

P346**CHARACTERIZATION OF TIGER TAIL BANDING AND HAIR SHAFT ABNORMALITIES IN TRICHOITHIODYSTROPHY**

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Trichothiodystrophy (TTD) is a rare disorder characterized by short brittle hair with low cystine content and alternating dark and light (tiger tail) bands under polarizing microscopy. Some TTD patients show Ichthyosis, Brittle hair, Intellectual impairment, Decreased fertility, and Short stature (IBIDS). Others also have Photosensitivity (PIBIDS), or immune or neurological abnormalities including leukodystrophy. TTD patients are not predisposed to skin cancer. Xeroderma pigmentosum (XP) is markedly different, with lentiginous pigmentation and a 1000-fold increase of UV-induced skin cancers associated with defective DNA repair. Most PIBIDS patients have a mutation in an XP DNA repair gene (XPD or XPB). Rarely, TTD occurs in combination with XP. We studied hairs from 14 TTD and 4 XP-TTD patients for tiger tail banding and hair shaft abnormalities. Using a rotating microscope stage, all hairs in each sample showed tiger tail banding under polarizing light. A variety of hair shaft abnormalities (trichoschisis, trichorrhexis nodosa-like defects, surface irregularities, ribboning) was seen in TTD hairs using light or scanning electron microscopy and documented by digital photography. These varied in severity from patient to patient. The severity of hair shaft abnormalities was quantified by microscopic examination of 50 hairs from each patient. Amino acid analysis was performed on hair from 10 TTD and 2 XP-TTD patients. We observed an inverse relationship between hair sulfur (cystine) content and the percent of hairs with shaft abnormalities ($R_{\text{val}} = 0.9$) in keeping with the key role sulfur plays in hair toughness. Hairs that show tiger tail banding without shaft abnormalities have higher sulfur content than those with shaft abnormalities. There was no correlation between the presence of photosensitivity, or neurological or immune abnormalities and the percent of hairs with abnormalities among these patients. As controls, we examined hairs from 15 normals, 12 XP patients, 101 patients with various cornification disorders, 10 family members of XP or TTD patients, and 32 leukodystrophy patients. None of these hairs showed tiger tail banding, and 5 of 174 donors had weathering hair shaft abnormalities. Tiger tail banding, seen in all hairs on polarizing microscopy, and determination of the percent of hairs with certain shaft abnormalities, provides a reliable TTD diagnostic test and an estimation of the reduction in cystine content.

Disclosure not available at press time.

P347**A ONE-YEAR OBSERVATIONAL STUDY WITH MINOXIDIL 5% SOLUTION IN GERMANY: RESULTS OF INDEPENDENT EFFICACY EVALUATION BY PHYSICIANS AND PATIENTS**

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A 12-month observational study was conducted by dermatologists in Germany, in 984 male patients with androgenetic alopecia (AGA) to evaluate the efficacy of a 5% minoxidil topical solution. In addition, patients were asked to assess efficacy and tolerability of the treatment. Twice daily, patients applied 1 ml of the solution to the hair-loss region of the scalp. At the end of the study, physicians reported that the affected area had become smaller in 561 of the 904 eligible subjects (62.0%), was unchanged in 317 subjects (35.1%), and had become larger in 26 subjects (2.9%). Regarding hair regrowth, the topical solution was rated as very effective in 143 of the 902 eligible patients (15.9%), effective in 431 patients (47.8%), moderately effective in 186 patients (20.6%) and ineffective in 142 patients (15.7%). At the beginning of the study and every 3 months thereafter, patients collected hair that had shed during washing using a supplied sieve. Lost hairs were sent to a center where they were counted. The mean number of hairs lost during washing at the time of the screening examination was 69.7, compared to 33.8 at the end of the study. 209 patients evaluated satisfaction with treatment using a visual analogue scale that ranged from 0 (extremely dissatisfied) to 10 (very satisfied). Mean score increased from 2.9 points at the beginning of the study to 4.4 points at 12 months. When comparing data obtained from physicians to those generated by patients, physicians rated the efficacy of the treatment as good or very good 25% more often than patients did. Adverse events were documented in 38 patients (3.9%) and were dominated by dermatological events. None of the adverse events was classified as serious. Tolerability was assessed as very good by 26.4%, good by 62.2%, and moderate by 11.0% of the patients. In conclusion, physician and patient evaluations of hair regrowth and decrease of hair shedding clearly demonstrated the efficacy of the 5% minoxidil topical solution in the treatment of AGA under post-marketing conditions.

The author is employed by Pharmacia AB (part of the Pfizer Group)

P348**RAPID ONSET OF ACTION OF MINOXIDIL 5% TOPICAL SOLUTION IN A 4-MONTH GERMAN OBSERVATIONAL STUDY ON BOTH PATIENTS AND PHYSICIANS**

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In a 4-month post-marketing surveillance study involving 733 male subjects with androgenetic alopecia (AGA), onset of action, efficacy, and safety of a minoxidil 5% topical solution were evaluated. The study population included 150 physicians who treated themselves for AGA with the solution. Those physicians were expected to be more critical and thus make more rigorous assessments. Subjects applied 1 ml of the solution twice a day to the affected area of the scalp. At month 4, the following results were reported: the area affected by AGA had become smaller in 488 of the 725 eligible subjects (67.3%), was unchanged in 231 subjects (31.9%), and had become larger in six subjects (0.8%); regarding new hair growth, the solution was found very effective in 54 of the 725 eligible users (7.5%), effective in 399 users (55.0%), moderately effective in 227 users (31.3%), and ineffective in 45 users (6.2%); hair density had improved in 74.2% of the 721 eligible subjects, was unchanged in 24.3%, and had worsened in 1.5%. During the first month of treatment, efficacy of minoxidil 5% solution was observed in 93 users (13.9%). The majority (350 subjects; 52.3%) reported efficacy during the second month of treatment and a third (226 users; 33.8%) experienced efficacy during the third month. No information was provided for 64 users. Adverse events were documented in 13 patients (1.8%). The total number of reported adverse events was 14 and dominated by skin-related events. In conclusion, the minoxidil 5% topical solution was proven effective in the treatment of AGA, reducing the affected area, promoting new hair growth, and improving hair density in most subjects. The onset of action was fast, with over 60% of users reporting efficacy after only 2 months of treatment. Differences between physicians and patients were minor in the overall results.

The author is employed by Pharmacia AB (part of the Pfizer Group).

P349**NAIL SEVERITY INDEX (NAILDEX): BURDEN OF ONYCHOMYCOSIS**

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Objective: To develop a severity index by which to quantify the burden of disease in patients with onychomycosis.

Methods: 252 U.S. veterans were recruited from the Atlanta and Minneapolis Veteran Affairs Medical Centers to evaluate their fingernails (FN) and toenails (TN). The area of each FN and TN were compared to the area of the fifth digit (P), such that if the third left TN was twice as large as the fifth left TN, it was assigned an area of 2P. The FN and TN were then evaluated for: (1) clinical signs of onychomycosis and (2) the percent diseased area measured by quartiles (0, 25, 50, 75, or 100%). Thus if the third left TN was 50% affected, the burden from that nail was calculated as 0.5(2P). The nail severity index (Naildex) was then determined by summing the individual products of the percent affected and the area involved of each nail, which in turn was divided by the sum of the total area of all nails (e.g., $(0.5(2p) + 0.25(P))/((2P) + P)$). Affected nails were sampled for laboratory evidence of infection, but all patients with clinical evidence were included. Participants provided demographic information and completed a validated nail-specific quality-of-life instrument, NailQoL. Relationships between the Naildex and NailQoL and demographic questions were evaluated using Spearman's correlation coefficient.

Results: KOH and/or culture confirmed fungal infection in 69% of participants. Most participants were male (94%) with a mean age of 68 (SD: 11.6) years. A mean of 0.9 FN and 4.5 TN were involved per participant. The majority (54%) of patients had never sought treatment for their nail fungus. The patients' estimated mean duration of infection was approximately 14 (SD: 11.7) years. Naildex did not correlate with the emotion, symptom, and function subscales of NailQoL. The duration of the subjects' infection correlated with Naildex scores for the FN, TN, and FN/TN (0.14, 0.24, and .26, respectively, all $p < 0.05$). The number of affected TN correlated with the Naildex score for TN alone (0.36, $p < 0.001$) as well as the Naildex score for combined FN and TN (0.38, $p < 0.001$). The number of affected FN correlated with Naildex score for FN (0.68, $p < 0.001$).

Conclusion: Naildex is a novel, valid way to measure the burden of disease in onychomycosis. Quality of life does not appear to correlate with severity, as measured by Naildex. Future studies are needed to evaluate the generalizability of this nail severity index for other nail dystrophies.

Disclosure not available at press time.