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BRUCE JANCIN/ELSEVIER GLOBAL MEDICAL NEWS

From left, dermatologists John Y.M. Koo, M. Shane Chapman, and Craig L. Leonardi discussed the risks of efalizumab.

Warn Patients About Risks of Efalizumab

BY BRUCE JANCIN

MAUI, HAWAII — Some psoriasis patients are choosing to discontinue efalizumab treatment in response to the recently reported third case of progressive multifocal leukoencephalopathy in users of the drug.

"I've had many patients who've decided to come off therapy. It's unfortunate because a lot of these patients have been on the drug for quite a long time and have been well served," Dr. Craig L. Leonardi said during a panel discussion at the annual Hawaii dermatology seminar sponsored by Skin Disease Education Foundation.

The meeting was held a week before the Food and Drug Administration issued a public health advisory about three confirmed and one possible case of progressive multifocal leukoencephalopathy (PML) in patients treated with efalizumab. (See related story on pg. 15.)

Dr. Leonardi of the department of dermatology at Saint Louis University and his fellow panelists agreed that all patients on efalizumab (Raptiva) need to be informed of their increased risk of PML, a uniformly fatal brain disease.

The panelists also addressed the daunting challenge in switching patients from efalizumab to another medication without triggering a serious rebound effect.

The third case of PML, discovered in late January, involved a 47-year-old German who had been on efalizumab for 3.2 years. In contrast, the first two confirmed cases occurred in elderly patients, aged 70 and 73 years. They too had been on efalizumab for longer than 3 years, noted Dr. M. Shane Chapman of Dartmouth-Hitchcock Medical Center, Lebanon, N.H.

PML is a demyelinating disease of CNS white matter caused by polyomavirus JC. Roughly 80% of all adults carry the virus, having been infected in childhood. In normal

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Look for coverage of the Hawaii Dermatology Seminar throughout this issue.

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AJCC to Institute New Melanoma Staging System

New edition to de-emphasize Clark level.

BY BRUCE JANCIN

MAUI, HAWAII — Look for tumor mitotic rate to supplant Clark level in the forthcoming 7th edition of the American Joint Committee on Cancer melanoma staging system.

"Clark level will now only be considered for staging in the rare instances when mitotic rate is not known; otherwise it will no longer be part of the staging system," Dr. Jeffrey E. Gershenwald said at the annual Hawaii Dermatology Seminar sponsored by Skin Disease Education Foundation.

This represents a break with the past. Within melanoma staging, Clark level enjoyed near-equal billing with tumor thickness before being downgraded in clinical relevance in the still-current 6th edition of the AJCC staging system, issued in 2002.

The 6th edition relegated Clark level to a limited role, with Clark level IV and V resulting in upstaging of thin melanomas from T1 to T1b, explained Dr. Gershenwald, vice chair of the AJCC task force charged with developing the new edition of the staging system.

The 7th edition of the AJCC melanoma staging system will be published this spring and will take effect early next year. The same changes will be made in the European staging system in coordinated fashion.

Mitotic rate will be intro-

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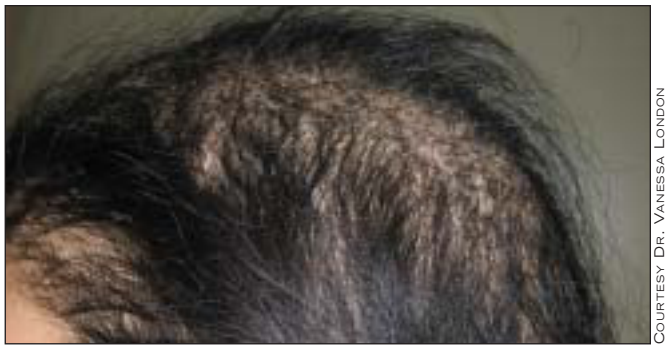
CASE OF THE MONTH



COURTESY DR. VANESSA LONDON

A 22-year-old woman presented with a lifelong history of "very dry hair" and hair loss, repeatedly diagnosed as telogen effluvium in her native Mexico. She reported that the condition improved during pregnancy, but had recently worsened. She was concerned that her 1-year-old daughter's hair was similar. What's your diagnosis? *See* **Case of the Month,** *page 59*.

SKIN & ALLERGY NEWS has been selected to receive two Gold Triangle Awards at the 2009 American Academy of Dermatology annual meeting.

Gold Triangles are awarded annually by the AAD to media for demonstrating excellence in furthering the public understanding of dermatologic issues and for encouraging healthy behavior in the care of skin, hair, and nails.

Clark Level Confuses Patients

Staging *from page 1*

duced into the staging system on the basis of recent evidence suggesting that it is an independent prognostic factor. The presence of at least one mitosis per square centimeter will be sufficient to upgrade a thin melanoma from T1 to T1b.

As the AJCC staging system is rolled out, reports will be issued detailing how pathologists should determine mitotic rate, according to Dr. Gershenwald, professor of surgery at the University of Texas M.D. Anderson Cancer Center, Houston.

The 7th edition will make no major changes in the core TNM and stage grouping criteria for stages I-III melanoma.

DR. GERSHENWALD

Clark level, he added, has caused a great deal of confusion among patients, who often confuse Clark level IV with stage IV melanoma.

"I can't tell you how many patients have come into the clinic thinking they have a stage IV melanoma and are reading their death sentence on the Internet when in fact they might very well have had a thin melanoma that happens to be Clark level IV," he commented.

"In dialoging with your patients, please make sure they understand the difference," Dr. Gershenwald urged.

The 7th edition of the staging system will make no major changes in the core TNM (tumor, node, metastasis) and stage grouping criteria for stages I-III melanoma. A thin melanoma will remain one that's up to 1.0 mm in thickness, and a thick one will still have to be greater than 4.0 mm. This was an evidence-based decision in response to analysis of an international database of more than 50,000 melanoma patients which validated the models utilized in the 6th edition.

There will be a few minor changes in the 6th edition having clinical relevance, however. For one, there will no longer be a lower limit as to what constitutes node-positive disease.

Also, immunohistochemical detection of nodal metastases—already in wide use in clinical practice—will for the first time become acceptable for staging purposes in the upcoming edition, Dr. Gershenwald said.

In the 7th edition, the essential elements of a pathology report for primary melanoma will be Breslow thickness, the presence or absence of ulceration, mitotic rate, and margin status.

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Staging, Lymph Node Assessment Are Key to Surgical Melanoma Management

The surgical management of primary melanoma varies by patient and depends in large part on key elements of the pathology report and the assessment of lymph node involvement, according to Dr. Gershenwald.

In terms of staging the disease, Breslow thickness, ulceration, mitotic rate, Clark level, and margin assessment should be considered prior to wide local excision of the tumor, he noted.

And because nodal involvement is the best predictor of recurrence and survival in melanoma, determining which patients have lymph node involvement and which patients do not is critical to the optimal management of the disease.

Lymphatic mapping together with sentinel lymph node biopsy is a relatively noninvasive way to accurately stage the regional nodal basin and enables a selective approach to regional node dissection, whereby lymphadectomy is reserved only for patients found to have pathologically documented disease, Dr. Gershenwald explained.

This combined diagnostic approach—in which a radioactive tracer is injected around the primary tumor site and a blue dye is used to identify sentinel lymph nodes to be removed for analysis—identifies regional lymph node disease that might not be seen with complete lymph node dissection and identifies patients in whom adjuvant therapy is warranted, he said.

Studies have suggested that early detection by sentinel node biopsy of sentinel lymph node metastasis is associated with a survival benefit when compared with a watch-and-wait approach in patients who develop clinical lymph node recurrence, Dr. Gershenwald noted.

With respect to the use of fluorodeoxyglucose positron-emission tomography (FDG-PET), which has been shown in several reports to be a more sensitive indicator of metastatic melanoma than conventional imaging, limitations in the study designs may overestimate the utility of this imaging modality for this indication, he said.

The literature supports the use of adjunctive PET imaging in properly selected patients with metastatic or recurrent melanoma, but it does not provide evidence suggesting that FDG-PET should be obtained in all melanoma patients, he reported.

Specifically, FDG-PET rarely identifies the presence of occult distant metastases in early stage melanoma patients who have been staged using sentinel node biopsy, whch means the likelihood is low that these patients will be upstaged based on the FDG-PET results.

—Diana Mahoney

Do Beach Trips During Childhood Cause Later Melanoma?

BY DENISE NAPOLI

Each beach vacation from birth to age 6 by white Colorado children was associated with a 5% increase in small nevi when the children were examined at age 7, but not with large nevi development.

In addition, the total estimated UV dose received on waterside vacations and the number of days spent on vacation were not significantly related to nevi count, suggesting that a threshold dose of UV exposure is received relatively early during each waterside vacation, such that 3-day-long getaways may have the same effect on nevi development as 10-day trips, according to the authors.

Although it is the larger nevi (greater than or equal to 2 mm) that are most commonly associated with skin cancer, increased numbers of small nevi in childhood also confer melanoma risk.

"Parents should be aware of the effect that vacations may have on their children's risk for developing melanoma as adults, and they should be cautious about selection of vacation locations," wrote Dr. Kelly J. Pettijohn, the study's lead author, from the department of community and behavioral health at the Colorado School of Public Health, Denver, and associates.

LOUISE A. KOENIG/ELSEVIER GLOBAL MEDICAL NEWS

"Parents should be aware of the effect that vacations may have on their children's" melanoma risk, warned an investigator.

A total of 681 children born in 1998 who were lifetime residents of Colorado were studied.

Patients' parents were asked in 20- to 30-minute phone interviews about the child's vacation history, sunburn history, and demographic data. Skin exams were also conducted in 2005, when the patients were 7 years old, and nevi were grouped into two categories: less than 2 mm, or greater than or equal to 2 mm (Cancer Epidemiol. Biomarkers Prev. 2009;18:454-63).

Vacations were classified as either "waterside" or "nonwaterside" depending on their location.

For example, all vacations to Miami were considered waterside because it is assumed that the child would have spent a large amount of time in the sun with minimal clothing coverage. Some locations were considered waterside only in the summer season—for example, Duck, N.C.

And other locations, though technically waterside, were included in the nonwaterside category because they are not typically associated with water activities that lead to sun exposure in any season of the year; San Francisco fell into this category.

A history of severe sunburn, of sunscreen use, of hat use, or of sun sensitivity failed to predict the development of nevi. "The only significant linear relationship between vacations and nevi less than 2 mm was for number of waterside vacations before age 6," wrote the authors. Each vacation was associated with a 5% increase in these small nevi after other factors were controlled for.

In addition, the authors found that waterside vacations taken within 1 year of the skin exam did not affect small nevi counts.

This finding suggests a time lag of at least 1 year may be necessary for the effects of sun exposure during waterside vacations to result in new nevi, they noted. Alternatively, the finding could be due to a physiologic change in childrens' melanocytes, "which become less susceptible to the intense sun exposure received on waterside vacations as [children] age."

The obvious limitations of this study, including the lack of behavioral information (for instance, on the exact amount of time spent outside while on vacation, the type of clothing worn, or the sun protection practices used), as well as reliance on parent recall, are countered by the study's strengths. "It is one of the few large longitudinal cohort studies of nevus development in children," said the authors, and it is the only one to report the link between vacations and nevi in North American subjects.

The authors reported no potential conflicts of interest related to this story. ■