^{5,8} and improves the identification of suspicious lesions by GPs.¹³ SDDI improves the detection of early melanoma lacking dermoscopic features of melanoma.^{14–19} A combination of these interventions would almost certainly improve the detection of melanoma while reducing the significant healthcare costs of excisions or referrals of benign lesions in primary care.

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