

General Practice Dermoscopy Skin Cancer Study

GP info

Summary

- Early detection of skin cancer is problematic.
- GP's have a low diagnostic accuracy rate for skin cancer.
- Dermoscopy helps increase diagnostic accuracy in specialist hands.
- It is not known if dermoscopy helps GP's improve diagnostic accuracy.
- The 3 Point Check List is a simplified algorithm to help those inexperienced with dermoscopy.
- **This study wants to determine if skin cancer diagnosis is improved using the 3 Point Check List in a GP setting.**

- This is a pivotal study and may have a huge impact on how GP's assess skin lesions. Your participation is needed and greatly appreciated. This study has been designed to minimize the impact on your time by using your PMS to gather and send the data to the study database.

Background to the study

You are no doubt aware that New Zealand has one of the highest rates of skin cancers in the World^{1,2} with the melanoma rate being the highest at 40-50: 100,000. This compares to 7:100,000 in the US and Europe. With the addition of epithelial cell carcinoma (BCC's and SCC's), New Zealanders have a 2 in 3 lifetime chance of developing a skin cancer. It is clear that early diagnosis and treatment can be instrumental in affording a complete cure². This goal is hampered however, as early diagnosis in the general practice setting can be problematic.

GP's are usually the "first port of call" in New Zealand for someone concerned about a skin lesion. GP's are also in a prime position to check skin lesions opportunistically, eg while checking a shoulder injury or heart or chest examination. Skin lesions can be difficult to assess with the naked eye as benign lesions can be indistinguishable from skin cancers and studies suggest GP's "get it right" only 60% of the time³. Dermoscopy may well be the tool that helps GP's improve their diagnostic rate and therefore detect cancers earlier. There have been suggestions however that dermoscopy should not be used in a general practice setting⁴ because of the intense training required before benefits of increased diagnostic accuracy are gained. Concern was also expressed in the same review that diagnostic accuracy could deteriorate using dermoscopy without intense training. These concerns however have not been borne out in recent studies^{3,5,6}.

So what is dermoscopy? It is the use of a hand held skin microscope that shows skin morphology not able to be seen with the naked eye. The dermoscopic morphological features of common benign skin lesions and skin cancers are now well described and have been correlated with their histopathological findings⁷. Menzies⁸ has calculated the sensitivity and specificity of dermoscopic features of invasive melanoma. Diagnostic accuracy is greatly enhanced using this method in trained hands, i.e. dermatologists^{8, 9-14}. It is not clear if dermoscopy is useful in General Practice. Dermoscopy training unfortunately can be difficult and time consuming to learn. Simplified algorithms to aid learning have been developed¹⁵⁻¹⁷. These have been

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shown to improve diagnostic accuracy in “nonexperts”¹⁸⁻¹⁹. The most recent is the Three-point checklist¹². A short training session (3-4 hours) has been designed to teach medical doctors basic dermatological features. In particular asymmetry, atypical pigment network and blue white structures. The presence of more than one of these features is suggestive for malignancy. An initial study in Italy and Spain with Primary Care Physicians⁵ demonstrated that diagnostic accuracy could be greatly enhanced in this group with dermoscopy.

Your Participation

Your participation in this study will help to determine if this training and method of skin assessment will allow GP's to detect more skin cancers and “weed out” benign lesions than the current “naked eye” assessment. If this is confirmed it will have huge impact on how General Practitioners assess skin lesions in the future. I urge you to consider participation in this study. There is a small window of opportunity to complete this type of study in New Zealand.

Study Design

GP's will be randomly assigned to the Dermoscopy Arm or the Control Arm.

For those GP's in the **Control Arm** they continue assessing and treating skin cancers as per the current best practice. Histology results will be collected and the clinical diagnosis and the histopathological diagnosis will be compared.

The **Dermoscopy Arm** will be given an approximately 4 hour Internet or CD based dermoscopy training session in the use of the 3 Point Check List. They will be provided with a hand held dermoscope (3-Gen Dermlite DL100). All skin lesions will be assessed with the dermoscope using the 3 Point Check List. Any lesion that scores 2 points or more will then be treated for skin cancer. Again the clinical/ dermoscopic diagnosis and the histopathological diagnosis will be compared.

Patient Selection and consent

Patients attending the GP's rooms will be invited to join the study. They will be required to give written consent after reading the participant information sheet. Use of a free interpreter is available via Language Line – your personal 0800 number established last year should be available to you.

Data Input and Collection of Data

Those using MedTech will have an advanced form that will allow rapid entry of data and generation of Lab Forms and specialist referrals. The specimens will be collected and delivered to that GP's Lab service as per their current practice. The Laboratory staff will be blinded – i.e. they will not know which GP's are in the dermoscopy or control arms.

Lab results will be sent electronically to the GP and a copy will be forwarded to the Study Data Base via HealthLink.

Duration of Study

The study will run for approximately 12 to 18 months. This will depend on the number of GP's and therefore lab specimens received. The current estimate is approximately 100 melanoma's will be needed to be detected in each arm to give the study sufficient statistical power to demonstrate emphatically if the 3 Point Check List is beneficial.

Results

At the completion of the study all GP participants will receive a summary and the conclusions of the study. Dr Giuseppe Argenziano, a co-author of the paper published on the use of the 3 Point Check List and author of the Italian Primary Care Physicians study, is involved in the planning and analysis of the study.

Funding has been sought from the New Zealand Cancer Society (pending), 3-Gen – suppliers of the dermlite, The Skin Clinic Marlborough. Southlink Health have provided IT support for the study.

Conflict of Interest There is no conflict of interest to declare.

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