DERMATOSCOPY
MED201.023
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

COVERAGE:

Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, is considered **experimental or investigational** as a technique to evaluate or serially monitor pigmented skin lesions.

DESCRIPTION:

Dermatoscopy describes a family of noninvasive techniques that allow in vivo microscopic examination of skin lesions, and is intended to help distinguish between benign and malignant pigmented skin lesions. The technique involves application of immersion oil to the skin, which eliminates light reflection from the skin surface and renders the stratum corneum transparent. Using a magnifying lens, the structures of the epidermis and epidermal-dermal junction can then be visualized. A hand-held or stereomicroscope may be used for direct visual examination. Digitization of images (typically after initial visual assessment) permits storage and facilitates their retrieval. The images are often used for comparison purposes if a lesion is being followed over time.

A variety of dermatoscopic features have been identified that are suggestive of malignancy, including pseudopods, radial streaming, the pattern of the pigment network and black dots. These features in combination with other standard assessment criteria of pigmented lesions, such as asymmetry, borders and color, have been organized into algorithms to enhance the differential diagnosis of pigmented skin lesions. Dermatoscopic images may be assessed by direct visual examination, or by review of standard or digitized photographs. Digitization of images, either surface or dermatoscopic images may permit qualitative image enhancement for better visual perception and discrimination of certain features, or actual computer-assisted diagnosis.

Specialized clinics have been developed specifically to offer dermatoscopy. The evaluation may be marketed as a “melanomagram.” The MoleMax II TM is a dermatoscopy device that includes a microscopic camera, image digitizer, storage and retrieval of images, and computer-aided diagnostic tools.

Dermatoscopy, which has been more widely investigated and adopted in Western Europe, may also be referred to as dermoscopy, mole mapping, skin surface microscopy, incidence light microscopy, or digital epiluminescence microscopy.

RATIONALE:

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Introduction

As with any diagnostic tool, assessment of dermatoscopy involves a determination of its sensitivity, specificity, and positive and negative predictive values in different populations compared to a gold standard, and whether the results of the diagnostic tests are ultimately used to benefit health outcomes. The gold standard for evaluation of pigmented skin lesions is excision with histologic diagnosis, whose sensitivity and specificity, depending on the skill of the pathologist, are considered near 100%. The relevant health outcome is early diagnosis of a malignancy. Clinically, dermatoscopy is used in combination with clinical assessment, either based on direct visual inspection or review of photographs. Therefore, the diagnostic performance of dermatoscopy combined with clinical assessment must be compared with clinical assessment alone and then compared to the gold standard of histology. There are 3 general clinical situations in which dermatoscopy might be of benefit.

1. Many patients present with an individual pigmented skin lesion, and a decision must be made whether or not its clinical appearance suggests malignancy and thus whether or not the skin lesion should be excised. Given the importance of early identification of melanoma and the relative ease of excision, most suspicious skin lesions will be excised. However in many cases excised lesions turn out to be benign, and thus the patient has undergone excision unnecessarily. Therefore, when patients present with a lesion with a low pretest possibility of malignancy, dermatoscopy could potentially be used to determine which lesions did not require excision, i.e., a deselection process. In this clinical situation, the negative predictive value of dermatoscopy is the most relevant diagnostic parameter.

2. Some patients may present with multiple suspicious pigmented skin lesions such that excision of all or even some of them is not possible. In this clinical situation, a determination must be made which of the lesions is most clinically suspicious and requires excision. In this setting of positive predictive value dermatoscopy is the most relevant diagnostic parameter.

3. Serial assessment of lesions over time, as a technique to prompt excision when the lesion changes in shape or color, is commonly performed in patients with multiple pigmented lesions, or lesions in locations difficult to excise. Serial conventional photography has been used for the follow up of pigmented lesions. In addition, the use of digital photography has facilitated the storage and retrieval of images. Serial assessment using digitized dermatoscopic images has also been suggested. Both the positive and negative predictive

values of the results of serial imaging using clinical or dermatoscopic assessment are relevant. For example, do dermatoscopic changes precede clinical changes, thus increasing the sensitivity and positive predictive value of clinical assessment?

Clinical Studies

A variety of studies have reported on the diagnostic parameters of dermatoscopy criteria compared to clinical assessment with histologic examination serving as the gold standard. Unfortunately, most studies are retrospective and most compare clinical assessment only to dermatoscopic assessment of stored photographs instead of the more clinically relevant comparison of clinical assessment alone compared with combined clinical and dermatoscopic assessment. In addition, the studies do not subcategorize lesions into varying levels of pretest probabilities as outlined. Few studies have specifically looked at the use of dermatoscopy as a serial monitoring tool. There were no studies identified that specifically looked at the potential diagnostic advantages of digitization of images as opposed to conventional photography. The majority of the studies report on the performance of clinicians who have extensive experience with dermatoscopic imaging, and thus whether or not these results can be duplicated in a community setting, or what kind of formal training would be required are other issues. Finally, there is extensive discussion in the literature regarding the optimal dermatoscopic criteria for malignancy, and the optimal method of using the criteria to assess malignancy. For example dermatoscopic images may be evaluated qualitatively with semiquantitative scoring according to algorithms, evaluated using statistical methods to assess risk of malignancy, or evaluated using artificial neural networks. Dermatoscopic criteria for malignant melanoma have undergone multiple modifications, with questions raised regarding their validity and reproducibility. This variety of methods obviously complicates the evaluation of the data. A representative review of the larger clinical studies follows:

Soyer and colleagues reported on a series of 159 pigmented skin lesions, including 65 melanomas. The patients were members of a population referred to a dermatology clinic because of a pigmented skin lesion that was difficult to diagnose on clinical grounds alone. Each lesion was clinically assessed by one of the investigators and the clinical diagnosis noted. Each lesion was then examined dermatoscopically and a dermatoscopic diagnosis noted. It is not clear whether the same clinician provided the clinical and dermatoscopic diagnosis. The sensitivity and specificity of diagnosing malignant melanoma based on clinical assessment or dermatoscopy alone were the same: 94% and 82%. However, if clinical assessment was combined with dermatoscopy, the sensitivity rose to 95% with a specificity of 80%.

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Binder and colleagues reported on a study of 240 pigmented skin lesions, photographed both with surface photography and with dermatoscopy (both images were magnified 16 times). Histologic diagnosis was available for all. The resulting 480 photographs were randomly and in an unpaired fashion presented to a group of 6 dermatoscopy experts and 13 dermatologists who were not specifically trained in dermatoscopy. Although not explicitly described, evaluation of the dermatoscopic images was presumably qualitative. To assess intraobserver variability, 24 pairs of slides were presented twice. The slides were arranged such that corresponding pairs of slides from an individual lesion were not presented sequentially, and thus the clinically relevant combined assessment of surface and dermatoscopic images for a single lesion was specifically excluded. Among the 240 lesions, about 24% were malignant melanoma and 17.5% were histologically classified as a dysplastic nevus. The rest were benign lesions. Among the dermatoscopic experts, the intraobserver agreement was 0.57 for surface photography versus 0.56 for dermatoscopy. The intraobserver agreement was 0.40 for surface microscopy versus 0.47 for dermatoscopy, indicating only a moderate degree of agreement for either technique. The median sensitivity and specificity for surface microscopy in detecting malignant melanoma was 58% and 91% respectively, compared to 68% and 91%, respectively for dermatoscopy. While the improvement in sensitivity from 58% to 68% was clinically significant (p=0.02), the more clinically relevant positive and negative predictive values were not reported. In addition, the sensitivity of dermatoscopy among non-experts actually significantly decreased compared to surface photography. A subsequent study by Binder reported that short-term formal training improves the diagnostic performance of dermatologists.

Cristofolini and colleagues reported on a series of 220 pigmented skin lesions in which the diagnostic parameters of clinical assessment, dermatoscopic assessment and combined assessment were compared with histology. The sensitivity and specificity of the techniques are summarized below:

Technique	**Sensitivity (%)**	**Specificity (%)**
Clinical assessment alone	85	75
Dermatoscopy	88	79
Combined	94	72

Nachbar and colleagues reported on a semiquantitative method of evaluation of 172 dermatoscopic images compared to a clinical assessment. The ABCD rule of dermatoscopy was applied (asymmetry, border, color, differential structure) and those scoring above or below 5.45 were classified as malignant or benign, respectively. The following results were reported.

Technique	Sensitivity (%)	Specificity (%)	Pos. Pred. Value (%)	Neg. Pred. Value (%)
Clinical	84	84	90	73
Dermatoscopy	83	91	96	85

As noted above, while dermatoscopy was associated with an improved negative predictive value, it is unlikely that a negative predictive value of 85% would be adequate to eliminate consideration of excision. In addition, it is not known whether the improvement of the positive predictive value from 90% to 96% is statistically or clinically significant.

More recently Ascierto and colleagues reported on a series of 8,782 subjects with 15,719 skin lesions evaluated dermatoscopically. Based on dermatoscopic assessment the lesions were further classified from very low to very high risk for malignant melanoma. Excision was advised for all high-risk lesions. In medium- and low-risk lesions, excision was justified for “cosmetic or functional” reasons. The sensitivity and specificity of dermatoscopy were then compared to the histologic results of the 2,731 excised lesions. For very high- and high-risk lesions, the positive and negative predictive value of dermatoscopy was 86.4% and 96.6%, respectively. In the low-risk group, the positive and negative predictive values were 93.1% and 95.4%, respectively. There are no data regarding the diagnostic performance of dermatoscopy compared to clinical assessment alone, or in combination with dermatoscopy.

Only one study was identified that specifically examined the role of dermatoscopy in the serial monitoring of lesions. Kittler and colleagues reported on 1,862 sequentially digitally recorded dermatoscopic images from 202 patients with multiple clinically atypical nevi. Excision was recommended if substantial modifications in the dermatoscopic images were noted. A total of 75 lesions from 52 patients were excised; 67 (89.3%) were histologically diagnosed as benign lesions. The 8 malignant lesions showed a change in size in addition to appearance of dermatoscopic structures that are associated with malignancy. It is unclear from these data whether or not dermatoscopic evaluation can better target changing lesions for excision. In addition, the study did not compare the use of serial dermatoscopy with serial surface photography.

Summary

While there is extensive literature regarding dermatoscopy, the literature is inconclusive regarding its clinical role in the

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management of pigmented skin lesions, i.e., as a technique to either select or deselect lesions for excision, considered the gold standard. Only one study mimicked the actual clinical practice of combining clinical assessment with dermatoscopic assessment and compared its diagnostic performance to clinical assessment alone. While this study reported an improved sensitivity with the combined technique, it is not clear whether the improved sensitivity is statistically or clinically significant. There are inconclusive data regarding the role of serial dermatoscopic monitoring compared to serial clinical monitoring and inadequate data regarding computer-assisted analysis of dermatoscopic lesions. Since there is inadequate documentation regarding the clinical value of dermatoscopy in various clinical situations, its use in conjunction with clinical assessment is considered not medically necessary. There are inadequate data regarding the use of digitized photographs compared to conventional photographs.

PRICING:

Visual examination of skin lesions may be coded using evaluation and management CPT codes. There is no specific CPT code for dermatoscopy. Digitization of images is essentially a type of photography.

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