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Testing a Test

Critical Appraisal of Tests for Diagnosing Scabies

ANYONE WHO HAS EVER TRIED TO SCRAPE THE foot of a crying and kicking infant will welcome the possibility of using simple packing tape instead of a scalpel to find mites. Given the problem of trying to find mites, eggs, or scybala, especially in children, many practitioners diagnose scabies clinically[1,2] and treat even if neither mite nor products can be found.

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The article by Walter et al[3] in this issue of the *Archives* has the potential to substantially change the way we approach the diagnosis of scabies. It singles out the packing tape test as the most useful test for the diagnosis of scabies. It should be stressed that the evaluated test used packing tape and not office tape, which is not as strong. Packing tape was also used by Katsumata and Katsumata,[4] who first described the test. In addition, the tape remains on the skin for a surprising 30 seconds, which may be time-consuming if many lesions are assessed. For the practitioner, the issue is not the strength of the tape but the strength of the evidence presented and the implications of this study for clinical practice. In clinical appraisal terms, are the results valid and important, and can they be applied to your setting?

BASIC CRITERIA TO EVALUATE A STUDY OF DIAGNOSTIC TESTS

Studies reporting diagnostic tests should adhere to established international reporting standards to facilitate critical appraisal.[5] The study by Walter et al[3] is well reported.

To be valid, studies about diagnostic tests should include evaluation in an appropriate spectrum of patients, masked comparison with a criterion ("gold standard"), and consistent application of the criterion standard.[6] The study by Walter et al does not meet this standard. Walter et al defined the *presence of scabies* as identifying a mite in a scalpel scraping or on packing tape. However, it is impossible to know what percentage of patients with negative results for scraping and for the tape test actually did have scabies. In the setting of this study, that percentage is likely to be quite high. Joseph et al[7] described Bayesian methods to estimate the parameters of diagnostic tests in the absence of a criterion standard. However, the methods are difficult to perform and to understand, and they have rarely been used.

CRITERION STANDARD

Without a criterion standard, the true test performance remains uncertain. Neither sensitivity nor specificity can be established without this knowledge. Although the criterion standard for the diagnosis of scabies is seeing a mite, there is no criterion standard for the exclusion of scabies. Not finding a mite does not prove that a patient does not have scabies, as many physicians have discovered when they detected mites at the return visits of presumed patients with eczema. In addition, we do not have information about other findings, such as burrows, eggs, or scybala, which may identify more cases of scabies if found.

In another study evaluating dermoscopy and scraping, Dupuy et al[8] performed independent assessment of the patients by a physician who only performed dermoscopy and another who only performed scraping. When dermoscopy identified possible infestations but scraping results were negative, the patient returned for scraping of the specific lesions found to be positive by dermoscopy. This procedure identified additional cases but was not practical in the resource-poor setting of the study by Walter et al.[3]

To come closer to a criterion standard, the study could have provided clinical follow-up of patients who had no mites found. Scabies has a very low spontaneous cure rate. Thus, the disease could have been reconsidered and the tests could have been repeated, with a possible increase in sensitivity, if patients remained symptomatic. However, in the setting of the study by Walter et al,[3] the prevalence of scabies is so high (approximately 9%)[1] that diagnosis of scabies at a later stage might not exclude its absence at a previous visit.

REPRESENTATIVENESS OF THE POPULATION

The population chosen by Walter et al[3] certainly reflects the symptomatic population in a resource-poor country with a high prevalence of scabies. The prevalence of scabies in this population is likely to be much higher than that in the practices of most readers of this journal. However, the population studied by Walter et al is useful for testing the diagnostic accuracy of tests for scabies, and the authors clearly defined the population.

SPECIFICITY AND SENSITIVITY

For a binary test, we need to know primarily sensitivity (ie, does the test detect the disease in question) and specificity (ie, how well does it identify patients without the condition). These statistics are generally thought to be transferable between different populations but do not answer all the questions related to test performance that are relevant to the physician.

A highly specific test rules in the diagnosis when positive, and a highly sensitive test can rule out the disease when negative. Mnemonics to remember these rules are SpPins (a highly Specific test when Positive rules in the disease) and SnNouts (a highly Sensitive test when Negative rules out the disease).[9] How high do the sensitivity and specificity have to be to be useful as SpPins or SnNouts? Most authors would say greater than 0.95. Finding a mite on a scraping or tape test is highly specific for scabies and thus these tests are SpPins. None of the tests for scabies in this study are highly sensitive, and therefore they do not rule out the disease when negative.

LIKELIHOOD RATIO, PRETEST PROBABILITY, POSTTEST PROBABILITY, AND THRESHOLD FOR ACTION

In addition, likelihood ratio, pretest probability, posttest probability, and threshold for action are useful in determining whether the results of this study are clinically important. The positive likelihood ratio provides a tool to determine the increase in the probability that a disease is present, given a positive test result (posttest probability), compared with the probability before the test was performed (pretest probability). The likelihood ratio is calculated by dividing the proportion of people with the disease who have a positive test result by the proportion of people who do not have the disease but have a positive test result.[10,11] An ideal test is one that almost always will be positive when the disease is present (ie, is sensitive), and almost always will be negative when the disease is absent (ie, is specific), and this test will have a high likelihood ratio (**Table 1**).

Table 1. Interpretation of Likelihood Ratios[10]

Likelihood Ratio	Diagnostic Effect
>10	Conclusive changes from pretest to posttest probability
5-10	Moderate shifts in probabilities
2-5	Small but sometimes important changes in probabilities
1-2	Altering of probabilities to a small and rarely important degree
1	None
0.5-1	Altering of probabilities to a small and rarely important degree
0.2-0.5	Small but sometimes important changes in probabilities
0.1-0.2	Moderate shifts in probabilities
<0.1	Conclusive changes from pretest to posttest probability

The negative likelihood ratio provides a tool to determine how much lower the probability that a disease is present, given a negative test, compared with the probability before the test is done. The negative likelihood ratio is the proportion of people with the disease who have a negative test divided by the proportion of people who do not have the disease who have a negative test. An ideal test is one that will rarely be negative when the disease is present and almost always will be negative when the disease is absent. Thus, it is again one with a high sensitivity and specificity. Such a test would have a very low negative likelihood ratio (Table 1).

For the likelihood ratio to be useful, one must have an idea of how likely the disease is to be present before the test is performed (ie, the pretest probability) and a sense of how certain one needs to be to conclude that the patient has the disease and to act on it (ie, the threshold for action).[11] The pretest probability is determined from available published data, such as the prevalence of the disease in a population, or based on the patient's signs and symptoms and the physician's experience and judgment. After the pretest probability is known or estimated and the likelihood ratio determined, a nomogram can be used to estimate the posttest probability (**Figure**).[12] If the nomogram is not available, then the calculations can be performed manually.[10]

Whether formally or informally, physicians develop thresholds of certainty at which they are comfortable with establishing a diagnosis and acting on the diagnosis. In the case of scabies, action means communicating the diagnosis to the patient and prescribing treatment for him or her and close contacts. When historical and physical evidence leads a clinician to suspect a diagnosis but the degree of certainty does not reach the threshold for establishing a diagnosis, a test is performed to increase the degree of certainty to the clinician's threshold for action.[11] Tests with likeli-

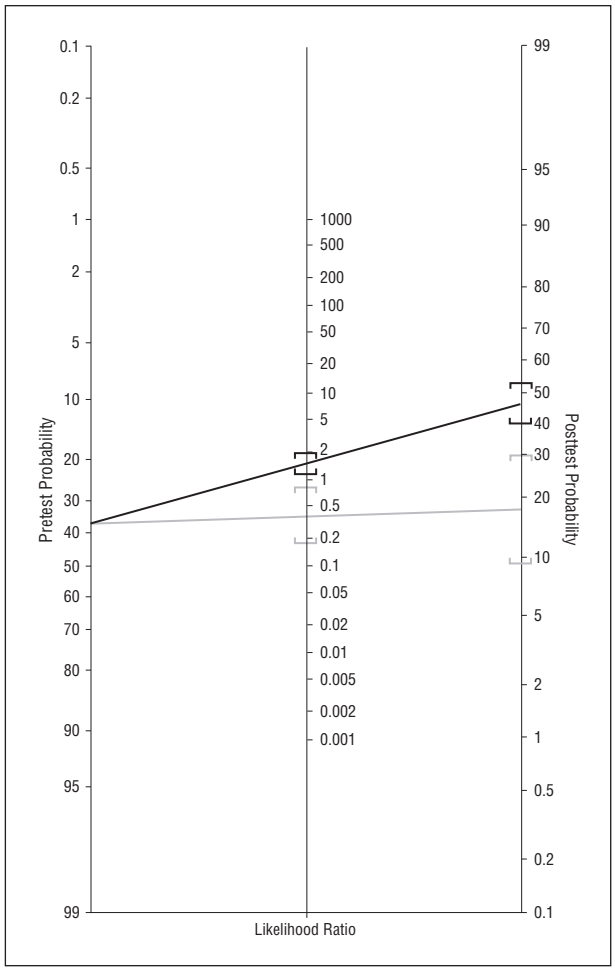

Figure. Pretest and posttest probabilities of scabies illustrated with a Fagan nomogram. The pretest probability for both examples was 0.36. Example 1 (bold line): The positive likelihood ratio for dermoscopy was 1.52. If a patient's dermoscopy result were positive, then his or her posttest probability of scabies would be 0.46. Example 2 (gray line): The negative likelihood ratio for dermoscopy was 0.37. If a patient's dermoscopy results were negative, then his or her posttest probability of scabies would be 0.17.

Table 2. Likelihood Ratios for Different Examination Methods Used to Diagnose Scabies

Diagnostic Test	Positive Likelihood Ratio	Negative Likelihood Ratio
Study by Walter et al[3]		
Package tape test	Not calculable (diagnostic)	0.3
Skin scraping	Not calculable (diagnostic)	0.5
Dermoscopy	1.5	0.4
Study by Dupuy et al[8]		
Skin scraping	Not calculable (diagnostic)	0.1
Dermoscopy	6.5	0.1

hood ratios close to 1 are not likely to significantly increase the degree of certainty to the threshold (Table 1 and Figure).

For the geographical area described by Walter et al,[3] we know on the basis of previous work that the prevalence of scabies in the population is likely to be approximately 9%.[1] However, because Walter et al performed scraping, the tape test, and dermoscopy only on patients suspected of having scabies, the prevalence of scabies among tested patients was 36%, and thus the pretest probability was 0.36. The positive likelihood ratio for dermoscopy was 1.5 (**Table 2**). If a patient's dermoscopy result were positive, then his or her posttest probability of scabies would be 0.46 (Figure). Because the likelihood ratio for dermoscopy was close to 1, a positive result of dermascopy does not significantly change the probability of disease when it is positive, and it is not a useful test for scabies in the present study.

The negative likelihood ratio for dermoscopy was 0.4 (Table 2). Therefore, if mites were not found on dermoscopy, then the posttest probability would be 0.17 (Figure). Whether this probability is low enough to exclude the presence of disease is unclear.

Dermoscopy fared better in the study by Dupuy et al[8] than in the study by Walter et al[3] (Table 2). In the French study, the likelihood ratio is more than 6 (ie, moderately positive) (Table 1). The French study allowed 2 independent physicians, one performing the scraping and one using dermoscopy, to examine the whole patient and then, when disagreement was identified, the observation of the dermoscopist was tested by scraping. By allowing the examiners to go back to the patient to scrape the areas where dermoscopy had found mites, dermoscopy was shown to be more specific than it would have seemed had this step been omitted. In addition, the dermoscopists in the French study were more experienced.

BLINDING

The study by Walter et al[3] was not blinded, which can be a serious shortfall in diagnostic studies because knowledge of the first test may influence performance and analysis of the subsequent test. The physician who performed the tape stripping and scrapings may have performed the previous dermoscopy because the protocol did not ensure that someone else did it. Dermoscopy was always performed first, followed by tape stripping and then scraping. It can well be argued that this process inflated the sensitivity of the tape test at the expense of the sensitivity of the scraping. Because tape stripping was always performed second, the lesions likely to contain mites may have been preferentially tape tested. Any mite found by the tape test cannot be found by the final scraping.

CONCLUSIONS

The current study shows that the tape test can easily be used to demonstrate scabies mites and rules in the diagnosis when positive. The sensitivity of 0.68 reported by Walter et al[3] is an estimated upper limit. The true sensitivity is likely to be less because the true presence of disease cannot be determined without a criterion standard. Dermoscopy was not a useful test in the setting studied because its positive likelihood ratio is close to 1 and does not significantly increase the posttest probability and because the positive predictive value is less than .50. It is only slightly more useful when its results are negative. Dermoscopy, however, has been shown to be slightly more sensitive and specific in another study.[8] Dermoscopy-guided skin scrapings can help to identify mites that even careful observers previously missed with the na-

ked eye.[7] Dermoscopy-guided tape testing may be similarly helpful and should be studied.

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Archives Web Quiz Winner

Congratulations to the winner of our January quiz, Vijay Adhe, DVD, Department of Dermatology, Seth Gordhandas Sunderdas Medical College and King Edward Memorial Hospital, Mumbai, India. The correct answer to our January challenge was *pustular cryoglobulinemic vasculitis*. For a complete discussion of this case, see the Off-Center Fold section in the February *Archives* (Poonawalla T, Longley BJ, Aughenbaugh W. Serpiginous erythematous plaques on the feet. *Arch Dermatol*. 2010;147[2]:235-240).

Be sure to visit the *Archives of Dermatology* Web site (http://www.archdermatol.com) to try your hand at the interactive quiz. We invite visitors to make a diagnosis based on selected information from a case report or other feature scheduled to be published in the following month's print edition of the *Archives*. The first visitor to e-mail our Web editors with the correct answer will be recognized in the print journal and on our Web site and will also receive a free copy of *The Art of JAMA II*.