

ACNE

P100

Efficacy of benzoyl peroxide (5.3%) emollient foam and benzoyl peroxide (8%) wash in reducing propionibacterium acnes on the back

James Leyden, MD, KGL, INC. (Skin Study Center), Broomall, Pennsylvania, United States

BACKGROUND: A benzoyl peroxide (BP) emollient foam is suited for broad body surface areas and offers a treatment alternative to a BP wash for body acne. BP exerts its therapeutic effect in acne through the reduction of *P. acnes* as has been previously demonstrated by a 1.0 to 2.0 logarithmic colony reduction on the face, with leave-on formulations achieving greater reductions than wash-off formulations. Prior to this trial, no data on *P. acnes* reduction on the back existed for any BP formulations or other acne treatments.

OBJECTIVES: To evaluate the effectiveness of topical BP (5.3%) emollient foam and a BP (8%) wash in reducing *P. acnes* levels on the back.

METHODS: A 5-week open-label single center study of 20 healthy subjects (>18 years old), colonized with *P. acnes* on their backs (>10,000 colonies per cm²). Each subject was treated once daily with BP emollient foam on the back during the first two weeks. Subjects received no treatment in week 3 and were subsequently instructed to apply BP wash during weeks 4 and 5 at least once daily in the shower to the same area of the back treated with BP emollient foam. Quantitative bacteriologic cultures were obtained at baseline and weeks 1, 2, 3, 4 and 5.

RESULTS: 19 patients were evaluable. Total *P. acnes* counts were reduced by 1.9 log after 1 week of treatment with BP emollient foam, and by 2.1 log after 2 weeks of treatment with BP emollient foam. *P. acnes* counts increased during the week of no treatment. Subsequent treatment with BP wash for two weeks showed no reduction in *P. acnes* counts from this new baseline. **DISCUSSION:** The leave-on BP emollient foam was superior to BP wash in reducing *P. acnes* populations on the backs of subjects. The lack of effect of BP wash in reducing *P. acnes* levels on the back is surprising in view of the demonstrated results on the face and warrants further study.

CONCLUSIONS: BP (5.3%) emollient foam effectively reduced *P. acnes* populations on the back and may offer a useful therapy for patients with acne on broad body surface areas, such as the back. BP (8%) wash applied in the shower did not effectively reduce *P. acnes* populations on the back.

Commercial Support: 100% is sponsored by Onset Therapeutics

P101

Effects of a 1450-nm diode laser on facial sebum excretion, porphyrin production of propionibacterium acnes, and inflammatory acne vulgaris in Asians

Ying-Yi Chiang, MD, Taipei Medical University-Wan Fang Hospital, Taipei, Taiwan; Chia-Lun Chou, MD, Taipei Medical University-Wan Fang Hospital, Taipei, Taiwan; Tsung-Hsien Tsai, MD, Taipei Medical University-Wan Fang Hospital, Taipei, Taiwan

Background and Objectives: The 1450-nm diode laser is an effective treatment for inflammatory acne vulgaris. We conducted a small prospective clinical trial to investigate the effects on facial sebum excretion and porphyrin production of *Propionibacterium acnes* after 1450-nm diode laser treatment. This study also attempted to evaluate the clinical efficacy and safety of this low-energy, single-pass, 1450-nm diode laser in treating inflammatory facial acne in Asians.

Methods: Twelve patients (Fitzpatrick skin phototypes III or IV) with inflammatory facial acne were enrolled in this study. Subjects were treated 3 times at monthly intervals using a 6-mm spot, a fluence of 12 J/cm², and a dynamic cooling device (DCD) setting of 25 ms; the entire face was treated with a single pass. The amount of facial sebum excretion was measured with a Sebumeter, and porphyrin was measured using a VISIA complexion analysis system 1 h prior to each treatment and 3 months after the third treatment. Global acne grade scores, adverse effects, and patients' subjective assessments were evaluated at the baseline, prior to each treatment, and 3 months after the third treatment.

Results: Of the 12 patients, 10 patients completed the study. All patients had a significant reduction in global acne grade scores. The mean acne grade scores decreased from 20.7 to 14.7 ($p < 0.01$). The percentage reductions in acne grade scores from the baseline were 21% after 1 treatment, 40% after 3 treatments, and 29% at the 3-month follow-up. Subjective moderate-to-marked improvements in inflammatory acne and skin oiliness were noted. However, no significant reduction in facial sebum excretion or a decrease in porphyrin production was observed. Adverse effects were limited to transient erythema.

Conclusions: Use of low energy, a shorter duration of DCD, and a single-pass 1450-nm diode laser significantly improved facial inflammatory acne. Nevertheless, objective reductions of the facial sebum excretion and porphyrin amount were not found. Further study with larger patient population should be carried out to try and explain the mechanisms of the laser's clinical efficacy.

Commercial Support: None Identified

P102

Granulomatous rosacea

Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Lina Nicolae, MD, Department of Pathology, Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: Granulomatous rosacea is a variant of rosacea that may present similar to other granulomatous diseases.

CASE REPORT: An otherwise healthy 54-yr-old man presented with a month history of itching lesions on the face. Physical examination revealed erythematous papules and plaques with scales on the cheek, forehead and eyelids with blepharitis. The remainder of the skin exam was unremarkable. Histological examination presents epithelioid histiocytes and multinucleate giant cells in tuberculoid granulomatous, which may be centered on ruptured hair follicles. Non-pustular lesions show a nonspecific perivascular and perifollicular lymphohistiocytic infiltrate accompanied by occasional multinucleated cells, plasma cells, neutrophils, and eosinophils. Papulopustular lesions show more pronounced granulomatous inflammation and occasional perifollicular abscesses. Laboratory testing revealed an increased of cholesterol level.

ANA antibodies were negative.

DISCUSSION: - Additional tests that pathologists may utilize include special stains such as an Acid Fast, Fite, Gram, Warthin-Starry, PAS, and GMS stains. In addition, polarization with refractile light examination may be helpful in identifying some causes like a foreign body with giant cell reaction. - The differential diagnosis is with granulomatous periorificial dermatitis, seborreic dermatitis, sarcoidosis and cutaneous leishmaniasis

Commercial Support: None Identified

P103

Two fixed-dose combination gels for the treatment of acne vulgaris: Two randomized, split-face studies of tolerability in acne subjects

Lawrence Green, MD, Aesthetics, Skin Care & Dermatology, Rockville, Maryland, United States; Eduardo Rodriguez, MD, Lumipiel, Buenos Aires, Argentina; Pablo Gonzalez, MD, Buenos Aires SKIN, Buenos Aires, Argentina; Steven Grekin, DO, Grekin Skin Institute, Warren, Michigan, United States; Tania Zarowsky, MD, Centro de Investigacion y Prevencion de Enfermedades Cardiovasculares (CIPREC), Buenos Aires, Argentina

Objectives: The primary objective of these studies was to compare the tolerability of clindamycin 1%-benzoyl peroxide 5% with hydrating excipients, dimethicone and glycerin, (C/BPO HE) and adapalene

0.1%-benzoyl peroxide 2.5% gel with dimethicone (A/BPO) during the first two weeks of acne treatment. Methods: Two multi-center, investigator-blinded, comparative, split-face studies randomized 76 subjects with acne vulgaris to 8 weeks of treatment with C/BPO HE and A/BPO applied once daily in a bilateral split-face fashion (each treatment randomly allocated to left and right side). The primary endpoint was signs and symptoms (erythema, peeling, dryness, and irritant/allergic contact dermatitis) over the first 2 weeks of treatment. These tolerability measures were assessed by the Investigator on a 4-point scale (0-None; 1-Slight; 2-Moderate; 3-Intense) at weeks 1 and 2.

Results: For most measures of tolerability (erythema, dryness, and peeling) at weeks 1 and 2, the side of the face treated with C/BPO HE demonstrated a superior tolerability profile. At week 1, mean scores for erythema, dryness, and peeling were measurably different between the treatment groups, erythema: 0.52 vs 0.79 (P= 0.0001); dryness: 0.36 vs 0.78 (P<0.0001); and peeling: 0.27 vs 0.63 (P<0.0001) for BPO/C HE and A/BPO, respectively. Differences between the treatment groups continued to be measurably different at week 2 with erythema: 0.41 vs 0.60 (P=0.0001); dryness: 0.31 vs 0.51 (P=0.0019); and peeling: 0.32 vs 0.45 (P=0.0293) for BPO/C HE and A/BPO, respectively. Irritant/allergic contact dermatitis was the same between treatment groups, and was rarely reported.

Conclusions: BPO/C HE demonstrated a better tolerability profile in the treatment of facial acne during the first 2 weeks of treatment.

Commercial Support: 100% is sponsored by Stiefel, a GSK company

P104

The tolerability profile of a novel clindamycin-tretinoin gel when used in conjunction with benzoyl peroxide 4% wash for mild to moderate acne

Zoe Draelos, MD, Dermatology Consulting Services, High Point, North Carolina, United States

Topical retinoids are a cornerstone of acne therapy. Combining retinoids with antimicrobial agents targets more of the pathogenic aspects of acne resulting in more effective and faster treatment. In 3 large randomized trials of subjects with mild to moderate acne, a novel hydrogel formulation of solubilized clindamycin 1% and tretinoin 0.025% (CT Gel) has proven to be well tolerated and more effective than its individual agents. Benzoyl peroxide (BPO), another important component of acne therapy, can reduce P. acnes and mitigate antimicrobial resistance; therefore, using BPO with a retinoid and antibiotic can provide an optimal 3-prong treatment approach. Because BPO has the potential to irritate the skin, this study was designed to evaluate the local tolerability, irritation potential and safety of CT Gel when used in combination with a BPO 4% Wash formulated in a unique creamy vehicle. The study was a multicenter, 4-week, randomized (1:1), investigator-blinded, parallel-group study of CT Gel applied once daily in the evening, in conjunction with a BPO 4% Wash (BPW) or soap-free cleanser (control) once daily in the morning in subjects with mild to moderate facial acne. The primary endpoint was local tolerability. Subjects self-evaluated burning/stinging and itching and Investigators assessed scaling, dryness and erythema using a 6-point scale at weeks 1, 2, and 4. Sixty-one patients 13-37 years of age were enrolled. The combination of CT Gel with BPW led to a slightly higher rate of application site reactions within the first week of treatment; however, these were generally mild and improved within 1-2 weeks. At week 4, mean scores for dryness, scaling, erythema, burning/stinging, and itching in the CT Gel with BPW group compared with the control group were 0.39 vs 0.42; 0.36 vs 0.23; 0.89 vs 0.74; 0.15 vs 0.65; and 0.33 vs 0.39, respectively. The frequency of moisturizer use was similar for both groups. Four subjects in the control group experienced treatment-related adverse events, of which 3 resulted in an interruption or reduction of study product usage. The tolerability and adverse event profile of CT Gel when used with this BPW did not indicate increased irritation potential or safety concerns compared to the use of CT Gel with a non-medicated cleanser. This study demonstrated that CT Gel was safe and well tolerated and that BPO 4% Wash may be safely used as adjunct therapy with CT Gel for the treatment of mild to moderate acne vulgaris.

Commercial Support: 100% is sponsored by Stiefel, a GSK company

P105**Efficacy and safety of a novel clindamycin-tretinoin gel versus clindamycin or tretinoin alone in acne vulgaris: a randomized, double-blind, vehicle-controlled study**

Michael Jarratt, MD, DermResearch, Inc., Austin, Texas, United States

Objectives: A novel topical formulation has been developed to stabilize and solubilize clindamycin and tretinoin for once-daily acne treatment. This study evaluated the safety and efficacy of this novel hydrogel formulation containing clindamycin 1% and tretinoin 0.025% (CT Gel) compared with its monotherapy constituents and vehicle in subjects with acne vulgaris.

Methods: 1649 subjects with acne vulgaris were randomized (2:2:2:1) to 12 weeks of double-blind treatment with CT Gel, clindamycin, tretinoin or vehicle applied once daily in the evening. Primary efficacy measures were treatment success, defined as the proportion of subjects who achieved at least a 2-grade improvement in the Investigator's Static Global Assessment (ISGA) score from baseline to week 12, and the absolute change in total, inflammatory and non-inflammatory lesion counts from baseline to week 12. Safety was evaluated by adverse event reporting, vital signs, and local tolerability assessments.

Results: The proportion of subjects achieving treatment success was significantly greater with CT gel versus all other treatment groups ($P \leq 0.002$). Overall, treatment success was achieved by 35%, 26%, 25%, and 19% of the subjects in the CT Gel, clindamycin gel, tretinoin gel, and vehicle gel groups, respectively. CT Gel was associated with significantly greater mean reductions in total, non-inflammatory and inflammatory lesion counts at week 12 compared with clindamycin monotherapy ($P \leq 0.022$) and vehicle ($P < 0.001$). Compared with tretinoin monotherapy, CT gel was associated with greater mean reductions in inflammatory ($P = 0.002$) and total ($P = 0.025$) lesion counts, but not in non-inflammatory lesion counts ($P = 0.524$). Overall, the adverse event frequency and local tolerability profile of CT Gel were similar to tretinoin monotherapy.

Conclusions: CT gel is more effective than clindamycin or tretinoin monotherapy for the treatment of acne, with a safety and tolerability profile similar to tretinoin.

Commercial Support: 100% is sponsored by Stiefel, a GSK company

P106**Managing acne: The impact of dryness and irritation from acne treatments on patient practices**

Steven Feldman, MD, PhD, Wake Forest University Baptist Medical Center, Winston-Salem, North Carolina, United States; Diana Chen, MD, Coria Laboratories, Redwood City, California, United States

BACKGROUND: Fixed-combination products containing clindamycin and benzoyl peroxide (BPO) are widely used in the treatment of acne. The combination is rapidly bactericidal, reduces development of antibiotic-resistant bacteria and is highly effective. However, a potential limitation of BPO is concentration-dependent irritation and dryness that may impact patient compliance and limit product use. How patients manage the irritation and dryness has not been well characterized.

OBJECTIVES: To conduct a survey to determine self-reported dryness and irritation from facial acne treatments, their impact and coping mechanisms in acne patients.

METHODS: An internet-based survey was administered to 200 patients, aged 15-40 years who had used a commercially available clindamycin-BPO (5%) fixed combination product (Aventis Pharmaceuticals, Inc; Stiefel, a GSK Company) in the last six months on at least 50% of their face, at least 5 days per week.

RESULTS: The majority of participants (57%) rated their acne as moderate severity and 28% severe. Most had received treatment by a dermatologist (76%). On a scale of 1-10 with 10 being extremely bothersome and 1 being not at all bothersome, 55% of patients were bothered to extremely bothered (score of 6 or higher) by having dry skin, flaky/peeling skin (45%), irritated skin (44%), itchy skin (39%) and redness (37%) from using a clindamycin-BPO (5%) product. As a result, subjects either did not use the products optimally – on pimples rather than whole face (33%) or only when breakouts seemed worse (28%) – or adjusted their use – less often than recommended (32%), stopped using from time to time (32%). 31 out of 200 patients switched to another prescription product and 25 patients switched to an

OTC product. 10% of patients stopped using altogether. 41% of subjects applied moisturizers to counteract dryness and redness.

CONCLUSIONS: Dry skin or irritation related to clindamycin-BPO (5%) fixed combinations is a common complaint among acne users. These side effects can be rather bothersome and result in coping mechanisms that influence patients' use of medication and may decrease likelihood of achieving full benefit. Dermatologists can help their acne patients through selection of effective treatments that have been shown to have minimal irritation or dryness, improved communication on possible side effects related to product use and written instructions on how to manage irritation and dryness. A fixed-clindamycin-BPO combination with a lower concentration of BPO could be highly desirable.

Commercial Support: 100% sponsored by Coria Laboratories, a division of Valeant Pharmaceuticals North America

P107

The efficacy of a benzoyl peroxide 5.3% emollient foam in the treatment of truncal acne

Jason McBean, MD, Cohen Dermatology Associates, Fairfield, Connecticut, United States

Acne vulgaris affects the face, the upper chest, and the back. These are areas rich in pilosebaceous units. Approximately 50% of patients presenting with facial acne also present with truncal acne. Clinical information is limited regarding the treatment of truncal acne vulgaris. Because benzoyl peroxide may bleach fabric, a wash-off formulation is commonly recommended for truncal acne, with or without a systemic antibiotic. However, this treatment regimen is not without issues. A recent study demonstrated that a benzoyl peroxide wash applied in the shower did not reduce *P. acnes* populations on the back. In addition, the use of systemic antibiotics is sometimes problematic due to patient reluctance, adverse events, and concerns about antibiotic resistance. In this report, we examine the efficacy of an emollient foam formulation of benzoyl peroxide 5.3% in controlling acne as a monotherapy in six (6) patients. In addition to efficacy, tolerability is an important consideration when a topical acne therapy is applied over a broad surface area. Benzoyl peroxide 5.3% emollient foam features micronized benzoyl peroxide particles in a formulation containing the humectant glycerin and the emollient skin protectant dimethicone which may serve to improve its tolerability. Because the potential for bleaching of clothing can reduce treatment compliance, patients were instructed in the proper use of the emollient foam to minimize the risk of bleaching. Instructions included using at night, wearing white cotton undershirts, and using white sheets. In this study, patients were evaluated for reduction in acne lesions, the tolerability of the emollient foam applied over large body areas. In addition, the bleaching of clothing and fabrics associated with the use of the emollient foam was evaluated. The foam was found to be effective as a monotherapy in controlling truncal acne, was well tolerated, and patients were able to avoid bleaching clothing and fabrics. The results of the case studies indicate that benzoyl peroxide 5.3% emollient foam may offer a useful therapy for patients with truncal acne.

Commercial Support: 100% is sponsored by Onset Therapeutics

P108

Evaluation of a new blue light device for the self-treatment of mild to moderate acne

Ronald Wheeland, MD, University of Missouri Healthcare, Columbia, Missouri, United States; Dawn Weinstein, RN, NP, TRIA Beauty, Inc., Dublin, California, United States; Sunil Dhawan, MD, Center for Dermatology, Fremont, California, United States

Introduction: A blue light device recently cleared by the FDA is available over the counter for the self-treatment of mild to moderate inflammatory acne. It offers effective treatment without the need for antibiotics or other prescription medications. Furthermore, compared with in-office blue light therapy, it is more convenient and offers cost savings.

Methods: A total of 33 subjects aged 25-45 years who had mild to moderate inflammatory acne were instructed to use the blue light device twice daily for 8 weeks in conjunction with a proprietary foaming cleanser (containing salicylic acid and glycolic acid) used before each treatment and a proprietary serum (containing salicylic acid, azelaic acid, and niacinamide) applied after each evening treatment. Within this acne treatment system (cleanser, blue light device, and serum), the topicals offer keratolytic activity that is complementary to the anti-bacterial and anti-inflammatory actions of the blue light device. The light-emitting diode device emits light at 410 nm and was used to treat a 3 x 5 cm target area containing 3-25 inflammatory lesions for 3 minutes (~29 J/cm²), twice daily.

Results: Treatment was associated with significant ($P \leq .05$) reductions from baseline in the inflammatory lesion count (median 25% at week 1, 80% at week 8) and non-inflammatory lesion count (median 25% at week 4, 53% at week 8). The median severity of breakouts declined from moderate to mild, the median redness from breakouts declined from moderate to minimal, and all subjects reported a reduced frequency of breakouts. At week 8, more than 90% of subjects reported improvements in their skin's overall appearance, clarity, radiance, tone, texture, and smoothness. In addition, 82% of subjects reported better improvement than with their prior skin care regimen, 56% reported significantly faster improvement than with their prior regimen, and 82% were satisfied with the study treatment.

Conclusion: The acne treatment system offers rapid, effective, and convenient treatment of inflammatory and non-inflammatory lesions—as well as reductions in the severity, redness, and frequency of breakouts. More than 80% of subjects reported better improvement than with their prior skin care regimen. Indeed, comparisons with results from other reports suggest that the system may be at least as effective as a range of topical prescription acne medications. The acne treatment system is a valuable alternative to traditional approaches to acne therapy.

Commercial Support: Supported by TRIA Beauty, Inc.

BASIC SCIENCE

P200

Sebaceous gland and follicular delivery of clindamycin and tretinoin from a topically applied gel

Jon Lenn, MS, Stiefel, a GSK company, Palo Alto, California, United States; Hans Hofland, PhD, Stiefel, a GSK company, Palo Alto, California, United States

Objectives: The distribution of radiolabeled drug substances in skin and its appendages was evaluated following single dermal application of 3H-Clindamycin - 3H-Tretinoin Gel (3H-CT Gel) to mice and ex vivo human skin using micro-autoradiography (MARG).

Methods: Balb/C mice (~6-8 weeks of age) were treated topically with 0.1 mL of 3H-CT Gel. Elizabethan collars were placed on each mouse to avoid ingestion of the test agent. All mice were placed in the dark immediately after dosing to avoid light-mediated degradation of tretinoin. Mouse skin at the site of application was harvested at 1 and 4 hours after application. Human scalp skin obtained from elective surgery was cut into 2-3 cm² sections and treated within one hour of harvest. The ex vivo scalp skin cultures were treated topically with 0.1 mL of 3H-CT Gel and incubated at 37°C, for 0, 1, 4 and 18 hours. All tissues were frozen in OCT and processed for autoradiography to visualize the localization of radiolabeled material in cells/tissues.

Results: The mouse skin showed 3H-Clindamycin and 3H-Tretinoin diffusely distributed throughout the dermis, but the highest density was in and around the hair follicles and sebaceous glands at both 1 and 4 hours post-administration. In human scalp skin, the 3H-Tretinoin appeared to diffuse into the skin in a temporal manner. At time zero, 3H-Tretinoin was found below the squamous epithelial layer of cells associated with the sebaceous glands and hair shafts. At one hour, 3H-Tretinoin was more evident throughout the tissue with greater grain activity in the sebaceous glands. By 4 hours, 3H-Tretinoin appeared to be greatest in glands and hair shaft cells and diffuse labeling was detectable throughout the tissue. 3H-Tretinoin was notably lower by 18 hours, but was found in glandular tissue and hair cells, while higher amounts appeared to be in the connective tissue.

Conclusions: As early as one hour after application in the mouse, significant amounts of 3H-Tretinoin and 3H-Clindamycin accumulated in and around the hair follicles and sebaceous glands. Both clindamycin phosphate and tretinoin appeared to have similar skin distribution profiles and distribution kinetics in the

mouse. The results obtained with ex vivo human skin were comparable to those obtained with mouse skin in vivo. 3H-Tretinoin appeared to rapidly associate with the sebaceous glands and hair shafts and accumulate over time.

Commercial Support: 100% is sponsored by Stiefel, a GSK company

P201

Genetic polymorphism of PTPN12 and PAPA syndrome-associated gene CD2BP1 in patients with pyoderma gangrenosum

Andrew Nesterovitch, MD, Rush Medical Center, Department of Dermatology, Chicago, Illinois, United States; Mark Hoffman, MD, Rush Medical Center, Department of Dermatology, Chicago, Illinois, United States; Melinda Simon, MD, Rush Medical Center, Department of Dermatology, Chicago, Illinois, United States; Michael Tharp, MD, Rush Medical Center, Department of Dermatology, Chicago, Illinois, United States; Tibor Glant, MD, PhD, Rush Medical Center, Chicago, Illinois, United States

BACKGROUND: Pyoderma gangrenosum (PG) is a rare, non-infectious form of skin ulceration typically accompanied by conspicuous neutrophilic infiltration. Although the etiology of PG is unknown, many cases are associated with autoimmune disease (IBD, DM, RA) and/or with hematologic disease and neoplasia. Several familial cases were reported, suggesting the involvement of genetic factors in the etiology of PG. Two mutations in the gene encoding CD2-binding protein 1 (CD2BP1) were identified in the patients with PAPA syndrome, a rare autoinflammatory disorder with autosomal dominant inheritance, characterized by pyogenic sterile arthritis with PG and acne. PAPA-associated mutations A230T and E250Q in CD2BP1 and an experimental mutation W232A were shown to disrupt interaction of CD2BP1 with protein tyrosine phosphatase PTPN12 and other proteins that play essential role in proinflammatory signaling pathways. A recent study reports that (CCTG) tandem repeats in the promoter region of CD2BP1 gene are associated with aseptic abscesses (AA) in French patients. AA are associated with PG and Sweet's syndrome in 20% of cases.

OBJECTIVE: To sequence the coding region of PTPN12 for mutations and study genetic polymorphism in the promoter region of CD2BP1 in patients with PG.

METHODS: DNA and RNA from peripheral blood leukocytes of 14 PG patients and 20 healthy individuals were sequenced.

RESULTS: Homozygous G/G genotype (rs9640663) in PTPN12 was present more frequently in white patients with the classic form of PG (n=8) than in the matched healthy population (n=113, HapMap database) (25% vs. 13%) Heterozygous A/G genotype was also more frequent in white patients with the classic PG (n=8) than in the general healthy population (n=113) (63% vs. 48%). The calculated allele G frequency was 25% in the same group of PG patients in contrast to 12% in the healthy population. Both homozygous G/G and A/A genotypes (rs3750050) in PTPN12 were less frequent in white PG patients (n=8) than in the general population (n=113) (0% vs. 4% and 50% vs. 79%, respectively). We also found novel polymorphisms (CCTG)₆ and (CCTG)₈ in the CD2BP1 tandem repeats, but these showed similar distribution in PG (n=14) and in healthy control (n=20) samples.

CONCLUSIONS: PTPN12 polymorphism rs9640663 could be associated with PG. Continued investigation with larger numbers of PG patients is warranted. However, the (CCTG)_n tandem repeats in the promoter region of CD2BP1 showed no association with PG in our study.

Commercial Support: None Identified

P202

Investigation of drug resistance in trichophyton mentagrophytes onychomycosis infection

Muhammad Zaman, PhD, Mediprobe Research Inc, London, Canada; Aditya K Gupta, MD, PhD, Sunnybrook Health Sciences Center and the University of Toronto, Toronto, Canada

Introduction: Though in vitro efficacy of antifungals for onychomycosis is high, in vivo efficacy remain relatively low. There is evidence suggesting the main agents of onychomycosis, Trichophyton spp, acquire resistance to antifungals. Research was undertaken to identify and characterize T. mentagrophytes drug resistance genes.

Methods/Results: PCR primers identified a Trichophyton mentagrophytes candidate gene called multiple drug resistance gene 1 (TmMdr1), with 98% homology to T. rubrum MDR1 (TruMdr1) and 63-87% homology to other fungal mdr1 genes. It carries a 127 amino-acid (aa) open reading frame (ORF) upstream of a 1205aa ORF, separated by a 45bp spacer. As TruMdr1 has a single ORF of 1331aa, it was postulated the 45bp spacer is an intron spliced out during RNA editing. Northern blots of total RNA hybridized with labelled TmMdr1 probe detected TmMdr1 RNA as a doublet of 4.5Kb full-length RNA and 4.0 Kb RNA. The difference is highly suggestive of the 127aa ORF being spliced out of the transcript, and suggests either the 127aa serves a different function in TmMdr1 relative to TruMdr1, or is processed differently in TruMdr1. TmMdr1 upregulation with ketoconazole was investigated using TmMdr1 cell lines continuously cultured in different concentrations of ketoconazole for 7 days. Genomic DNA was digested with BstEII restriction enzyme, and hybridized against TmMdr1 DIG-labelled DNA probes. The copy number of TmMdr1 increased from 2 to 20 copies per cell upon exposure to 2ug/ml ketoconazole. Further increases in ketoconazole concentrations did not further increase copy number. This suggests that cells adapted to higher ketoconazole exposure may use additional resistance methods.

Discussion and Conclusion: A clear understanding of the molecular mechanisms for Trichophyton drug resistance is critical in new drug formulation and devising effective treatment regimens. This project is adding to the knowledge of T. mentagrophytes drug resistance genes, and further investigations are proceeding.

Commercial Support: None Identified

CLINICAL DERMATOLOGY AND OTHER CUTANEOUS DISORDERS

P300

Oxalosis involving the skin

Brooke Jeffy, MD, University of Louisville, Dept of Medicine, Division of Dermatology, Louisville, Kentucky, United States; Alfred Knable, MD, University of Louisville, Dept of Medicine, Division of Dermatology, Louisville, Kentucky, United States; Janine Malone, MD, University of Louisville, Dept of Medicine, Division of Dermatology, Louisville, Kentucky, United States; Joseph Blackmon, University of Kentucky School of Medicine, Lexington, Kentucky, United States

Background: The primary hyperoxalurias are a group of rare autosomal recessive metabolic disorders associated with abnormal overproduction of serum oxalate and subsequent deposition in tissue. The majority of patients present at an early age with recurrent urolithiasis and renal failure. Vascular deposition of oxalate producing skin manifestations such as livedo reticularis, acrocyanosis, peripheral gangrene and ulcerations is typical of the primary hyperoxalurias although cutaneous manifestations are rare.

Observation: A 38 year old female with end-stage renal disease on hemodialysis was referred for dermatologic evaluation of progressive skin changes including livedo reticularis, superficial eschars and brawny, woody fibrosis of her extremities. Clinically she was suspected to have calciphylaxis or nephrogenic systemic fibrosis. Cutaneous biopsy specimens revealed rectangular, birefringent, yellow-brown, polarizable crystalline material suggestive of oxalate within the dermis, subcutis and medium-sized vessels along with areas of focal epidermal and superficial dermal necrosis. Subsequently a history of recurrent nephrolithiasis was obtained that, in combination with her biopsy findings, suggested a diagnosis of oxalosis. More specifically, our patient's dermatological findings most closely resemble those of primary hyperoxaluria as the underlying etiology although confirmatory genetic testing has not been done.

Comment: Skin manifestations of oxalosis are not common. This case highlights the variability of clinical presentations in primary hyperoxaluria and that the disease can be diagnosed in adulthood. Additionally,

our case demonstrates that oxalosis should be included in the differential diagnosis of calciphylaxis and nephrogenic systemic fibrosis.

Commercial Support: None Identified

P301

Evaluating a rosacea treatment system containing a cleanser, metronidazole, hydrating complexion corrector, and sunscreen

James Leyden, MD, KGL, Inc., Broomall, Pennsylvania, United States

Introduction: A rosacea treatment system (consisting of four components—cleanser, metronidazole 0.75% gel, hydrating complexion corrector, and sunscreen SPF30) has been developed to treat rosacea pharmacologically and non-pharmacologically. The system aims to reduce the appearance of redness as rapidly as possible while also providing other clinical benefits in the longer term.

Methods: Adult women with mild or moderate rosacea, and mild or moderate erythema on the malar area of the face, were eligible to enroll in this investigator-blind, parallel-group study. Participants were randomly assigned to receive one of the following three treatments for 28 days: the rosacea treatment system; the rosacea treatment system minus metronidazole; or metronidazole 0.75% gel plus standard skin care (standard cleanser and moisturizer/sunscreen). Each product was applied twice daily except the sunscreen in the rosacea treatment system was applied each morning and as needed.

Results: Overall, 30 patients enrolled and 29 (97%) completed. The proportion of patients who, at day 28, had at least slight global improvement ($\leq 24\%$ improvement) was 90% with the rosacea treatment system, 60% with the rosacea treatment system minus metronidazole, and 67% with metronidazole plus standard skin care. The proportion with at least moderate global improvement (25-49%) was 40% with the rosacea treatment system, 10% with the rosacea treatment system minus metronidazole, and 11% with metronidazole plus standard skin care. At day 14, the mean erythema score had declined in the rosacea treatment system group and remained unchanged with metronidazole plus standard skin care. At day 28, the proportion of patients considering their study regimen to be very effective, effective, or somewhat effective in reducing dryness was 90% with the rosacea treatment system, 90% with the rosacea treatment system minus metronidazole, and 78% with metronidazole plus standard skin care. Also at day 28, the proportion of patients who reported their skin was easily irritated at least sometimes was 40% with the rosacea treatment system, 70% with the rosacea treatment system minus metronidazole, and 89% with metronidazole plus standard skin care. Two adverse events were reported (both in the metronidazole plus standard skin care group)—dry chin and burning sensation.

Conclusion: The rosacea treatment system may offer superior efficacy and tolerability to metronidazole plus the standard skin care used in this study.

Commercial Support: Supported by OMP, Inc.

P302

Cutaneous sclerosis: A novel marker of sclerosing mesenteritis

John Bernardi, MD, University of Louisville, Louisville, Kentucky, United States; Brian Hinds, University of Louisville, Louisville, Kentucky, United States; Jeffrey Callen, MD, University of Louisville, Louisville, Kentucky, United States; Soon Bahrami, MD, University of Louisville, Louisville, Kentucky, United States

Sclerosing mesenteritis (SM) is a rare, self-limited, fibroinflammatory condition of unknown etiology characterized by inflammation and fibrosis of the mesenteric adipose tissue. More common in men, this condition usually afflicts those in the seventh decade of life. No association with any internal malignancy has been definitively elucidated. Treatment is complex and depends on the clinical situation. If either progression of disease or debilitating symptoms develop, first line therapies include tamoxifen and prednisone. Refractory SM has reportedly been responsive to cyclophosphamide, thalidomide, and azathioprine. To our knowledge, neither extra-abdominal extension nor cutaneous involvement has ever

been reported with SM. A 68-year-old white woman presented with multiple indurated, subcutaneous nodules on the bilateral upper extremities and abdomen. Following an abrupt onset three years ago, these lesions have been asymptomatic. At the time of our evaluation, she was four months status-post exploratory laparoscopy because of an abdominal mass identified on computed tomography after complaints of early satiety and a 20-pound weight loss. Histopathological evaluation of this mass was consistent with sclerosing mesenteritis. Physical examination revealed two slightly hypopigmented and atrophic, non-scaly, indurated nodules on each upper extremity and two larger and more elevated such lesions on the abdomen. Two 4mm punch biopsy specimens were obtained from the right arm and abdomen. The findings of woody sclerosis replacing subcutaneous fat along with fat necrosis surrounded by a mild lymphocytic and histiocytic component were identical to the microscopic appearance of the abdominal mass. Because of the relatively stability of her disease, no therapies were initiated. She will continue to be monitored for expansion of existing lesions or the development of new lesions at which time systemic therapy may be considered. The chronological and histological overlap of this patient's abdominal and cutaneous sclerosis suggests a common pathogenesis involving these organ systems. This case illustrates a previously undescribed manifestation of a very rare gastrointestinal disease. Clinicians and dermatopathologists alike should be aware that cutaneous sclerosis in the setting of mesenteric sclerosis might represent extra-abdominal extension of disease. Additionally, if these sclerotic features are described in cutaneous lesions prior to known abdominal disease, one should perform a comprehensive review of systems and physical examination with directed imaging to evaluate for sclerosing mesenteritis.

Commercial Support: None Identified

P303

Cutaneous vasculitis associated with cocaine adulterated with levamisole

Jennifer Jenkins, MD, MPH, Alpert Medical School of Brown University Department of Dermatology, Providence, Rhode Island, United States; Ellen Hsu Hung, MD, Alpert Medical School of Brown University Department of Emergency Medicine, Providence, Rhode Island, United States; George Krompouzou, MD, PhD, Alpert Medical School of Brown University, Providence, Rhode Island, United States; Leslie Robinson-Bostom, MD, Alpert Medical School of Brown University Department of Dermatology, Providence, Rhode Island, United States

Since 2002, the United States' cocaine supply has become increasingly contaminated with levamisole. Levamisole, an anthelmintic agent, which was withdrawn from the U.S. market in 2000, has been linked to agranulocytosis and death in cocaine users. We present the first case of widespread cutaneous necrotizing vasculitis associated with the use of cocaine adulterated with levamisole. A 47-year old male presented with acutely painful purpuric/necrotic lesions of the medial thighs. Medical records indicated a history of cocaine abuse by positive toxicology screens. Due to increasing pain and a clinical suspicion for necrotizing fasciitis, emergent surgical debridement was performed and intravenous antibiotics administered. Gram stain and cultures of skin tissue were negative. Blood cultures were negative and the patient remained afebrile with a normal differential on complete blood count. Histopathology showed a neutrophilic necrotizing vasculitis of small- and medium-sized vessels. Systemic workup showed a positive p-ANCA (titer > 1: 10240), a weakly positive myeloperoxidase antibody, and a negative proteinase-3 antibody. This antibody pattern is consistent with cocaine-induced vasculitis. One week later, the patient developed edematous purpuric plaques of the helices. Histopathology of an acute lesion showed an occlusive vasculitis with extensive intravascular fibrin thrombi and overlying epidermal necrosis. The clinical presentation then dramatically worsened as several necrotic lesions developed over the cheeks, tongue, trunk, genitalia, and extremities. Systemic work-up ruled out renal disease and connective tissue involvement. The patient admitted to cocaine snorting 24 hours prior to the onset of new lesions and his urine toxicology was positive for both cocaine and levamisole. He was treated with oral corticosteroids, aspirin, pentoxifylline, and clobetasol 0.05% ointment with gradual resolution over the course of two months. Systemic use of levamisole has been reported to cause vasculitis but this is the first report of vasculitis after nasal levamisole intake. The purpuric lesions of the ears in our patient are reminiscent of previously reported cases of levamisole-induced vasculopathy. Our patient's dramatic

clinical presentation results from the combined adverse effects of cocaine and levamisole. We present this case to alert practitioners of this clinical presentation as a clue to potentially lethal illicit drug use.

Commercial Support: None Identified

P304

Multiple papular translucent lesions on the upper lip

Jose Aneiros-Fernandez, MD, Department of Pathology, Granada, Spain; Francisco O'Valle, MD, Department of Pathology, Granada, Spain; Husein Husein-ElAhmed, MD, Department of Dermatology, Granada, Spain; Jose Aneiros-Cachaza, MD, PhD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, Department of Dermatology, Granada, Spain

INTRODUCTION: Eccrine hidrocystomas are cystic tumor the sweat glands ducts, are relatively rare and account less than 1% of submitted cutaneous biopsies.

CASE REPORT: A 60-year-old woman caucasian who was referred to the dermatology department for presenting multiple lesions translucent papular asymptomatic two years of evolution on the upper lip. Increase in size in summer and physical exercise, improving winter. Excision was performed in one of the lesions. The histopathologic showed one cyst in the thickness of the dermis. The cyst wall composed of 2 layers of cuboidal cells with eosinophilic cytoplasm that secrete into the cyst, without decapitation. No evidence of PAS-positive. Immunohistochemistry presented positivity for high molecular weight cytokeratins and CEA, and negative for GCDFP-15. A diagnosis of multiple eccrine hidrocystoma was made.

DISCUSSION: - The occurrence of these injuries was caused by retention of sweat favored by increased temperature and physical exercise - There is an increased incidence in hyperthyroid patients, possibly related to hyperhidrosis. - In regard of treatment, when are unique lesions performed surgical excision when are multiple lesions several treatments have been described with favorable response; t6pica 1% atropine or scopolamine creams, with a 585 nm flashlamp-pupel pulse dye laser and botulim toxin.

Commercial Support: 100% Dako Diagnosticos SA

P305

Hair collar sign: Aplasia cutis

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, PhD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Maria Antonia Fernandez-Pugnaire, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: Aplasia cutis congenital usually affects the scalp and shows a variety of clinical features from fissure-like ulcers to atrophic macules. Among them, a cystic variant covered with a membranous round surface is called membranous or bullous aplasia cutis congenital. We report a case of aplasia cutis surrounded by a hair collar ("hair collar sign").

CASE REPORT: A 1 month-old-boy without relevant medical history and also pregnancy and the delivery had been unremarkable, presented with two atrophic areas of alopecia, 20 mm and 10 mm in diameter, with a membranous surface was observed near the vertex, accompanied by a rim of terminal hairs. This lesion was diagnosed as aplasia cutis congenital with a hair collar sign.

DISCUSSION: The pathogenesis of aplasia cutis congenita is still unclear, although various mechanisms have been proposed. Hypertrichosis is proposed to have a close association with neuroectodermal defects and 'hair collar' sign could suggest an underlying cranial neural tube defect.

Commercial Support: None Identified

P306

Nevus comedonicus: Presentation of two clinical forms

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Agustin Buendía-Eisman, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

Introduction: Nevus comedonicus is a rare congenital hamartoma of the pilosebaceous unit, characterized by cystic dilatation and extensive keratotic plugging characterized clinically by groups of comedones along the Blaschko lines. Lesions may develop any time from birth to middle age, but are usually present at birth or develop before the age of 10 years. Men and women are equally affected.

Clinical case: A 4 yr-old healthy girl presented asymptomatic grouped pits filled with black plugs over the left cheek which were present since birth. There was no history suggestive of skeletal, ocular or other systemic involvement. There was no history of any skin disease in the past. Histopathological features were consistent with the diagnosis of nevus comedonicus. A 5-yr-old healthy girl presented asymptomatic lesions over the gluteous with few comedones and scars without systemic symptoms. The biopsy was compatible with nevus comedonicus

Discussion: Clinically, nevus comedonicus is of two types. In the first type, comedones are predominantly seen. In the second type, comedones undergo inflammatory changes, with late sequelae such as scars, keloids, fistulae and formation of follicular cysts. The medical options rarely lead to any marked improvement and the surgical options require expertise with equivocal results and long downtime. We have presented two cases one of each group.

Commercial Support: None Identified

P307

Rowell syndrome and antiphospholipid syndrome

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, PhD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Maria Antonia Fernandez-Pugnaire, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

Introduction: The clinical spectrum of cutaneous lesions of lupus erythematosus is very wide. Occasionally vesicular lesions that resemble other dermatoses such as erythema multiforme, bullous pemphigoid or dermatitis herpetiformis are present. A case report of subacute lupus associated with erythema multiforme that met criteria of Rowell's syndrome is presented.

Case report: 45-year-old woman with personal history of antiphospholipid syndrome presented with a slightly pruritic rash located on the trunk and extremities for 2 weeks. Physical examination revealed erythematous annular lesions located in photoexposed areas compatible with subacute lupus histologically. A week of initiating treatment with prednisone (1mg/kg) the patient develops a pattern of generalized purple to erythematous skin lesions with central vesicular and mucosal involvement. The anti-Ro and RF were positive and the biopsy compatible was with erythema multiforme.

Discussion: Rowell's syndrome was first described in 1963 and is characterized by the following major criteria: discoid, acute or subacute lupus erythematosus, erythema multiforme with or without mucosal involvement and ANA speckled pattern. Minor criteria are chilblain lupus, anti Ro / La and rheumatoid factor positive. The diagnosis requires the presence of three major criteria and at least one minor. About 35 cases of Rowell's syndromes have been reported in literature and some of them were not present all

the criteria required for diagnosis. Our patient presented a typical disease, with all necessary diagnostic criteria and also was associated with antiphospholipid syndrome, a situation not described in literature

Commercial Support: None Identified

P308

Urticarial vasculitis in a newborn

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, MD, PhD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Ramón Naranjo-Sintes, MD, PhD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

Introduction: Urticarial vasculitis is characterized by recurrent episodes of urticaria lasting more than 24 hours and leukocytoclastic vasculitis. Fever and arthralgias are common findings.

Clinical case: A 1-month-boy, born normally to non-consanguineous parents presented with evanescent erythematous-edematous lesion on trunk and extremities since birth. Physical examination revealed multiple annular wheals with purpuric papules. Blood count, basic biochemistry, complement, ANA and ESR was normal. Cutaneous biopsy was compatible with urticarial vasculitis. Treatment with systemic corticosteroids reduces the lesions in two weeks.

Discussion: Urticarial vasculitis is characterized by a chronic course often associated with angioedema and systemic symptoms with a heterogeneous clinical spectrum. Some patients associated with other autoimmune and hypocomplementemia. Treatment is complex and requires the association of several drugs for disease control. Despite this disease has been described during the infancy this is the first case described in a newborn.

Commercial Support: None Identified

P309

Dermatology clinic in Gaborone, Botswana

Saurabh Singh, MD, Georgetown University Hospital, Washington, District of Columbia, United States; Carrie Kovarik, MD, University of Pennsylvania, Philadelphia, Pennsylvania, United States; David Carr, MD, Wright State University Boonshoft School of Medicine, Dayton, Ohio, United States

We will present cases of African patients that presented to a routine medical dermatology clinic at Princess Marina Hospital in Gaborone, Botswana during the month of February 2010. This poster will compare and contrast the type of patients that a medical dermatologist will see at a teaching institution in the United States to a teaching institution in a sub-Saharan African capital.

Commercial Support: None Identified

P310

Neutrophilic dermatosis of the dorsal hands with extracutaneous involvement

Min Wee Chia, MD, MBBS, Changi General Hospital, Singapore; Yong Kwang Tay, MD, Changi General Hospital, Singapore

A 55-year-old man with known myelodysplasia presented with a 1-week history of painful, erythematous plaques on the dorsal aspect of the hands. Physical examination revealed violaceous, oedematous

plaques in the dorsal aspects of the hands bilaterally. Laboratory studies showed moderate leukocytosis, neutrophilia, anemia, and markedly elevated inflammatory indices. Bacterial cultures were negative. The histology of a skin biopsy is consistent with a neutrophilic dermatosis. A diagnosis of neutrophilic dermatosis of the dorsal hands (NDDH) was made based on the predominant presentation on the hands. Interestingly, the patient was also found to have multiple suppurative right cervical lymph nodes. However, cultures and extensive infectious work-up returned negative. The skin lesions and the cervical abscess showed marked improvement after prednisolone (1mg/kg/day) was started. NDDH is a localized form of Sweet's syndrome. Sweet's syndrome is frequently associated with haematological malignancies, solid tumours and inflammatory bowel disease. A similar pattern is seen in NDDH. A review of 55 cases of NDDH reported in the literature showed that haematological malignancies (18%) were most commonly associated with NDDH, as is present in our patient. Interestingly, aseptic abscesses and neutrophilic infiltrates in organs other than the skin are uncommon systemic manifestations of neutrophilic dermatoses, and there have been reports of pulmonary, renal, bone, neurological, intraabdominal visceral and ocular involvement in Sweet's syndrome. These can often be mistaken as infectious abscesses, and lead to unnecessary systemic antibiotics and surgical procedures.

Commercial Support: None Identified

P311

Interesting cases from Indiana University

Andrew Bridge, MD, MBA, Indiana University, Indianapolis, Indiana, United States; Ann-Marie Hyatt, MD, Indiana, Indianapolis, Indiana, United States; Brandie Tackett, MD, Indiana University, Indianapolis, Indiana, United States; Marjorie Yang, MD, Indiana University, Indianapolis, Indiana, United States; Michael Sheehan, MD, Indiana University, Indianapolis, Indiana, United States

Selected interesting cases culled from the clinics of Indiana University including rare genodermatoses and unique presentations of less commonly seen dermatoses such as tuberculosis verrucosa cutis will be presented with a brief review of the literature.

Commercial Support: None Identified

CONNECTIVE TISSUE DISEASE

P400

Acute syndrome of apoptotic pan-epidermolysis

William Adams, MD, University of Louisville, Louisville, Kentucky, United States; Cindy Owen, MD, Univ Of Louisville Dept of Dermatology, Louisville, Kentucky, United States; Jeffrey Callen, MD, Univ. of Louisville Dept of Dermatology, Louisville, Kentucky, United States

Background: Acute Syndrome of Apoptotic Pan-Epidermolysis (ASAP) is a variant of systemic lupus erythematosus (SLE) that mimics Toxic Epidermal Necrolysis (TEN). This entity was first described by Ting et al. in 2004 and is characterized by full thickness epidermal necrosis with widespread bullae, sloughing, and erythema as seen with traditional TEN. However, unlike classic TEN, ASAP usually is not triggered by a drug or infection and is associated with slower progression. ASAP must be differentiated from bullous LE, Rowell's syndrome, and other immunobullous diseases including bullous pemphigoid, dermatitis herpetiformis, pemphigus vulgaris, epidermolysis bullosa acquisita, and porphyria cutanea tarda.

Observation: A thirty-six year-old woman with a known history of Ro (SS-A) positive SLE presented with bullae and sloughing of her back, shoulders, and posterior thighs. She was also noted to have two oral erosions and scaly erythematous plaques of her face, chest, arms, and legs. Two weeks prior to presentation she began to notice a widespread erythematous pruritic eruption that gradually became painful before developing bulla. She denied any new medications or infections in last two months prior to

admission. During her hospital course she was noted to have severe pancytopenia, glomerulonephritis, and a pericardial effusion. Punch biopsies showed a lichenoid interface with epidermal necrolysis. DIF showed a pattern characteristic for a bullous form of LE. High dose intravenous and oral corticosteroids eventually resulted in resolution and healing of her cutaneous findings over a three week period. Comment: ASAP has been described as a variant of TEN in SLE patients. Many of these patients have been found to be Ro (SS-A) positive leading some to believe this could be an immunological marker for this entity. ASAP differs from classic TEN in that there is rarely a medication or infectious etiology found. DIF can be used to differentiate this process from other LE-related immunobullous diseases. Rowell's usually contain targetoid macules and have a different histopathologic presentation. SCLE with bullae usually is associated with annular plaques, spares mucous membranes, and has a vacuolar interface. Bullous LE typically presents with a photo-distribution pattern. Corticosteroids appear to be the mainstay of treatment in ASAP; however, other therapies used in classic TEN such as IVIG may also serve a role. Further randomized controlled trials will have to be performed before any standard regimens or dosings can be determined.

Commercial Support: None Identified

P401

Tumid lupus in the lines of Blaschko

Genevieve Egnatios, MD, Mayo Clinic Arizona, Scottsdale, Arizona, United States; Susan Laman, MPH, MD, Mayo Clinic Arizona, Scottsdale, Arizona, United States

A 26 year-old woman presented for evaluation of asymptomatic papules that over the last 5 years had coalesced into plaques. Initially, the eruption only involved the superior aspect of her left breast. Over time, she had developed additional similar lesions unilaterally on the left arm, leg, buttock, and dorsal foot. Prior to the current evaluation, the patient had seen two outside dermatologists and undergone three skin biopsies. These biopsies from the left upper chest, left upper arm, and left lower leg revealed findings consistent with dermal mucinosis. She had alternatively been told that she could have nevus mucinosis or papular mucinosis. Her past medical history was remarkable for numbness on the left side, temporary vision loss in the left eye, and occasional aching joints. She denied joint swelling. She had one child who was without skin issues. Her physical examination revealed multiple flesh-colored to pink firm papules and plaques distributed in a linear fashion across the left chest extending onto the upper arm. She had a similar although more subtle eruption on her left leg and a plaque on the dorsal surface of her left foot. CBC, ANA, and ENA were normal. A skin biopsy performed of the left upper arm showed focal vacuolization of basal keratinocytes with apoptotic keratinocytes focally clustered at the basement membrane zone. Within the dermis, there was a minimal superficial and deep, perivascular and peri-eccrine lymphocytic inflammatory infiltrate. Interstitial dermal mucin was markedly increased. The elastic tissue fiber network appeared intact. The basement membrane had relatively normal thickness. Findings were consistent with tumid lupus. Skin lesions that follow Blaschko lines are thought to be a cutaneous manifestation of mosaicism arising from a mutation in keratinocytes during embryogenesis. The patient presents with normal skin adjacent to abnormal skin. Congenital skin disorders such as linear bullous ichthyosiform erythroderma have been described in this distribution, but also many inflammatory conditions such as lichen planus, lichen striatus, and psoriasis. Rarely, cutaneous lupus can be seen in a unilateral linear pattern along the lines of Blaschko. It is hypothesized that the somatic mutation uncovers susceptibility to autoimmunity.

Commercial Support: None Identified

P402

Clinical and serological manifestations of parvovirus-B19 associated systemic lupus erythematosus

Meghan Hession, Tufts Medical Center, Boston, Massachusetts, United States; Alice Gottlieb, MD, PhD, Tufts Medical Center, Boston, Massachusetts, United States

Background: Parvovirus B19 (B19) infection and systemic lupus erythematosus (SLE) share striking similarities clinically and serologically. In some patients, B19 infection can transiently mimic or exacerbate SLE; in others, symptoms and lab abnormalities consistent with SLE persist for months or years, leading some clinicians to hypothesize a causal role for B19 in the development of autoimmunity.

Objective: To describe a case of SLE with urticarial vasculitis possibly associated with prior B19 infection and to identify adult cases in the literature of individuals with confirmed B19 infection who by definition met the American Academy of Rheumatology (ACR) criteria for SLE. We aim to identify clinical and serological features common to B19-associated SLE and to identify differences in such features between those whose SLE symptoms resolved and those who developed a full-blown disease course.

Methods: A MEDLINE literature search was performed using the following terms: parvovirus, B19, systemic lupus erythematosus; relevant references from these articles not previously identified were also included.

Results: 24 adult cases (23 women, 1 man) of B19-associated SLE were identified: 9 with transient SLE symptoms, 10 who developed SLE symptoms persisting at least a year, and 5 whose infections occurred in the context of previously established SLE. The mean age was 36.8. Among the 11 ACR criteria, positive anti-nuclear antibody (ANA) titers occurred in all 24 patients; arthritis in 22; immunologic manifestations in 21 (18 anti-double-stranded DNA, 7 anti-cardiolipin and/or anti- β_2 -glycoprotein, 4 anti-RNP, 2 anti-Smith, 2 anti-SSB, 1 anti-SSA, and 1 anti-Scl-70); cytopenias in 17; malar rash in 12; renal involvement in 6; serositis in 4; oral ulcers in 3; photosensitivity in 1; CNS involvement in 1. There were no reports of discoid rash, although other cutaneous manifestations were noted. When comparing patients with transient versus persistent SLE symptoms, the majority of patients with transient symptoms met only four ACR criteria (6/9), while those with persistent SLE met 5 or more (7/10). All 9 patients with a self-limited SLE course had anti-nuclear antibody (ANA) titers of 1:320 or less, whereas 9/10 patients who developed persistent SLE had titers of at least 1:640 at the time of diagnosis. In terms of specific clinical manifestations, systemic features occurred more frequently in those with persistent rather than transient SLE (serositis: 4 vs. 0; renal involvement: 2 vs. 1).

Conclusions: Cutaneous and joint symptoms, cytopenias, and elevated ANA and anti-dsDNA titers are among the most common manifestations of parvovirus B19-associated SLE. Whether patients later develop chronic autoimmune disease following infection may depend on genetic and environmental predisposition, as well as relative titers of ANA and degree of systemic involvement at the onset of symptoms.

Commercial Support: None Identified

DERMATITIS, ATOPIC

P500

Exploring the impact of atopic dermatitis on the social relationships of Canadian adolescents

Katie Armstrong, University of Toronto, Toronto, Canada; Miriam Weinstein, MD, The Hospital for Sick Children, Toronto, Canada

Introduction: Atopic dermatitis (AD) is an increasingly common, chronic disease of Western nations. AD typically appears in early childhood, and patients may experience intermittent flare-ups often into adulthood. Scientific literature concerning the affects of AD on social relationships is sparse. This study explores why and how AD impacts the social relationships of Canadian adolescents. Social relationships are an important determinant of health. The health risks associated with lower levels of social integration are comparable to those of smoking, hypertension and obesity. Adolescents are a crucial target population because this is a critical period for the development of self-esteem and where peer-relationships often take on a heightened importance. The goal of the study is to explore the social relationships of Canadian adolescents with AD

Methods: This study used the qualitative research method of grounded theory. Grounded theory is an inductive approach to research that builds theory from interview data. According to grounded theory, the authors broadly "explore" and then develop theories from the data collected. Data collection consisted of in-depth semi-structured interviews with adolescents with AD. Interviews were anonymized and transcribed. Data analysis was cumulative and concurrent throughout the data collection period. A grounded theory approach was used to uncover emergent themes from the data.

Results: This study found that the reactions of friends help explain why AD impacts social relationships. Overall, it is the balance of supportive and negative reactions from friends that determine the level of perceived peer-acceptance and seem to dictate how AD impacts social relationships and interactions. Individuals who experience high levels of peer acceptance are less likely to avoid, feel self-conscious or hide their AD during social situations.

Conclusions: Understanding the ways in which AD contributes to differences in social relationships including the potential for diminished peer- and self-acceptance may inform current clinical care.

Commercial Support: None Identified

P501

Nonsteroidal barrier repair therapy: Utility in complicated severe atopic dermatitis

Ellen Frankel, MD, Private Dermatology Practice, Cranston, Rhode Island, United States; Amylynne Frankel, MD, Private Dermatology Practice, Cranston, Rhode Island, United States

Atopic Dermatitis is a chronic, cyclical, inflammatory skin condition characterized by pruritus, typical lesion morphology and distribution, family history, and relapsing course. In practice, topical corticosteroids are the standard of care in managing the inflammation of atopic dermatitis, but problems with their usage such as cutaneous complications, HPA axis suppression, and tachyphylaxis, limit the long-term and broad surface use of these agents. Recent research indicates that atopic patients have a genetic predisposition for epidermal barrier dysfunction that may allow easy penetration of irritants/allergens and excessive transepidermal water loss, inevitably leading to pruritus and inflammation. Subsequently, epidermal barrier repair has become a focal point in treatment regimen goals. Well designed clinical studies suggest that barrier treatment is effective for maintenance therapy and may be beneficial in managing mild-moderate eczematous flares, but there has been little clinical work to evaluate these products as monotherapy treatment of patients with severe atopic flares. This poster presents a complex case of severe atopic dermatitis. The patient's vast body surface area involvement, lesion severity, and history of non-compliance limited the use of available treatment options. A barrier repair therapy-- a hyaluronic acid based emollient foam, was prescribed as monotherapy BID. After two weeks of treatment, a 48% improvement of SCORAD was achieved, improving to a 79% recovery after 4 weeks of treatment. The patient reported a significantly improved pruritus severity score and the patient conveyed high satisfaction ratings with the outcome. The work done here suggests that prescription topical barrier therapies may have expanded utility in managing more complicated severe atopic cases commonly seen in everyday clinical practice.

Commercial Support: 100% is sponsored by Onset Therapeutics

P502

A case study evaluating a hyaluronic acid based barrier repair emollient foam in the clinical management of atopic dermatitis

Amy Forman Taub, MD, Advanced Dermatology, LLC, Lincolnshire, Illinois, United States

Atopic Dermatitis is a chronic inflammatory pruritic skin disease that occurs most frequently in children, but can continue into adulthood with relapsing course. Researchers have identified a breakdown in epidermal barrier function as an important etiologic factor in the development of the disease. The treatment of atopic dermatitis usually encompasses two phases, flare control and maintenance therapy.

Each treatment phase should address four primary goals: inflammation reduction, epidermal barrier function normalization, itch control, and flare prevention. A non-steroidal, hyaluronic acid based, prescription emollient foam was developed to normalize and maintain epidermal function. This poster reports a series of case studies of patients with atopic dermatitis treated with the hyaluronic acid based barrier repair foam. Four patients with moderate to severe atopic dermatitis involving >10% of their body surface area (BSA) were enrolled at a single clinical research site to evaluate the clinical utility and patient tolerability for a hyaluronic acid based prescription emollient foam. Enrolled patients were required to have active, visible evidence of atopic dermatitis with >10% BSA involved. Patients were instructed to use the product BID as monotherapy or PRN as an adjunctive therapy. Three out of the four patients were previously using topical steroids with unsatisfactory results. The other patient, who had previously experienced limited success with topical steroid therapy, used the product as monotherapy for clearance and maintenance. Patients achieved a mean SCORAD improvement of 42%, an itch reduction (visual analogue scale) of 55%, and a sleep score recovery (visual analogue scale) of 49%. Patient surveys indicate that the aesthetic characteristics of the emollient foam are highly regarded and may drive patient adherence to treatment. The results of the case study series indicate that the hyaluronic acid based barrier repair foam may be a valuable addition to the treatment armamentarium for atopic dermatitis.

Commercial Support: 100% is sponsored by Onset Therapeutics

P503

A clinical demonstration of the spreadability of a non-steroidal hyaluronic acid emollient foam in atopic dermatitis

Zoe Diana Draelos, MD, Dermatology Consulting Services Research Center, High Point, North Carolina, United States

Atopic dermatitis is a common skin condition characterized by inflammation, pruritus, and xerosis. While topical corticosteroids represent the mainstay of treatment, emollients to reduce skin roughness and moisturizers to enhance the water-holding capacity of the skin are important skin care adjuncts. Hyaluronic acid, a naturally occurring glycosaminoglycan, has recently been formulated in a prescription non-dissipating emollient foam. This study was undertaken to determine the spreadability of the foam as compared to a standard oil-in-water emulsion cream. 10 consented subjects with mild to moderate symmetric forearm atopic dermatitis were enrolled in an IRB-approved single investigator double blind split body study. An equivalent amount of the hyaluronic acid emollient foam and the oil-in-water emulsion cream were pigmented with iron oxide and randomized for application to the back of the hand. The dermatologist investigator then spread the foam and cream from the hand as far up the forearms as possible while leaving a therapeutic film over the skin surface. The hyaluronic acid emollient foam spread twice as far as the oil-in-water emulsion cream, as documented by measurements on study photographs. In addition, 9/10 subjects preferred the foam over the cream in terms of ease of spreadability. The hyaluronic acid emollient foam may be valuable in the treatment of atopic dermatitis due to the non-greasy aesthetics and ease of use, factors important in patient compliance. In addition, the ability of foam to cover a large body surface area decreases the cost per application of the prescription emollient foam. Emollient foam hyaluronic acid technology offers an additional therapeutic option in the treatment of atopic dermatitis.

Commercial Support: 100% is sponsored by Onset Therapeutics

P504

The efficacy of hyaluronic acid foam in the treatment of mild to moderate atopic dermatitis

Zoe Diana Draelos, MD, Dermatology Consulting Services Research Center, High Point, North Carolina, United States

A variety of prescription devices have been developed to improve barrier function in persons with atopic dermatitis. These products are based primarily on the use of occlusive agents to decrease transepidermal water loss, creating an environment for optimal healing. A newly developed hyaluronic acid based, pH neutral foam technology formulated to maximize humectancy and normalize transepidermal water loss was evaluated for its ability to optimize barrier repair while minimizing unnecessary irritation. The double blind split body study enrolled 20 subjects with mild to moderate symmetrical atopic dermatitis involving body surface area greater than or equal to 10% using the arms or the legs as the target site. Subjects were randomized to apply the hyaluronic acid emollient foam or the reference ceramide-dominant emulsion cream to one side of the body with the other test product applied to the opposite side. Subject and investigator ratings were made for erythema, scaling, lichenification, excoriation, itching, stinging, and burning at baseline, week 2, and week 4. Both formulations achieved statistically significant improvement in all clinical signs and symptoms of atopic dermatitis by week 4; however the hyaluronic acid foam achieved statistically significant improvement in overall eczema severity by week 2, whereas the ceramide-dominant emulsion cream did not. The subject's preference statistically significantly favored the foam in terms of ability to spread, moisturize, ease of use, and lack of odor. In addition, the foam was preferred for effectiveness and ability to soothe. A prescription hyaluronic acid-containing foam device offers an aesthetic formulation with excellent efficacy in patients requiring an environment for barrier repair with mild to moderate atopic dermatitis.

Commercial Support: 100% is sponsored by Onset Therapeutics

P505

The epic atopic dermatitis community-based trial: evaluating safety and efficacy of ceramide-dominant lipid emulsion

James Del Rosso, DO, Las Vegas Skin and Cancer Clinic, Las Vegas, Nevada, United States; Leon Kircik, MD, Physicians Skin Care, Louisville, Kentucky, United States

Background: The ceramide-dominant lipid emulsion, the only available non-steroidal prescription formulation of its kind for the treatment of atopic dermatitis, works to help repair the skin barrier with a unique 3:1:1 ratio of ceramides, cholesterol and free fatty acids. This poster presents the results of the EPIC trial, the largest community-based trial in atopic patients ever published with a particular emphasis on results analyzed in consideration of subject baseline severity, gender, race, and age. **Study Objective/Design:** The EPIC trial is being conducted as an open label trial for 21 days to evaluate the efficacy and safety of the ceramide-dominant lipid emulsion in subjects with mild to moderate atopic dermatitis. More than 200 subjects at 57 clinical sites used the ceramide-dominant lipid emulsion alone or in combination with a topical steroid. Investigator-assessments are Fitzpatrick skin type, adverse event, satisfaction, and global assessments at Days 1 and 21. Subject assessments include pruritus at Days 1 and 21, and various quality of life assessments.

Study Results: Interim results reported that physicians who used the emulsion for their mild to moderate atopic dermatitis patients either as monotherapy or in combination with a topical steroid, reported their satisfaction as 'very satisfied' or 'satisfied' or 'somewhat satisfied' in 82% of their cases and 'very satisfied' or 'satisfied' in 65% of their cases. These results were consistent when data was compared across gender and race subgroup analyses.

Conclusions: The data suggest that the ceramide-dominant lipid emulsion is a safe and effective treatment for mild to moderate atopic patients regardless of gender, race or age.

Commercial Support: Poster production is supported by Promius Pharma

DERMATITIS, CONTACT AND ALLERGIC IRRITANTS

P600

Multiple lichenoid papules associated with antiresorptive drug

Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Antiresorptive drugs have had an enormous impact on the therapy of osteoporosis. However, cutaneous eruptions associated with this therapy has been reported. The clinical presentation of this side-effect is variable and may mimic the immune-mediated diseases as lupus erythematosus and lichen planus. A case of lichenoid dermatosis induced by alendronate is presented. **CASE**

PRESENTATION: A 54-year-old male was referred for evaluation of skin lesions on trunk, palms and soles. The patient reported that lesions were itchy and appeared abruptly 2 week before. A past medical history revealed he had initiated a treatment with alendronate 70 mgr per week for vertebral fracture due to intense osteoporosis. No other drugs were found in his medications. On physical examination there were erythematous papules coalescing into plaques on trunk, palms and soles. Laboratory tests showed slightly elevated C reactive protein, erythrocyte sedimentation rate and Immunoglobulin E, and eosinophilia. Histopathologic examination demonstrated a lymphohistiocytic infiltrate with eosinophils in the superficial dermis and marked basal hidropic degeneration with cytoid bodies identifiable within the basal epithelium and the papillary dermis. These findings were consistent with a lichenoid drug reaction. Alendronate was discontinued and treatment with oral steroids was initiated. Six weeks later, skin lesions cleared without scarring.

CONCLUSION: The overall safety of bisphosphonate has been very good and any serious adverse events related to this therapy are rare. With this report we want to increase the clinician's awareness of bisphosphonate-associated skin adverse events in the hope of further increasing the safety of a therapy which has been proven to be beneficial to many patients.

Commercial Support: None Identified

P601

Atypical histological patterns of allergic contact dermatitis

Meghan Hession, Tufts Medical Center, Boston, Massachusetts, United States; Pamela Scheinman, MD, Tufts Medical Center, Boston, Massachusetts, United States

Allergic contact reactions can occasionally present as non-eczematous eruptions, with several unique histological subsets described. Often, these cases are mistaken clinically and histopathologically for more serious, systemic diseases. We report a case of a patient with an unusual groin eruption resembling cutaneous T-cell lymphoma histologically. Biopsy revealed a superficial and deep lymphoid infiltrate with palisading granulomatous features. The patient suspected that her eruption was clothing-related. Subsequent patch testing revealed relevant contact allergens, including textile dyes and rubber additives. The rash resolved upon avoidance of proven allergens. In addition, we present a review of eight non-eczematous patterns of allergic contact dermatitis (ACD)—lymphomatoid, granulomatous, purpuric, pustular, lichenoid, bullous, scleroderma-like, and vascular-occlusive—and the allergens associated with each type. This case, as well as those presented in our review, highlights the importance of considering patch testing in patients presenting with histories suggestive of ACD, despite biopsies showing non-eczematous histologies. It is important for clinicians to recognize these unusual forms of ACD to avoid unnecessary anxiety for patients and to prevent morbidity and costs associated with pursuing work-up for non-existent systemic diseases.

Commercial Support: None Identified

DERMATOPATHOLOGY

P700**Bullous acral erythema: An additional entity in the differential diagnosis of pauci-inflammatory subepidermal bullae**

Joshua Podjasek, MD, Mayo Clinic, Department of Dermatology, Rochester, Minnesota, United States; Michael Camilleri, MD, Mayo Clinic, Department of Dermatology, Rochester, Minnesota, United States,

Chemotherapy-induced acral erythema was first described in 1982, and is now regarded as a frequent cutaneous complication of chemotherapy administration. The bullous variant of chemotherapy-induced acral erythema, or bullous acral erythema, was subsequently documented in 1993. The condition typically begins up to three weeks after chemotherapy with acral dysesthesias, and then produces symmetrical erythema that blisters and eventually desquamates. Overall, thirty-two cases of bullous acral erythema have been described in the literature with twenty-one cases related to cytarabine administration and eleven cases attributed to methotrexate. We present a 61 year-old woman with diffuse large B-cell lymphoma who developed bullous acral erythema after receiving both cytarabine and methotrexate. She represents the first case of bullous acral erythema to present with vesicles in an annular configuration suggestive of linear IgA bullous dermatosis. Histopathologic results revealed a pauci-inflammatory subepidermal bulla, similar to previously reported cases of bullous acral erythema. We provide a comprehensive review of the previously reported cases of bullous acral erythema and particularly focus on the dermatopathologic findings. We suggest that bullous acral erythema is an important diagnostic consideration in the differential diagnosis of pauci-inflammatory subepidermal bullae in patients that have recently received chemotherapy.

Commercial Support: None Identified

P701**Cutaneous metastasis: Clinically resembles basal cell carcinoma**

Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Alina Nicolae, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: Around 10% of all visceral malignant tumors develop cutaneous metastases, which represent 2% of all skin tumors. Cutaneous metastases most frequently derive from carcinomas of breast, lung, colon, rectum, ovary, head, neck, kidney and gastrointestinal tract.

CASE REPORT: A 69-year- old man presented with a 15-day history of asymptomatic indurated scar lesion on the chest and clinically resembles basal cell carcinoma. Histopathological study reported infiltrating neoplastic cells dispersed in the dermis thickness with no ulcerated epidermis. The tumor comprised cell nests and cords and scattered cells, mostly appearing as signet ring cells surrounded by dense fibrous stroma with predominantly eosinophilic inflammatory infiltrate. Signet ring cells contained mucicarmine stain cytoplasmic areas. Immunohistochemical studies showed positivity for AE1-AE3, CK20 (Fig 3B), and CK18 antibodies and negativity for GCDPF-15, CK7, S-100, HMB-45, MELAN A, and CD45 antibodies. The diagnosis was metastasis of signet ring cell adenocarcinoma of probable gastric origin. We therefore searched for a primary tumor in the gastrointestinal system using gastroscopy and biopsies, detecting a gastric signet-ring cell adenocarcinoma. Computed tomography then revealed the presence of six metastatic lesions in liver, mesentery, and retroperitoneal and peripancreatic lymph nodes. Due to the advanced stage of the disease, no surgery was undertaken

DISCUSSION: -Clinically, cutaneous metastases from gastric carcinoma can be red or violet, presenting as a single or multiple hyperpigmented nodule, showing zosteriform, erysipela-like, allergic contact dermatitis, or cellulitis-like patterns, and have been reported to appear on neck, head, eyebrow, axilla, chest, and fingertip.

Commercial Support: DAKO DIAGNOSTICOS SA.

P702**Pityriasis lichenoides et varioliformis acuta and pityriasis lichenoides chronica; comparison of lesional T cell subsets and possible association with HHV-8**

Jeong Eun Kim, MD, Department of Dermatology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Jee Ho Choi, PhD, MD, Department of Dermatology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Seung Gyun In, MD, Department of Dermatology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Sung Eun Chang, PhD, MD, Department of Dermatology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea

Background : Pityriasis lichenoides (PL) exhibits a broad clinical spectrum that includes acute and chronic forms. Despite a number of studies, however, the true nature of PL remains unclear. **Objectives :** The purposes of this study were to evaluate the immunohistological characteristics of PL and investigate lesional T-cell subsets and the role of viral infection in the pathogenesis of PL. **Patients and Methods :** Six cases of PLEVA, ten cases of PLC were analyzed immunohistochemically. In situ hybridization was used to detect Epstein-Barr virus early regions (EBERs), and PCR was used to detect HHV-8 and T-cell receptor- γ (TCR- γ) gene rearrangements. **Results :** Both PLEVA and PLC showed intraepidermal CD3+CD8+ cytotoxic lymphocytes. CD8+, TIA-1+, and CLA+ cells were more abundant in PLEVA cases. Notably, FOXP3 regulatory T cells were more abundant in PLC than in PLEVA. HHV-8 DNA was detected in two cases of PLC and two cases of PLEVA. Clonality in TCR- γ gene rearrangement was seen in only one PLEVA case. **Conclusions :** Although PLEVA and PLC have been categorized into a single disease entity, the acute course of PLEVA with its occasionally severe systemic symptoms may suggest a relative lack of regulatory T cells compared with PLC.

Commercial Support: None Identified

P703**Osteoma cutis**

Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Ovidiu Preda, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: Osteoma cutis is a benign rare disease characterized by the presence of osseous nodules in the reticular layer of the skin. The nodules are composed of lamellar bone with osteocytes in the centre and osteoclasts in the external area. The etiology of this osseous deposit is still unknown. **CASE REPORT:** A 25-year-old men presented with 1.5 year history of eritematous papules on the face. Histological examination of an excised lesion showed a central crater enclosed by squamous epithelium, corresponding to a transepidermal elimination channel. Inside this channel was a well formed bony spicule with calcification mixed with keratin. Also seen was an area of ossification with osteocytes and cement lines surrounded by cicatricial fibrosis. **DISCUSSION:** The exact histogenesis of bone formation in osteoma cutis is not known. Clinically there are four subtypes of primary osteoma cutis: isolated osteoma, generalized or widespread osteoma, multiple military osteoma of the face and plate-like cutaneous osteoma.

Commercial Support: DAKO DIAGNOSTICOS SA

P704**Perforating pilomatricoma**

Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Ovidiu Preda, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: Pilomatricoma is a benign cutaneous neoplasm with differentiation toward the hair matrix. The tumor presents as a firm subcutaneous nodule, commonly located on the face, neck, and upper extremities. Three variants of pilomatricoma have been described morphologically well defined: anetodermic, proliferating, and perforating. These variants may be a problem in the differential diagnosis clinical with benign tumors (keratoacanthoma, foreign body granuloma, pyogenic granuloma) and malignant tumors (squamous cell carcinoma, dermatofibrosarcoma protuberans, amelanotic malignant melanoma and cutaneous lymphoma). **CASE REPORT:** A 46-year-old female with a 3-month history of a growing mass on her leg. On physical examination, a 1.5 -cm diameter, asymptomatic, erythematous, ulcerated mass was noted on the leg. Inguinal lymphadenopathy was not detected. The patient had no history of pain, trauma, infection, radiation or surgery. Histologic examination showed that the nodule was composed of sharply demarcated nests of tumor cells, located in the dermis. The typical cell nests of pilomatricoma were observed in the upper dermis.

DISCUSSION: - The mechanism of perforation of pilomatricoma is still unsolved. Mehregan⁴ proposed that perforation of the epidermis is accomplished by means of the biologic phenomenon of transepithelial elimination; that is, foreign material, such as calcium salts and bony tissue, acts as a mechanical irritant and is eliminated to the skin surface through the epidermis or hair follicle

Commercial Support: None Identified

P705**Rosai-Dorfman disease**

Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Francisco O'Valle, PhD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: Rosai-Dorfman disease is rare lesion that affects lymph nodes and less frequently extranodal, location being the most common skin. When this limited to the skin without systemic involvement, is called Rosai-Dorfman disease of the skin.

CASE REPORT: Male 39 years old, has for two months with a shoulder injury 3x3 cm, tumor appearance, infiltrated, hard, slightly raised and slightly erythematous. Clinical suspicion was of lymphoma versus dermatofibrosarcoma protuberans. The study presents a histological examination showed a predominance of histiocytic cells with abundant cytoplasm with vesicular nuclei, some of them multinucleated, demonstrating the phenomenon of emperipolesis. Immunohistochemistry shows positivity of tumor cells to S-100, CD 68, vimentin and negative for CD1a. With the diagnosis of Rosai-Dorfman disease, the study found no patient involvement in other organs, and diagnosis of Rosai-Dorfman disease of the skin.

DISCUSSION: - The histopathologic diagnosis of the disease may be difficult when the component tumor cells is limited and it is clinically suspected, having to differentiate with inflammatory histiocytic with broad cytoplasm. - The histochemical study, immunohistochemistry and in situ hybridization have not shown the presence of bacteria or viruses. - In our case the patient who has been deal only with surgery, is undergoing periodic review, as it could evolve to systemic illness.

Commercial Support: None Identified

P706

Indurated mass in the subcutaneous tissue breast

Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Francisco O`Valle, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: Granular cell tumor (GCT) is a rare benign neoplasm of soft tissues of probable peripheral nervous tissue or Schwann cell origin. The most frequent site is the tongue (40% of cases), but it has been reported in various localizations (skin and visceral). In around 5-6% of cases GCT is observed in the breast, where it can be clinically and radiologically confused with a malignant breast tumor.

CASE REPORT: A 83-year-old women presented with an abnormality detected by screening mammography three months earlier. Her mother and sister had a history of breast cancer. Physical examination revealed a painless palpable mass of around 1 cm in the lower inner quadrant of the left breast, with no skin alteration or nipple discharge. Mammography showed an ill-defined, high-density spiculated mass of 1 cm in left inner breast. Histological examination showed an ill-defined tumor in dermo-hypodermal junction and subcutaneous fat (Fig. 2A). The lesion was composed of compact nests and sheets of cells containing eosinophilic cytoplasmic granules (Fig. 2B) with well-defined cell borders and prominent nucleoli. The tumor cells were arranged in a fascicular pattern with an infiltrating growth pattern at the margins.

DISCUSSION: - The most frequent localizations are the head and neck (>50% of cases) and the tongue (≈40% of cases). GCT of the breast is very uncommon, representing around 1/1000 cases of breast cancer. - On radiographic or ultrasound images, GCT appears as a well-defined mass or as an infiltrating spiculated lesion, with no microcalcifications described in the majority of reports. - The message of the present report is that CGT of the breast should be included in the clinical differential diagnosis with carcinoma, especially in elderly patients with risk factors.

Commercial Support: None Identified

P707

Infiltrated exophytic lesions on neck in a farmer male

Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: The differential diagnosis of a neck mass include congenital anomalies, inflammatory and infectious conditions, trauma, autoimmune conditions and neoplasms. A malignant neoplasm in the neck can arise as a primary tumor or as metastasis. We present a case of basal cell carcinoma invading lymphatic nodules on neck.

CASE PRESENTATION: A 72 year-old farmer male presented with two masses on lateral region of neck with 8 months of evolution. His past medical history included hypertension, dyslipidemia and diabetes. He stated lesions were nontender and it increases gradually in size. Clinical examination showed two 4-cm diameter exophytic infiltrated masses with very firm consistency to palpation on lateral region of neck. The rest of skin exploration showed important photodamage with multiple actinic keratosis. Because of high

suspicion of malignancy, skin biopsy was performed and infiltrative basal cell carcinoma invading lymphoid tissue. He underwent radical surgery with skin graft reconstruction. The patient is on regular follow-up and still alive.

CONCLUSION: Biopsy should be considered for neck masses when suspicion of malignancy is high, diagnosis is unclear, masses with progressive growth or greater than 3 cm.

Commercial Support: None Identified

P708

Violaceous mass on nose presenting as malignant blue nevus

Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Ramón Naranjo-Sintes, PhD, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: This report presents a 63-year-old Caucasian woman with a malignant blue nevus, which is an extremely rare form of melanoma originating from or associated with a preexisting blue nevus. CASE PRESENTATION: A 63-year-old Caucasian woman attended to our department complaining of a violaceous nodule on nose, which had been present for 5 to 6 year. It has increased in size and darkened in color for 4 months. On examination, the lesion was sharply demarcated, non-ulcerated, elevated 1'5 cm above the surrounding skin and measuring 5 x 4 cm. There were no palpable lymph nodes. Although the tumor looked much like a nodular melanoma clinically, the diagnosis of malignant blue nevus was established histologically. Computerized tomography and magnetic resonance imaging of head, neck and thorax showed no metastasis. Following medical advice, patient underwent surgery. Skin grafts were used to reconstruct the radical surgical defect. The patient was free of disease one year following wide excision.

CONCLUSION: Malignant degeneration of blue nevi is extremely rare. The common occurrence of blue nevus makes it inappropriate to exercise all of them prophylactically, but we think it would be advisable to remove those greater than 2 cm in diameter.

Commercial Support: None Identified

P709

Eruptive asymptomatic papules on face of middle-aged woman

Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Ramón Naranjo-Sintes, PhD, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Eruptive syringoma is a rare clinical presentation of a benign tumor of the eccrine ducts. It consists in successive crops of small skin-colored papules on the body surfaces. A case of a 34-year-old female with eruptive syringoma is presented.

CASE PRESENTATION: A 34-year-old female presented with a 6-year history of eruptions that began as a few papules on both cheeks and spread to a larger area. The lesion were asymptomatic and since they first appeared, the patient's skin had never been completely clear. Physical examination revealed many flesh-colored or slightly reddish, smooth-surfaced papules around the eyes, both cheeks and temples. The lesion were bilateral and symmetrically distributed on the face. The remainder of the physical examination was unremarkable. Punch biopsy specimen revealed a normal epidermis overlying a dermis

with aggregations of small tubular structures, lined by two rows of epithelial cells. Most of which were characterized by comma- like tails giving them a tadpole shape. They are embedded in a fibrous connective tissue stroma. These findings were consistent with syringoma.

CONCLUSION: Syringoma is a benign adnexal tumor derived from the intraepidermal portion of eccrine sweat ducts. In eruptive syringoma, lesions occur in large numbers and in successive crops. Clinically, it may be mistaken for acne vulgaris, sebaceous hyperplasia, milia, lichen planus, eruptive xanthoma, urticaria pigmentosa or hidrocystoma. Definitive diagnosis can be made on histological examination, because syringomas demonstrate distinctive histopathological features. Treatment is cosmetic.

Commercial Support: None Identified

P710

Erythematous verrucous plaque on left axilla

Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Ramón Naranjo-Sintes, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Primary adenocarcinomas arising from the eccrine sweat glands are rare and represent approximately 0.005% of epithelial cutaneous neoplasms. Eccrine porocarcinoma, otherwise known as malignant eccrine poroma, is the most common variant among them. We present a case of a 62-year-old woman with an eccrine porocarcinoma.

CASE PRESENTATION: A 62-year-old female patient presented with an asymptomatic reddish nodule of the left axilla. The lesion had been present for six months and was slowly growing. At the time of presentation, the clinical diameter of the lesion was 3.5 cm. On clinical examination, the lesion was firm, fixed to the skin and non-tender. No other skin lesion was observed and no lymph nodes were palpated. The lesion was excised under local anesthesia. Primary closure was possible. Histologic analysis concluded porocarcinoma as diagnosis with free surgical margins. No adjuvant therapy was needed. Patient is on follow up with no evidence of local recurrence or disseminated disease.

CONCLUSION: Porocarcinomas can be cleared in 65 to 85% of cases by simple wide local excision. Early recognition is key to definitive treatment

Commercial Support: None Identified

P711

Pyoderma gangrenosum affecting the dorsum of foot

Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Cachaza, PhD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Pyoderma gangrenosum is an ulcerative necrotic dermatosis of unknown etiology. It may occur at various anatomical sites and in association with other conditions, but has rarely been reported on the dorsum of foot.

CASE PRESENTATION: A 86-year-old woman was referred for evaluation of an open wound with a large area of ulceration and necrotic tissue on the dorsum of foot. She noticed it two months before. She had been treated with topical antibiotics and antifungals, but the size of the ulcer increased. No organisms were grown from superficial swabs or deep tissue samples. Despite intravenous administration of

cefotaxime and metronidazole, the wound deteriorated. Her-reactive protein level was > 200 mg/l and her erythrocyte sedimentation rate 107 mm/hour. Histological specimens showed a neutrophilic infiltration in both superficial and deep dermis. No vasculitis neither organisms were seen. This findings were consistent with pyoderma gangrenosum. She was therefore given prednisolone 40 mgr daily and improved dramatically over the next two days. Three months later, the skin showed complete re-epithelization.

CONCLUSION: The diagnosis of pyoderma gangrenosum must be considered for ulcerative lesions which follow an unusual clinical course with conventional treatment.

Commercial Support: None Identified

P712

Henoch-Schönlein purpura associated with breast cancer

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain

Introduction: Henoch-Schönlein purpura is a systemic vasculitis that involves the small vessels, most notably those in the skin, gastrointestinal tract, and glomeruli, accompanied by arthralgia or arthritis. Palpable purpura and joint pain are the most common and consistent presenting symptoms.

Case report: A healthy 47-year-old woman presented with a 3-days history of widespread asymptomatic lesions in extremities associated with fever, arthralgias and mild abdominal pain. A physical examination revealed a symmetric rash in the lower limbs with erythematous-purple papules which do not get pale to diascopy, clinically compatible with palpable purpura. Skin biopsy was performed which showed leukocytoclastic vasculitis with IgA deposits in the vascular wall. During follow-up (one month later) our patient was diagnosed with breast cancer (adenocarcinoma).

Discussion: Cutaneous vasculitis may also be associated with malignant disorders and behave like a paraneoplastic syndrome. The pathophysiology of paraneoplastic vasculitis remains unclear but several mechanisms have been proposed. Although haematological malignancy has been shown to be three to five times more common than solid tumors in all types of vasculitis recently it has been suggested the association of Schonlein-Henoch purpura in adult patients (> 41 years) with various types of solid (liver, skin, colon, breast...) and haematological neoplasms, so it is recommended investigating associated neoplasm in this group and also patients with a known history of malignant tumor should undergo re-evaluation for metastatic lesion.

Commercial Support: None Identified

P713

Cutaneous nodule on abdomen in a 64-year-old woman

Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Metastasis to the umbilicus is rare among skin metastases. Here we report on an umbilical metastasis of an ovarian adenocarcinoma.

CASE PRESENTATION: A 64-years-old female presented with a history of constipation with weight loss over past 10 months. TC-study of abdomen and pelvis showed the presence of an nodular lesion in sigmoid colon, and bilobular lesion in left ovaria. Neoadjuvant chemotherapy was initiated following radical surgery. Two months later, the patient was referred to our department with a skin lesion on abdomen. It progressively grew up with not local symptoms such as pruritus or pain. Physical examination revealed a 7 cm, erythematous, nonpainful, smoothy, firm nodule. Histological study demonstrated cutaneous metastasis of a low-differentiated adenocarcinoma. Immunohistochemical techniques were needed to clarify the primary ovarian tumor as the hematoxylin eosin stain was not useful in reveal any clue.

CONCLUSION: Every practitioner should be highly suspicious of acute-onset, persistent, firm cutaneous nodules, specially on oncology patients.

Commercial Support: None Identified

DERMATOPHARMACOLOGY / COSMECEUTICALS

P800

Maternal exposure to topical corticosteroids and adverse pregnancy outcomes: Two population-based cohort studies

Ching-Chi Chi, PhD, MMSc, Department of Dermatology and Evidence-Based Medicine Center, Chang Gung Memorial Hospital-Chiayi, Chang Gung University College of Medicine, Putz, Taiwan; Fenella Wojnarowska, MS, MD, Nuffield Department of Clinical Medicine, University of Oxford, Headington, United Kingdom; Richard Mayon-White, MBBS, Department of Primary Health Care, University of Oxford, Headington, United Kingdom

Background: Topical corticosteroids may be indicated in pregnant women with skin conditions, but their safety in pregnancy is unclear.

Objective: To investigate whether maternal exposure to topical corticosteroids results in adverse pregnancy outcomes.

Design: Two population-based retrospective cohort studies.

Setting: UK General Practice Research Database. Participants: 57,641 pregnant women prescribed topical corticosteroids. Interventions: Topical corticosteroids prescribed during the period from 85 days before last menstrual period (LMP) to delivery.

Outcomes: Outcomes included orofacial cleft and its two subtypes (cleft lip \pm palate and cleft palate alone), fetal growth restriction, preterm delivery, and fetal death (including miscarriage and stillbirth).

Results: We found a significant association between fetal growth restriction and maternal exposure to potent/very potent topical corticosteroids shortly before and during pregnancy [adjusted relative risk 2.07 (95% confidence interval 1.39-3.09); number needed to harm (NNH) 152], which was confirmed by a significant dose-response relationship ($p = 0.024$) and the sensitivity analysis. In contrast, we found no associations between maternal exposure to topical corticosteroids and other adverse pregnancy outcomes including orofacial cleft, preterm delivery, and fetal death. The findings were similar when excluding exposure before LMP.

Conclusions: On this evidence, topical corticosteroid use in pregnancy does not result in orofacial cleft, preterm delivery, and fetal death. However, maternal use of potent/very potent topical corticosteroids increases the risk for fetal growth restriction. This risk should be considered when prescribing potent/very potent topical corticosteroids to pregnant women, and appropriate obstetrical care should be provided.

Commercial Support: None Identified

P801

Skin hydrating effects of a heat augmenting verses the surface moisturizing in adult women

Carlton Colker, MD, Peak Wellness, Inc., Greenwich, Connecticut, United States

Dermatopharmacological technology for hydrating skin to prevent an aged look has classically provided simple replenishing oils to lubricate and soften. In recent years, technology has advanced to incorporate a plethora of different commercialized ingredients in the moisturizing matrix intended to enhance the restorative effects. The latest technology utilizes novel self-contained, disposable, heat augmenting working in conjunction with heat activated ingredients to effectuate deep skin hydration. This clinical trial was undertaken to compare such heat activated moisturizing technology with a leading high-end but traditional surface replenishing approach. A heat activated product (manufactured by Meltology) was compared to a comparable surface replenishing product (manufactured by Estee Lauder) in a prospective, open label, two-arm study. The trial recruited 15 female subjects ranging in age from 30 to 71. Testing was done on the hands of subjects with the heat approach necessitating a topical rub containing heat activated ingredients immediately followed by a novel disposable water activated self-heating mitt. The surface replenishing approach utilized a two-step process of surface applied formulas containing a variety of ingredients in a moisturizing matrix. For each approach, objective skin moisture testing using a sensor/LCD digital technology device (manufactured by Skincare Digital) was performed at baseline and post-application. Results: There were no dropouts or untoward subject complaints for either regimen. Data was gathered for ANOVA analysis using a p value of <0.05 as the cut-off for statistical significance. Intra-group analysis of the heat approach revealed n=15; mean Δ +9.53; variance 57.03; p = 0.0003. Intra-group analysis of the surface approach revealed n=15; mean Δ +1.55; variance 14.72; p = 0.162. Intergroup comparative analysis revealed a statistically significant between-group difference favoring the heat technology (p = 0.001). Discussion: Objective data of skin hydration using digital technology revealed a clear superiority favoring the heat method with both intragroup and intergroup statistical significance (p<0.05). Conclusion: Heat activated moisturizing technology revealed superiority in skin hydration when compared with the traditional surface replenishing method.

Commercial Support: None Identified

P802

Evaluation of a prescription strength hydroquinone/vitamin C treatment system for normal to oily skin

Suzanne Bruce, MD, Private practice, Houston, Texas, United States

Introduction: A prescription strength treatment system has been designed to treat early signs of photodamage in youthful looking skin and help protect from further photodamage. In addition to the original version for normal to dry skin, a new version is now available for normal to oily skin.

Methods: Patients with facial photodamage (minimal or mild severity), facial hyperpigmentation (minimal or mild intensity), and normal to oily facial skin used the treatment system for 12 weeks. This involved applying a cleansing gel (twice daily), balancing toner (twice daily), clarifying serum (each morning), sunscreen (each morning and as needed), and night cream (each evening). Together, these contain 4% hydroquinone, vitamin C, vitamin E, witch hazel, aloe barbadensis leaf juice, proprietary penetrating ingredients, micronized zinc oxide, and octinoxate.

Results: Of 34 females enrolled, 30 completed. Their mean age was 32 years and the majority (88%) were of Fitzpatrick skin type II-IV. The proportion of patients with \geq 1-grade improvement from baseline in the following photodamage parameters (on a scale of none, minimal, mild, mild up to moderate, moderate, and severe) at weeks 4, 6, and 12 was: 7%, 47%, and 80% for the investigator overall integrated assessment; 57%, 87%, and 90% for tactile roughness; 10%, 30%, and 50% for fine lines and wrinkles; and 7%, 10%, and 33% for laxity. Similarly, 30%, 60%, and 87% of patients had \geq 1-grade improvement in overall intensity of pigmentation (on a scale of none, minimal, mild 2, mild 3, moderate, marked, and severe). At week 12, 90% of patients showed \geq 50% global improvement, 87% had at least a moderate (50%) increase in facial skin lightness/brightness, and 100% were satisfied or very satisfied with the overall appearance of their skin. One patient withdrew voluntarily and 3 discontinued due to mild facial adverse effects (dryness, contact dermatitis, and erythema/pruritus/dryness/rash). Conclusion: Use of the treatment system was associated with improvements in the overall appearance and

lightness/brightness of facial skin, and reductions in facial lines and wrinkles, pigmentation, tactile roughness, and laxity. At week 12, 100% of the patients were satisfied or very satisfied with the overall appearance of their skin. In conclusion, the prescription strength treatment system can help to ameliorate early signs of photodamage in youthful looking normal to oily skin and minimize the development of further photodamage.

Commercial Support: Supported by OMP, Inc.

P803

Patient-reported outcomes of bimatoprost for eyelash growth: Results from a randomized, double-masked, vehicle-controlled, parallel-group study

Sue Ellen Cox, MD, University of North Carolina, Chapel Hill, North Carolina, United States; David Wirta, MD, Aesthetic Eye Care Institute, Newport Beach, California, United States; Jean Carruthers, MD, Department of Ophthalmology and Visual Sciences, University of British Columbia, Vancouver, Canada; Steven Fagien, MD, Private Practice, Boca Raton, Florida, United States

Purpose: A phase 3 study demonstrated that once-daily, dermal application of bimatoprost ophthalmic solution 0.03% to the upper eyelid margin increased length, fullness, darkness, and overall prominence of eyelashes. The current analysis presents the patient-reported outcomes (PROs) from the clinical trial.

Methods: A total of 278 healthy adult subjects were enrolled in this multicenter, prospective, randomized, double-masked, vehicle-controlled study. Subjects' perspectives on the importance of improving eyelash qualities, satisfaction with overall eyelash prominence, and the impact of treatment on perceived attractiveness, confidence, and time spent to make their eyelashes presentable were measured by PRO questionnaires. A questionnaire was administered at baseline to rate the importance of improving eyelash length, fullness, darkness, and number. A 23-item questionnaire was collected at all study visits (week 1, 4, 8, 12, 16) which assessed 3 major constructs that influence eyelash satisfaction: length, fullness, and overall satisfaction (LFOS); confidence, attractiveness, and professionalism (CAP); and daily routine (DR). A final questionnaire was completed during the posttreatment follow-up visit (week 20) and assessed change in overall satisfaction with the appearance of their eyes, daily activities, and quality of life.

Results: At baseline, subjects thought it was very important to make their eyelashes longer, darker, and fuller or to increase eyelash number. Subjects' satisfaction with LFOS was significantly greater in bimatoprost-treated subjects at week 1 and weeks 8 through 20 ($P \leq .0052$). Bimatoprost-treated subjects reported statistically significant improvement in CAP at weeks 12 through 20 ($P < .0001$) and reported significant improvement in DR at weeks 16 and 20 ($P \leq .01$). At the posttreatment follow-up, significantly more subjects responded that they had a good, great, or very great deal of satisfaction with their overall change in the appearance of their eyes, daily activities, and aspects of quality of life ($P < .0001$).

Conclusions: As assessed by a wide range of PRO measures, improvement in eyelash prominence after dermal application of bimatoprost ophthalmic solution 0.03% was associated with a high degree of patient satisfaction with the LFOS of their eyelashes; improved CAP; and improvements in their DR.

Commercial Support: 100% is sponsored by Allergan, Inc.

P804

Moisturizing benefits of a novel serum containing low and high molecular weight hyaluronic acid

Nathan Trookman, MD, Rocky Mountain Laser Center, Colorado Springs, Colorado, United States; Elizabeth Ho, SkinMedica, Inc., Carlsbad, California, United States; Rahul Mehta, PhD, SkinMedica, Inc., Carlsbad, California, United States; Ronald Rizer, PhD, Thomas J. Stephens & Associates, Colorado Springs, Colorado, United States

One of the main aspects of intrinsic skin aging can be characterized as a loss of moisture, due to functional and structural changes in the skin. Hyaluronic Acid (HA) plays an essential role in the

extracellular matrix and has been shown to improve skin elasticity, maintain skin hydration and to also protect against free radical damage. A unique serum was specifically formulated to combine the benefits of both low and high molecular weight HA; low molecular weight HA allows for penetration into the stratum corneum or superficial layer of the skin, whereas the high molecular weight HA retains the skin's moisture level by forming a hydrating film at the surface of the skin. A single-center, investigator-blinded, parallel group comparison study was conducted to determine if a serum formulated with low and high molecular weight HA could provide hydrating benefits beyond that of a standard moisturizer. Thirty-two female subjects, aged 25-55 years with Fitzpatrick skin types I-V completed the two week study. Subjects were randomized into two groups, receiving HA serum plus moisturizer or moisturizer-only. Subjects applied the test products on their facial skin twice daily for two weeks. Investigator assessments for dryness, tactile roughness, softness were performed at Baseline and Week 2. Additionally, investigator and subject tolerability assessments, standardized photography and subject questionnaires were conducted. After two weeks of treatment, the HA serum plus moisturizer group demonstrated statistically significant improvements (all $P < 0.02$) in skin dryness and softness over the moisturizer-only group. The HA serum plus moisturizer group also showed a greater mean reduction in tactile roughness as compared to the moisturizer-only group (82% vs. 58% reduction, respectively). Standardized digital photography confirmed the significant improvements; positive benefits were also reflected in the subject assessments. In the moisturizer-only group, one treatment-related adverse event was reported but resolved without sequelae. No treatment-related adverse events were reported in the HA serum plus moisturizer group. Clinical study results demonstrate that this unique formulation of low and high molecular weight HA may help restore and retain moisture in the stratum corneum, resulting in softer, smoother and more hydrated skin.

Commercial Support: 100% is sponsored by SkinMedica, Inc.

P805

Skin penetration of desonide EF foam, 0.05% vs traditional vehicle formulations

Jon Lenn, MS, Stiefel, a GSK company, Palo Alto, California, United States; Hans Hofland, PhD, Stiefel, a GSK company, Palo Alto, California, United States; Mark Brown, Stiefel, a GSK company, Palo Alto, California, United States

Objectives: Desonide EF Foam, 0.05% is a petrolatum based, ethanol-free, emollient foam indicated for the treatment of mild to moderate atopic dermatitis. In-vitro skin penetration studies have shown that an Ointment delivered less desonide compared to the Foam. This goes against the currently held dogma in dermatology, which assumes Ointments provide the best delivery vehicle for corticosteroids. The objective of this in-vitro skin penetration study was to confirm and explain the results by comparing the desonide delivery from several generic Ointments to the delivery from the Foam.

Methods: Study products were uniformly applied to the outer surface of excised human skin (mounted in diffusion chambers to match in-vivo conditions) using a positive displacement pipette at a dose of 7.8 $\mu\text{L}/\text{cm}^2$. Drug penetration was measured by monitoring its rate of appearance in the receptor solution flowing underneath the surface of the skin. At 6 hours post-application, the skin surface was washed, tape-stripped twice, and the epidermis separated from the dermis using a heat block. Each formulation was tested on 4 separate donors. Drug content was measured by Mass Spectrophotometry with a lower limit of quantitation of 50 pg/mL. Microscopic evaluations of the test products were also conducted.

Results: The amount of desonide delivered into the epidermis from the Foam was approximately 3-fold higher compared to the Ointments ($p < 0.09$). The Foam demonstrated at least a 4-fold increase in desonide delivery into the dermis as compared to the Ointments ($p < 0.03$). The Foam delivered approximately twice the amount of desonide through the skin as compared to the four Ointments after 6 hours post-application ($p \leq 0.03$). There were no significant differences in delivery of desonide from the four Ointments ($P > 0.35$), thus confirming the results of the initial study that the Foam penetrates the skin more efficiently than Ointment. The amounts penetrating through the skin into the receiving fluid were less than 0.2% of the applied dose, suggesting very little systemic delivery. Microscopic analysis of the Ointments revealed the presence of crystals; however, the Foam did not show any crystals, which may explain why the Foam delivered up to twice the amount of desonide into the skin and through the skin.

Conclusions: This study suggests that an Ointment is not the best delivery vehicle for a corticosteroid, such as desonide, and this emollient Foam penetrates better than such traditional vehicle formulations.

Commercial Support: 100% is sponsored by Stiefel, a GSK company

P806

Chemical compatibility of clobetasol propionate 0.05% EF foam and spray in combination with calcitriol ointment and calcipotriene cream

Rose Ye, Stiefel, a GSK company, Rowville, Australia; Haritha Kommineni, Stiefel, a GSK company, Rowville, Australia; Richard Buchta, Stiefel, a GSK company, Rowville, Australia; Stefan Weiss, MD, Weiss Skin Institute, Boca Raton, Florida, United States

Objectives: In the treatment of psoriasis, it is common practice to combine super high potency topical steroids with topical vitamin D derivatives. Historically, it was thought that calcipotriene was only chemically compatible with clobetasol. Subsequent studies suggested its compatibility with clobetasol in a novel foam formulation. Recently there have been new topical formulations of clobetasol introduced into the marketplace as well as a second vitamin D derivative, calcitriol. Thus, it is important to understand if applied concomitantly, whether the vehicle in which the active ingredient is delivered influences chemical stability. The objective of this study was to assess the stability of the active pharmaceutical ingredients (APIs) in a calcitriol ointment (CAT) and a calcipotriene cream (CAL) when combined with either clobetasol propionate 0.05% EF foam (CP Foam) or clobetasol propionate 0.05% spray (CP Spray).

Methods: Equal amounts (400-500 mg) of CAT and [CP Foam or CP Spray] were mixed in a glass container and stored at 40°C for 6, 15, and 24 hours. Similarly, equal amounts (500 mg) of CAL and [CP Foam or CP Spray] were mixed and stored at 40°C for 6, 15, 24, 32 and 48 hours. Concentrations of CP, CAT, and CAL were determined by ultra performance liquid chromatography (UPLC) after each timepoint and compared to that of an unstressed freshly mixed sample (control).

Results: The potencies of both CAT and CP remained at >97% relative to control samples, thus CAT and CP are chemically stable for up to 24 hours at 40°C after CAT ointment is mixed with either CP Foam or CP Spray. Likewise, the potency of both CAL and CP remained at >97% relative to control samples, thus CAL and CP are chemically stable for up to 48 hours at 40°C after CAL cream is mixed with either CP Foam or CP Spray. There were no differences observed in the chemical stability of the APIs between the combinations.

Conclusions: Clobetasol propionate 0.05% EF foam and clobetasol propionate 0.05% spray were found to be equally compatible when combined with either calcitriol ointment or calcipotriene cream. This provides the clinician with the flexibility to combine calcitriol ointment or calcipotriene cream with clobetasol propionate 0.05% in either a spray or EF foam formulation.

Commercial Support: 100% is sponsored by Stiefel, a GSK company

P807

Topical nitroglycerin: A treatment option for chondrodermatitis nodularis helicis

Valerie Flynn, MD, Department of Dermatology, Scott and White Memorial Hospital / Texas A&M Health Science Center, Temple, Utah, United States; Cary Chisholm, MD, Department of Pathology, Scott and White Memorial Hospital / Texas A&M Health Science Center, Temple, Texas, United States; Ronald Grimwood, MD, Department of Dermatology, Scott and White Memorial Hospital / Texas A&M Health Science Center, Temple, Texas, United States

Background: Topical nitroglycerin has never been evaluated for the treatment of Chondrodermatitis Nodularis Helicis (CNH), which is a painful, inflammatory nodule that arises on the helix or antihelix of the ear. Other treatment modalities have included both surgical and conservative measures that have varying efficacy rates and can often demonstrate disappointing results.

Objectives: The purpose of this study was to evaluate the efficacy of 2% topical nitroglycerin for the treatment of Chondrodermatitis Nodularis Helicis. **Methods:** This retrospective chart review involved 12 patients with CNH, all treated with topical nitroglycerin twice daily. Therapeutic efficacy is determined by identifying improvement in the appearance and symptomatology of the lesion.

Results: A total of 13 lesions in 12 patients were treated, with 12 lesions (92%) demonstrating improvement with the use of topical nitroglycerin. Eight of 13 (61.5%) CNH lesions developed complete clearance and resolution of symptoms, requiring no further treatment. Four of 13 (30.8%) lesions were found to have symptomatic improvement and these patients continued to use the ointment as needed. One of 12 (8.3%) patients demonstrated no improvement, but had also failed multiple other treatments modalities. Side effects were found in 2 (17%) of our patients and included headache and dizziness. These side effects resolved with dilution of the topical nitroglycerin and decreasing the amount applied. **Limitations:** Limitations include the small number of patients treated and the retrospective nature of the study.

Conclusions: Topical nitroglycerin demonstrated efficacy in treating both the symptoms and lesional appearance of CNH in a non-invasive manner, with an overall success rate that is comparable to other published methods.

Commercial Support: None Identified

P808

Comparison of a non-petrolatum based ointment vs. a standard ointment for post-procedure use after an ablative laser treatment

Roy Geronemus, MD, Laser & Skin Surgery Center of New York, New York, New York, United States; Elizabeth Ho, SkinMedica, Inc., Carlsbad, California, United States; Rahul Mehta, PhD, SkinMedica, Inc., Carlsbad, California, United States

Following an ablative laser treatment, post-procedure skincare can play an important role in the overall treatment success. Since the skin lacks its normal protective outer layer, the topical products used during this vulnerable time period should be chosen with care to minimize irritation and enhance the healing process. Currently, standard post-procedure regimens are limited to include petrolatum-based ointments which may clog pores and cause skin irritation. This poses a particular concern for newly resurfaced skin since the introduction of irritation could result in prolongation of healing time, scarring and pigmentation changes. To help mitigate these issues, a new post-procedure ointment has been formulated with vegetable-based skin conditioners to provide patients with a petrolatum-free option. A single-center, randomized, investigator-blinded, split-face study was conducted to compare the tolerability of a non-petrolatum based ointment (Novel) vs. a standard ointment (Standard) when used immediately after an ablative laser procedure. Fifteen female subjects, aged 28-69 years with Fitzpatrick skin types I-IV, completed the three day study. Subjects received an ablative laser treatment on their entire face at baseline and were randomized to receive the Novel ointment on their left or right facial side and the Standard ointment on the other side. Immediately after the laser treatment, Novel and Standard ointments were used in conjunction with a gentle cleanser and cool water soaks until skin reepithelialization at Day 3. Tolerability was measured by investigator (facial side preference, erythema and edema) and subject (burning/stinging, redness, itching, discomfort and tightness) assessments at baseline and Day 3, using a four point scale. At Day 3, out of the subjects that demonstrated an Investigator facial side preference, 78% showed an investigator preference for the Novel ointment-treated side due to a decreased incidence of acne. No differences were observed between the two ointments in mean investigator scores for erythema and edema. Mean subject tolerability scores for Novel and Standard ointments were comparable and reflected minimal differences (<0.20). No treatment-related adverse events were reported during the study. Results from this study suggest that the Novel ointment can provide a well-tolerated, non-petrolatum based alternative for use during the vulnerable reepithelialization period following an ablative laser treatment.

Commercial Support: 100% is sponsored by SkinMedica, Inc.

P809**Lactobionic acid anti-aging mechanisms: Antioxidant activity, MMP inhibition, and reduction of melanogenesis**

Irina Brouda, NeoStrata Company, Inc., Princeton, New Jersey, United States; Barbara Green, MS, NeoStrata Company, Inc., Princeton, New Jersey, United States; Brenda Edison, NeoStrata Company, Inc., Princeton, New Jersey, United States; Ronni Weinkauf, PhD, NeoStrata Company, Inc., Princeton, New Jersey, United States

BACKGROUND: Lactobionic acid (LBA) is a polyhydroxy bionic acid that was previously reported to provide significant anti-aging and protective effects to human skin. In addition, LBA can chelate metal ions such as copper, iron, and zinc, protect ischemic organs from breakdown and oxidative stress during reperfusion, and improve stratum corneum barrier structure and function and prevent inflammation. Additional studies were conducted to further understand how LBA may act as an antioxidant and an anti-aging agent in skincare products.

OBJECTIVE: To identify mechanisms of lactobionic acid activity in a series of standard in vitro assays.

METHODS: LBA was tested for matrix metalloproteinase (MMP) inhibition, lipid peroxidation inhibition, and melanogenesis inhibition in cultured B16 melanocytes. MMPs are enzymes that break down and recycle collagen in skin's extracellular matrix. Blocking the actions of MMP is associated with firmer, tighter, and more supple and elastic skin. Lipid peroxidation is an oxidative degradation of cellular lipids during UV light exposure. Inhibition of lipid peroxidation is vital for maintaining cell membranes and mitochondria and protecting cells against sun damage. Melanogenesis inhibition is associated with the ability of a substance to lighten naturally-pigmented skin and/or prevent hyperpigmentation of sun-exposed skin.

RESULTS: LBA was found to be a strong inhibitor of MMP in vitro. LBA was found to be a moderate inhibitor of lipid peroxidation in vitro. LBA was found to strongly inhibit melanogenesis in cultured B16 melanocytes in the presence of melanocyte stimulating hormone. This action of LBA is associated with blocking melanin synthesis induced by an exogenous source such as ultraviolet light.

DISCUSSION: LBA's actions in vitro demonstrate that it has the capacity to preserve cell structure and function and to protect skin cells against sun damage. LBA's inhibition of MMP, lipid peroxidation, and UV-induced melanin synthesis may be some of the mechanisms through which LBA can help prevent the development of fine lines, wrinkles, sagging, uneven pigmentation, and other visible signs of aging in human skin.

Commercial Support: 100% sponsored by NeoStrata Company, Inc.

P810**Maltobionic acid, a powerful yet gentle skincare ingredient with multiple benefits to protect skin and reverse the visible signs of aging**

Irina Brouda, NeoStrata Company, Inc., Princeton, New Jersey, United States; Barbara Green, MS, NeoStrata Company, Inc., Princeton, New Jersey, United States; Brenda Edison, NeoStrata Company, Inc., Princeton, New Jersey, United States; Ronni Weinkauf, PhD, NeoStrata Company, Inc., Princeton, New Jersey, United States

BACKGROUND: Maltobionic Acid (MBA) is a naturally-derived, anti-aging polyhydroxy bionic acid. Histological studies with MBA demonstrated increased epidermal thickness and enhanced GAG staining, in conjunction with a more compact stratum corneum. In a clinical study, MBA cream (8%) improved facial skin elasticity, firmness, texture, and dryness and increased forearm skin thickness. Recently, a series of new tests was performed to further identify topical effects of MBA.

OBJECTIVE: To present a summary of the latest in vitro and human studies demonstrating the anti-aging and skin protective effects of MBA.

STUDIES: Protective effects of MBA were investigated in vitro via matrix metalloproteinase (MMP) inhibition (protection against collagen degradation), lipid peroxidation inhibition (protection against

oxidative stress), and melanogenesis inhibition in cultured B16 melanocytes (protection against UV induced hyperpigmentation). Humectant properties of MBA were explored through gel matrix formation at room temperature (RT). Repeat Insult Patch Tests (RIPT) and ophthalmological evaluations were conducted with MBA creams to evaluate dermal and ocular safety. Women, 40-60 years of age, applied a 3% (pH 3.8) MBA cream to periocular areas twice daily for 4 weeks and self-assessed anti-aging effects. FINDINGS: MBA inhibited MMP, lipid peroxidation, and melanogenesis in cultured B16 melanocytes in the presence of melanocyte stimulating hormone in vitro. These effects demonstrate MBA's ability to protect human skin against collagen loss, oxidative stress, and sun-induced photoaging. A solution of MBA at RT formed a gel matrix consisting of 71% MBA and 29% water after 72 hours, demonstrating superior humectant properties of MBA. A 20% (pH 3.8) MBA cream was found to be non-irritating and non-allergenic in the RIPT, and a 3% (pH 3.8) MBA cream was found to be safe for cosmetic use around the eye. Women applying 3% MBA cream to periocular areas reported improvements in skin texture, tone, and clarity, a reduction in fine lines and wrinkles, and a more youthful and radiant appearance. CONCLUSION: Maltobionic acid is a powerful yet gentle cosmetic ingredient that can help prevent and reverse the visible signs of aging by functioning simultaneously as an antioxidant, MMP inhibitor, moisturizer, and pigment evening agent.

Commercial Support: 100% sponsored by NeoStrata Company, Inc.

DIGITAL/ELECTRONIC TECHNOLOGY

P900

Reliability and consistency of digital moisture monitor devices measuring skin hydration

Carlton Colker, MD, Peak Wellness, Inc., Greenwich, Connecticut, United States

Electronic technology has rapidly developed to provide objective analysis of skin hydration. While a number of portable devices have emerged, digital versions lead the way due to numeric data representation, which has an advantage of providing a concrete numeric assessment to assess interventions. While popular devices use similar contact sensor/LCD technology, users report inconsistent reads, raising the age-old question of whether it is worth spending exponentially more for a "high-end" device. Our effort was to select a popular but cheap brand and compare to a much pricier "high-end" device. This trial was prospective, open label, and two-arm. A less expensive model (manufactured by Skincare Digital) was compared to a much more expensive model (manufactured by Bt-Analyze). The trial recruited a female and a male ages 33 and 34 respectively. Both subjects completed a trial with the "less expensive" model (LE) and a trial with the "more expensive" model (ME), making a total of four trials. Each trial consisted of taking repeated skin moisture readings at the same spot on the volar surface of the left wrist. Consecutive readings were taken with each analyzer. Room temperature at the time of the study was 74°F and remained constant. Data was gathered for F-Test variance analysis using $p < 0.05$ as cut-off for statistical significance.

Results: Neither subject dropped out or reported complaints for either device. Male subject ME trial revealed SD 2.764; Mean 28.3; Range 13.4. LE trial of 36 measures revealed SD 1.658; Mean 30.45; Range 7.6. F-test intergroup comparative analysis revealed LE Variance 2.829 and ME Variance 7.857 as well as statistically significant results in consistency and reproducibility favoring LE ($p = 0.002$). Female ME trial revealed SD 5.351; Mean 23.88; Range 15. LE trial of 33 measures revealed SD 0.509; Mean 30.58; Range 1.9. F-test intergroup comparative analysis revealed LE Variance 0.259 and ME Variance 29.359 as well as statistically significant results in consistency/reproducibility favoring LE ($p = 0.000$). Discussion: Both SD and range were significantly lower for LE versus ME ($p < 0.05$). Surprisingly, ME measurements were highly varied. Of note, variance for ME was widest for female (29.5). Conclusion: When selecting a portable digital moisture monitor for use either in clinic or to provide for home use, we would be well served to not rely on more expensive "higher-end" devices as being necessarily better.

Commercial Support: None Identified

EPIDEMIOLOGY AND HEALTH SERVICES ADMINISTRATION

P1000

Polypharmacy in dermatology patients: Analysis of an estimated 360 million dermatology related patient visits from 1995 to 2006

Madhulika A. Gupta, MD, Department of Psychiatry, Schulich School of Medicine and Dentistry, London, Canada; Aditya K Gupta, PhD, MD, Mediprobe Research Inc., London, Canada; Naomi H Fink, University of Western Ontario, London, Canada

BACKGROUND: Polypharmacy (PP), a term that describes the simultaneous use of multiple medications, has been associated with an increased risk of adverse drug events and drug-drug interactions, need for hospitalization, medication errors, and even mortality.

OBJECTIVES: Examine the prevalence of PP (defined as use of ≥ 4 drugs in our study), in an epidemiologically representative sample of dermatology patient visits. We tested the hypothesis that PP is associated with a higher frequency of psychotropic drug use, even in the absence of a psychiatric diagnosis, as patients receiving PP are likely to be presenting with more complex symptoms that may be assessed as having a larger functional component.

METHODS: Data collected between 1995 to 2006 by the National Ambulatory Medical Care Survey and National Hospital Ambulatory Care Survey, which are both nationally representative samples of outpatient and emergency department health care visits in the USA, were studied. There were an estimated 362,504,444 \pm (SE) 14,505,297 dermatology patient visits from 1995 to 2006 (total unweighted count=28063)(ICD9-CM diagnostic codes 680-709), without other comorbid medical disorders. The 'psychotropic medications' variable included the antidepressants (tricyclic, SSRI and others), mood stabilizers (lithium, valproate, carbamazepine and lamotrigine), antipsychotics (both typical and atypical) and benzodiazepines. Data analysis was carried out with the Complex Samples module of SPSS v15.

RESULTS: Overall, 10.1% \pm 0.4% of all patient visits with a dermatology diagnosis only, were associated with PP. The OR of PP was higher in women versus men (OR= 1.28, 95% CI 1.11 to 1.48) and increased with age: 0-24 yrs 8.3% \pm (SE) 0.6%; 25-65 yrs 10.3% \pm 0.5%; and >65yrs 13.7% \pm 1.1%. There was a significant increase in the frequency of PP from 2001-2006 vs. 1995-2000 among all age groups (OR= 1.60, 95%CI 1.314-1.939): 0-24 yrs age group: OR=1.36 (95% CI 1.04-1.78); 25-65yrs: OR=1.71 (95% CI 1.34-2.19); and >65yrs: 1.80 (1.23-2.64). The odds of using at least one psychotropic drug was significantly higher (OR=11.42, 95% CI 8.83-14.77) in the PP group.

COMMENT: There has been a significant increase in PP (≥ 4 drugs) from 1995 to 2006, with about 8% to 10% of younger dermatology patients receiving ≥ 4 drugs. Dermatology patients with PP were more likely to be receiving a psychotropic medication even in the absence of a psychiatric diagnosis.

Commercial Support: None Identified

GENODERMATOSES

P1100

Tuberous sclerosis in a 8-year-old girl

Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Tuberous sclerosis is a multi-system genetic disease that causes benign tumors in different organs. Here, we report a case of tuberous sclerosis.

CASE PRESENTATION: A 8-year-old girl presented with complaints of generalized tonic-clonic seizures for the last six years. Her birth history was unremarkable. The patient had normal psychomotor

development until 2 years of age, when developmental delay started. Neurological examination revealed she was slightly mentally retarded, autistic and physically handicapped. Dermatology examination revealed adenoma sebaceum on face and hypomelanotic macules on thorax. Renal function tests and serum electrolytes were normal. Echocardiographic examination was unremarkable. Cranial computerized tomographic scan showed multiple subependymal hyperdense nodules along lateral ventricles. With these clinical and neuroimaging features, a diagnosis of definite tuberous sclerosis was made. CONCLUSION: Clinical diagnosis of tuberous sclerosis is easy when the patients presents with classical triad of seizures, mental retardation and adenoma sebaceum. However, the incomplete form, mistakes in diagnosis may occur.

Commercial Support: None Identified

HAIR AND NAIL DISORDERS

P1200

Association between IL17A/IL17RA gene polymorphisms and susceptibility to alopecia areata in Korean population

Hee-Ryung Cho, MD, Department of Dermatology, East West Neo Medical Center, Kyunghee University,, Seoul, South Korea; Bark-Lynn Lew, PhD, MD, Department of Dermatology, East West Neo Medical Center, Kyunghee University,, Seoul, South Korea; Chang-Min Choi, MD, Department of Dermatology, East West Neo Medical Center, Kyunghee University,, Seoul, South Korea; Min-Joong Kim, MD, Department of Dermatology, East West Neo Medical Center, Kyunghee University,, Seoul,, South Korea; Woo-Young Sim, PhD, MD, Department of Dermatology, East West Neo Medical Center, Kyunghee University,, Seoul, South Korea

Background: Alopecia areata (AA) is marked by autoimmune assault on the hair follicle resulting in hair loss. T helper 17 (TH17) cell subset has important roles in protecting the host against extracellular pathogens, but also promotes inflammatory pathology in autoimmune disease, and it expresses both interleukin (IL)-17A and IL-17F, which can signal via the IL-17 receptor A (IL-17RA). Objective; To investigate the significance of IL17A and IL17RA gene polymorphisms in the susceptibility to AA and understand the pathogenesis of AA.

Methods: We conducted case-control association study of 238 AA patients and 270 matched healthy controls. Genotypes of total 2 single nucleotide polymorphisms (SNPs) in the IL17A gene and 4 SNPs in the IL17RA genes were studied. The statistical analyses were performed according to onset age, the presence of family history, clinical subtypes of AA, and presence of nail involvement or body hair involvement.

Result: Two SNPs (rs879575 and rs879577) of IL17RA gene showed significant difference between AA patients group and controls group. One SNP (rs2229151) of IL17RA gene showed significant difference between the early onset AA and late onset AA. Two SNP (rs2275913 and rs3819024) of IL17A gene showed significant differences between patchy type of AA and AU or AT and between presence of nail involvement and normal nail appearance. Any SNPs of IL17A or IL17RA were not within a strong LD block.

Conclusion: IL17RA gene polymorphisms may contribute to the increased susceptibility to AA in Korean population, and IL17A or IL17RA gene polymorphisms may be associated with phenotype of AA.

Commercial Support: None Identified

P1201

Cylindroma on the scalp

Jose Aneiros-Fernandez, MD, Department of Pathology, Granada, Spain; Francisco O'Valle, PhD, MD, Department of Pathology, Granada, Spain; Husein Husein-EIAhmed, MD, Department of Dermatology,

Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, Department of Pathology, Granada, Spain; Salvador Arias-Santiago, MD, Department of Dermatology, Granada, Spain

INTRODUCTION: Dermal cylindromas are benign tumors assumed to differentiate towards apocrine sweat glands of the skin. Most arise as small solitary slow growing nodules in the head and neck region.

CASE REPORT: A 77 year-old healthy woman presented with an isolated exophytic lesion of the scalp for 4 years which had grown progressively. On exam, there was a 4 cm erythematous and lobulated tumor with telangiectasias and hard consistency on the scalp. The rest of her cutaneous exam was normal. No lymphadenopathy was appreciated. Histological sections showed a dermal proliferation of basophilic lobules which molded together in a jigsaw puzzle configuration (Fig 2). At the periphery, there was a thick eosinophilic PAS+ basement membrane material (type IV collagen). The nests were also punctuated by small round collections of this material with similar staining qualities (Fig 3). Cells with prominent vesicular nuclei were visible in the centre of the molded lobules. The erythematous nodule was treated with surgical excision without no evidence of recurrence after seven months of follow-up.

DISCUSSION: -It usually occurs in the sixth decade of life. There is no sex predilection. It presents most commonly on the head, neck, or scalp as slowly growing, pink to purple, solitary or multiple, smooth surfaced nodules, which can rarely grow and coalesce to produce the characteristic turban-like mass (turban tumor). -The differential diagnoses of intradermal growth on the scalp may include benign tumors as trichilemmal cyst, infundibular cyst or collagenoma, and malignant tumors as amelanotic malignant melanoma, squamous cell carcinoma, basal cell carcinoma, atypical fibroxanthoma, metastatic carcinomas to the skin or proliferating tricholemmal tumor.

Commercial Support: None Identified

P1202

Hyperglycaemia and diabetes in patients with androgenetic alopecia

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; María Teresa Gutiérrez-Salmerón, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

Introduction: Low circulating levels of SHBG are a strong predictor of the risk of type 2 diabetes.

Androgenetic alopecia (AGA) has been related to an increase in cardiovascular risk, but the mechanism of this association has not been elucidated. AGA can be associated with low levels of SHBG and insulin resistance which could be related with hyperglycaemia and type 2 diabetes. The objective of this study was to evaluate SHBG and blood glucose levels in men and women with early-onset androgenetic alopecia and controls to determine if low levels of SHBG are associated with hyperglycaemia.

Methods: This case-control study included 240 patients consecutively admitted to the outpatient clinic (Dermatology department of San Cecilio Hospital, Granada, Spain), 120 with early onset androgenetic alopecia (60 males and 60 females) and 120 controls (60 males and 60 females) with other skin diseases other than alopecia.

Results: 39.1% of patients with AGA presented hyperglycaemia (>110 mg/dl) versus 12.5 % of controls (P<0.0001). AGA patients with hyperglycaemia or diabetes presented lower significant levels of SHBG than alopecic patients without hyperglycaemia or type 2 diabetes. Patients with AGA and hyperglycaemia presented significantly lower levels of SHBG than controls with hyperglycaemia (22.3 vs. 39.4 nmol/l for AGA patients and controls respectively, P=0.004). No significant differences in SHBG levels were noticed between patients and controls without hyperglycemia.

Conclusion: An association between early-onset androgenetic alopecia, hyperglycaemia and low levels of SHBG was observed in the current study. Low levels of SHBG could be a marker of insulin resistance and hyperglycaemia in patients with AGA.

Commercial Support: None Identified

P1203**Use of a hydroxypropyl-chitosan based medical device on onychodystrophic nails**

Matilde Iorizzo, MD, Dermatology Specialist, Lugano, Switzerland; Federico Mailland, MD, Scientific Dept. Polichem, Lugano Pazzallo, Switzerland

Background: A hydrosoluble lacquer was recently developed for the protection of intact or damaged nails from moisture, friction or shear, relieving symptoms and signs of nail dystrophy. Main ingredients are hydroxypropyl-chitosan (HPCH), horsetail extract (*E. arvense*) and methylsulphonyl-methane (MSM). A trial was performed to verify whether this product was able to improve signs of nail dystrophy not associated to inflammatory or to infectious diseases.

Methods: Twenty-two subjects, 19 females and 3 males, aged 13.6-82.9 years (mean \pm SD 60.8 \pm 16.2) with dystrophy of the fingernails due to chemical aggressives, to trauma or to humidity, were included. Clinical signs included brittle or dystrophic nails, lamellar splitting and/or onycholysis. The nail lacquer was randomly applied once daily on the affected fingernails of one hand for an average of 3 months. The other hand served as untreated control. The extent and severity of nail signs was assessed pre- and post-treatment using the following scale: 0=no; 1=mild; 2=moderate; 3=severe.

Results: Mean dystrophy score was in treated hand 1.32 \pm SD 0.78 at baseline and 0.86 \pm 0.71 at the end ($p=0.0107$). In the untreated hand, the score was 1.23 \pm 0.81 at baseline and 1.00 \pm 0.87 at the end (not significant, NS). Mean score of lamellar splitting was in treated hand 1.00 \pm 0.82 at baseline and 0.46 \pm 0.6 at the end ($p=0.0078$). In the untreated hand, the score was 0.86 \pm SD 0.77 at baseline and 0.59 \pm 0.59 at the end (not significant, NS). Mean score of brittle nails was in treated hand 1.18 \pm 0.80 at baseline and 0.41 \pm 0.59 at the end ($p=0.001$). In the untreated hand, the score was 1.09 \pm 0.75 at baseline and 0.68 \pm 0.65 at the end ($p=0.0313$) ($p=0.0352$ between treated and untreated nails).

Onycholysis was evident in few subjects at baseline and did not change at the end in both treated and untreated nails. The total sign score was in treated hand at baseline 3.81 \pm 1.78 and 2.00 \pm 2.12 at the end ($p=0.0001$). In the untreated hand, the score was 3.45 \pm 1.57 at baseline and 2.65 \pm 1.66 at the end ($p=0.0234$) ($p=0.02$ between treated and untreated nails).

Conclusions: The new water-soluble nail lacquer proved to be effective in improving the nail structure in subjects with onychodystrophy. The effect was particularly evident on lamellar splitting and brittle nails.

Commercial Support: 10% is sponsored by Polichem

P1204**Randomized, within subjects study to evaluate the effect of two nail lacquers on aspect and structure of fingernails in subjects with onychoschizia**

Adele Sparavigna, MD, Derming laboratories, Monza, Italy; Federico Mailland, MD, Polichem SA, Lugano Pazzallo, Switzerland

Background: A water soluble nail lacquer (1) intended to relieve symptoms and signs of nail dystrophy, and containing as main ingredients hydroxypropyl-chitosan (HPCH), horsetail extract (*E. arvense*) and methylsulphonyl-methane (MSM) was compared to another nail lacquer (2), with the same qualitative composition, except for the presence of insoluble chitosan instead of hydroxypropyl-chitosan.

Methods: The study was open label, randomized, monocenter, under dermatological control for 4 weeks of treatment. The included subjects were 34 healthy female volunteers, 20 - 70 yo (mean = 46) with onychoschizia of the fingernails, due to chemical agents and/or trauma and/or humidity. Clinical signs at baseline mainly included brittle nails or lamellar splitting, while dystrophy and/or onycholysis were present in few individuals. Both products were randomly applied by all subjects once daily on the affected fingernails of either hand, for an average of 4 weeks. The extent and severity of nail signs was assessed pre- and post-treatment using the following scale: 0=no; 1=mild; 2=moderate; 3=severe. Nail surface profilometry was assessed by morphometrical analysis of the longitudinal nail grooves on nail casts.

Results: A significant reduction of rugosity at the morphometrical analysis of the longitudinal nail grooves

was noticed (Dunnett test $p < 0.05$ T0 vs. T4) by 19% for (1) 16% for (2) (not significant between treatments). No change was noticed on transverse grooves. Onychoschizia (lamellar splitting) was present in all subject at baseline. Visual score of onychoschizia improved at T4 in 74% of volunteers with (1) and in 52% with (2) (Wilcoxon test $p < 0.06$ between treatments). Severe onychoschizia was present in 35% of patients at baseline: it improved at the end in 80% of subjects with (1) (Dunnett test $p < 0.05$ T0 vs. T4) and in 42% with (2). Nail fragility improved at the end in 81% of subjects with (1) and in 74% with (2) (Dunnett test $p < 0.05$ T0 vs. T2 and T4 for both products, no significant difference between treatments). Both products were well tolerated.

Conclusions: The new nail lacquer proved to be effective in improving the nail structure and appearance in subjects with onychodystrophy. Presence of hydroxypropyl-chitosan in the formulation was specifically effective in decreasing lamellar splitting.

Commercial Support: 100% sponsored by Polichem SA

IMMUNODERMATOLOGY AND BLISTERING DISORDERS

P1300

Sclerodermatous graft-vs-host disease responsive to imatinib mesylate: A case report

Jozef Lazar, University of Wisconsin School of Medicine and Public Health-Dept of Dermatology, Madison, Wisconsin, United States; Joyce Teng, PhD, MD, University of Wisconsin School of Medicine and Public Health - Dept of Dermatology, Madison, Wisconsin, United States; Tasneem Poonawalla, MD, University of Wisconsin School of Medicine and Public Health - Dept of Dermatology, Madison, Wisconsin, United States

Sclerodermatous graft-vs-host disease (sGVHD) is a rare form of chronic GVHD with an estimated prevalence of 3-11% in patients receiving allogeneic bone marrow transplants. sGVHD may be localized or generalized, with common cutaneous findings including hyperpigmented and hypopigmented macular lesions, atrophy, sclerosis, ulceration and debilitating contractures that limit joint mobility. Management of sGVHD is challenging, and a safe, reliably effective treatment option has yet to be identified. Recently, the pro-fibrotic cytokine transforming growth factor β (TGF- β) and stimulatory autoantibodies against the platelet-derived growth factor receptor (PDGFR), have been implicated in the pathogenesis of sGVHD. Imatinib mesylate is a small molecule tyrosine kinase inhibitor that has been shown to selectively inhibit both PDGF and TGF- β signaling pathways. Our case involves a 16-year-old white female who was referred for evaluation of hyperpigmentation and hardening of the skin first noted 8-9 months following her second allogeneic, unrelated hematopoietic cell transplantation (HCT) for relapsed, stage II nodular sclerosing Hodgkin's lymphoma. On exam, the patient demonstrated nearly confluent hyperpigmentation and sclerodermatous changes with firm, indurated, scaly plaques most prominent on the face, back and upper trunk. These changes were consistent with sGVHD, and the patient was started on acitretin 25 mg daily and tacrolimus 0.1% topical ointment in addition to her immunosuppressive regimen of cyclosporine and prednisone. The sclerotic plaques continued to progress and the patient developed significant contraction of the right elbow, decreased range of motion in both ankles and painful, punctate ulcers on the lower extremities. Treatment with mycophenolate mofetil 1000 mg BID, extracorporeal photophoresis and topical therapy with calcipotriene, urea ointment and clobetasol were also largely unsuccessful in softening the skin and alleviating the accompanying pruritus and xerosis. Approximately four years after her second HCT, the patient was initiated on a trial of imatinib mesylate 400 mg daily. Over the next 4-6 months, her skin softened significantly, ulcers resolved completely and joint contractures diminished with markedly improved range of motion. Improvement has allowed for discontinuation of all topical and systemic therapies except calcipotriene cream. Given its favorable side effect profile, specificity for both PDGFR and TGF- β , and proven efficacy in other sclerodermoid diseases, imatinib mesylate is a promising new tool in the management of sGVHD.

Commercial Support: None Identified

INFECTION (BACTERIAL & PARASITIC)

P1400

Concurrent multiple familial trichoepithelioma and borderline leprosy

Eduardo Bornhausen Demarch, MD, Instituto de Dermatologia Prof. Rubem David Azulay - Santa Casa da Misericórdia do Rio de Janeiro, Rio de Janeiro, Brazil; Alice Miranda, PhD, MD, Fundação Oswaldo Cruz - FIOCRUZ, Rio de Janeiro, Brazil; Guillermo Loda, MD, Instituto de Dermatologia Prof. Rubem David Azulay - Santa Casa da Misericórdia do Rio de Janeiro, Rio de Janeiro, Brazil; João Carlos Regazzi Avelleira, PhD, MD, Instituto de Dermatologia Prof. Rubem David Azulay - Santa Casa da Misericórdia do Rio de Janeiro, Rio de Janeiro, Brazil; José Augusto da Costa Nery, PhD, MD, Instituto de Dermatologia Prof. Rubem David Azulay - Santa Casa da Misericórdia do Rio de Janeiro, Rio de Janeiro, Brazil

The multiple trichoepithelioma is a benign tumor with follicular differentiation, autosomal dominant, and frequent familial occurrence. It affects mainly the face and the lesions usually appear in childhood, increased during puberty. Leprosy is endemic in Brazil, with no predilection for sex or race, with frequent transmission between family contacts, despite the low pathogenic disease. We report two patients, father and daughter, complaining of "red spots" in the body, and paresthesia in arms and in the case of the daughter, in her legs. On examination we observed the presence of plaque lesions with visible inner edge and diffuse outer boundary, with changes in sensitivity, present in the abdomen of both patients. We also noticed papular-nodular lesions, skin-colored, hardened and in large numbers, located on the face of patients, present since childhood according to the report. In both patients the bacilloscopy was strongly positive and VDRL nonreactive. The histopathology of the lesion in abdomen with Wade staining showed a large amount of bacilli. Biopsy of the lesion on the face showed benign tumor proliferation in dermis, composed of nests of basaloid cells devoid of atypia, without changes in the epidermis. Patients are being treated with multibacillary multidrug therapy, with good improvement. They were referred for dermatologic surgery to removal of lesions of trichoepithelioma. The multiple trichoepithelioma is associated with several systemic diseases such as lupus erythematosus, myasthenia gravis, Rombo syndrome and Brooke-Spiegler syndrome. No association with leprosy has been described so far. We call attention to the fact that both patients had both multiple trichoepithelioma as leprosy. Are we facing a simple coincidence or a new causal association?

Commercial Support: None Identified

INFECTION (FUNGAL)

P1500

Cutaneous blastomycosis mimicking pyoderma gangrenosum in a patient with a history of chronic myelogenous leukemia

Matthew Hazey, MD, University of Louisville, Louisville, Kentucky, United States; Carol Kulp-Shorten, MD, University of Louisville, Louisville, Kentucky, United States; Jeffrey Callen, MD, University of Louisville, Louisville, Kentucky, United States

Background: Cutaneous blastomycosis can be difficult to clinically distinguish from other forms of pyoderma, and identification of *B. dermatitidis* to confirm the diagnosis can be challenging. Pyoderma gangrenosum (PG) can present with similar clinical and histologic features and can be associated with hematologic disease. We describe a patient with a history of chronic myelogenous leukemia (CML) who developed non-healing, ulcerated, verrucous plaques on the abdomen one month after undergoing drainage of an abdominal abscess. Multiple biopsies subsequently led to a diagnosis of cutaneous blastomycosis.

Observation: A 78-year-old man was referred for a 12-month history of non-healing, ulcerated, verrucous plaques on the abdomen. He had a history of CML diagnosed 2 months prior to the onset of skin disease and was in remission after completing a course of imatinib. One month prior to the onset of skin disease,

he underwent surgical drainage of a 'sterile' abdominal abscess. He was initially managed with local wound care unsuccessfully. Initial skin biopsy of an abdominal plaque demonstrated erosion, pseudoepitheliomatous hyperplasia, and acute inflammation; GMS, AFB, and Gram stains were negative for an associated infectious process. Three months prior to presentation, his lesions were surgically excised, and histologic examination redemonstrated initial findings. Unfortunately, plaques recurred one month post-operatively. He was referred to dermatology for suspected PG. Physical exam revealed well-demarcated, verrucous plaques with areas of central ulceration within his abdominal surgical scar. The lack of an undermined border typical of PG prompted a repeat skin biopsy that revealed broad-based budding yeasts; GMS staining was positive. Complete blood count and comprehensive metabolic profile were unremarkable; chest x-ray showed no evidence of pulmonary disease. We diagnosed cutaneous blastomycosis and began treatment with itraconazole.

Comment: Neutrophilic dermatoses are known to occur in patients with leukemia, and given our patient's overall clinical picture, PG was initially suspected. However, this case demonstrates that maintaining a high index of clinical suspicion as well as reviewing previous tissue specimens or performing additional biopsies may be needed to diagnose cutaneous blastomycosis. Accurate diagnosis is imperative as immunosuppressive treatments for PG can lead to progression and further dissemination of infection.

Commercial Support: None Identified

P1501

An open-label, proof of concept study to determine the safety and efficacy of ketoconazole 2% foam in the treatment of malassezia folliculitis

Wayne Fujita, MD, Wayne H. Fujita MD Inc, Aiea, Hawaii, United States

Objectives: Malassezia species is implicated in the etiology of seborrheic dermatitis, tinea versicolor, and malassezia folliculitis. Ketoconazole 2% foam is approved for the treatment of seborrheic dermatitis. This study assessed the clinical efficacy and safety of ketoconazole 2% foam for the treatment of malassezia folliculitis.

Methods: This was a 10 patient, open label, 90 day, single center/investigator study. Patients with clinical presentation of malassezia folliculitis on the back were instructed to apply ketoconazole 2% foam BID to the lesions for 2 to 4 weeks or until clinical clearance. Treatment would be restarted if the infection reoccurred. Patients were evaluated at baseline, and 1, 2 and 3 months after onset of treatment. At each visit, the following were recorded: the number of treatment days; lesion counts on the back; patients' perception of cosmetic acceptability; investigator and patient global assessment of response to treatment; photographs of the folliculitis; adverse events (AE), burning/itching and redness/peeling. At the Month 3 Visit, patient satisfaction with study medication and comparison of ketoconazole 2% foam treatment to past treatments for malassezia folliculitis were recorded.

Results: The patients in this study ranged in age from 18-29 years (6 females and 4 males). Seven out of 10 patients completed the 90 day study. Ketoconazole 2% foam was applied on average on 76% of the days of the study period (68 treatment days). Patients experienced a 51%, 81%, and 82% lesion count reduction after 1, 2, and 3 months of treatment, respectively. Based on both the investigator's and patient's global assessment, patients were "slightly better to almost clear" at 1 month and "almost clear" at 2 and 3 months. Cosmetic acceptability, ease of application, and convenience of treatment were all rated "good" to "superior" by the patients. The patients were "very satisfied" to "satisfied" with the treatment at the end of the study. Six patients that had experienced alternative treatments for the folliculitis in the past, all rated ketoconazole 2% foam as "better" therapy. There were no reports of redness or peeling of skin. Two patients reported "mild" burning and "mild" itching at week 4. One patient reported "mild" burning at week 8. No adverse events were reported at week 12.

Conclusions: Ketoconazole 2% foam was effective, safe, and preferred over past treatments when applied continuously or intermittently for the treatment of malassezia folliculitis.

Commercial Support: 100% is supported by Stiefel, a GSK company.

P1502**Comparison of visual assessments versus planimetry assessments in a large-scale clinical trial of onychomycosis**

Aditya K Gupta, PhD, MD, Sunnybrook Health Sciences Center and the University of Toronto, Toronto, Canada; Elizabeth A Cooper, Mediprobe Research Inc, London, Canada

Introduction: Computerized nail planimetry has been recommended as an objective means of accurately assessing affected nail areas, as compared to the standard visual estimation method. However, no comparison of visual assessment with planimetry is currently presented in the literature on onychomycosis to support this recommendation. To investigate this issue, visual assessments from an 84-week large-scale trial of subungual dermatophyte onychomycosis treatment cohort were compared with planimetry measurements of nails made from digital photos of the nails taken through the course of the trial.

Methods/Results: Visually-assessed percent affected area of the target toenail was compared with percent affected areas calculated by planimetry from digital photographs. Differences in assessment of affected area by visual and planimetry means were compared by linear regression, and by considering mean difference in area between assessments at baseline, week 48 and week 84 as per the analysis method of Bland and Altman, including determination of the limits of agreement.² Effective cure rates were calculated using alternately visual and planimetry areas for weeks 48 and 84, and compared using the Chi-square test. Comparison showed good statistical agreement of visual and planimetry measures based on correlation coefficient, but clinically, cure rates were overestimated by 9% and 11% at weeks 84 and 48 respectively using visual methods. Visual assessments at week 84 were within 10% of planimetry measurements in 91.7% of comparisons, and within 5% of planimetry measures in 74.1% of comparisons. Rates of agreement were lower at other visits considered in analysis.

Discussion: The results suggest that objective measures such as planimetry are required to reduce the impact of visual assessment errors, and techniques to increase the standardization of onychomycosis assessment during trials are warranted.

Commercial Support: None Identified

P1503**WITHDRAWN****P1504****Nitric oxide effectively treats tinea pedis**

Aditya K Gupta, PhD, MD, Sunnybrook Health Sciences Center and the University of Toronto, Toronto, Canada; Elizabeth A Cooper, Mediprobe Research Inc, London, Canada; Frank J McCaney, Nitric BioTherapeutics Inc., Bristol, Pennsylvania, United States; Tara Clayton, Mediprobe Research Inc, London, Canada

Introduction: Standard topical formulations for tinea pedis require daily application over 2-4 weeks. Compliance is an issue, and may contribute to high relapse rates seen with this condition. To avoid compliance issues, an in-office treatment with nitric oxide gas is being tested for tinea pedis.

Methods: A series of dose-finding clinical trials were performed to study the efficacy of a variety of exposure regimens for tinea pedis to identify optimal duration and timing of treatment. . During treatment, 1% nitric oxide gas circulates through a plastic 'boot' over the infected foot. Clinical responses were assessed using mycology testing and visual assessment measures.

Results: A phase 1 trial demonstrated total cure 12 days after cessation of therapy in n=7 patients receiving 2 hours of exposure over 5 days. Phase 2a of the trial (placebo-controlled) involved n=59 patients that received 2 hours exposure (3x40 minutes) over 3 days resulting in a 65% reduction in

clinical score in those treated with nitric oxide vs. 30% in the placebo treated patients after 12 days of follow up. In addition, 60% of nitric oxide treated patients were negative for mycology vs. 20% in placebo treated patients after the same follow up period. Phase 2b investigated the minimal effective dose required to treat n=120 patients. Participants received either a single or two 30 or 60 minute treatments. In all cases patients achieved approximately 60% clinical improvement after 29 days follow-up. Discussion and Conclusion: Nitric oxide therapy is efficacious in curing or dramatically decreasing the severity of tinea pedis in the majority of patients after a single treatment with a relatively short treatment duration.

Commercial Support: sponsored by NitricBio Therapeutics Inc

P1505

Strain typing of trichophyton rubrum isolates from onychomycosis patients failing antifungal therapy

Aditya K Gupta, PhD, MD, Sunnybrook Health Sciences Center and the University of Toronto, Toronto, Canada; Muhammad Zaman, PhD, Mediprobe Research Inc, London, Canada

Introduction: Antifungal treatment failure is high in cases of onychomycosis, and relapse frequently occurs following antifungal success. This study is investigating T. rubrum strain typing using isolates collected from patients at screening and post-treatment to determine if there are predominant strains associated with treatment failure.

Methods/Results: Restriction fragment length polymorphisms (RFLPs) of rDNA from T. rubrum isolates were used to differentiate strains. Genetic variation was analyzed by hybridization of EcoRI digested genomic DNAs with a probe amplified from the small-subunit (18S) ribosomal DNA and adjacent internal transcribed spacer regions (ITS) region. None of the RFLP types was unique to any specific patient; rather, genotypes were shared among the different patients. Patients P1, P3 and P4 showed similar genotypes of T. rubrum isolates collected before and after treatment, but 4 other patients (P2, P5, P6, and P7) showed different genotyping in their isolates. The small numbers of patients studied so far were not sufficient to conclude if there is any particular type of strain causing the reinfection. More isolates are available for analysis, and data continues to be collected. Future analysis will also consider MICs of the isolates to determine correlation between antifungal resistance and genotype. Discussion and

Conclusion: Treatment failure may result from reinfection with similar or different strains of dermatophyte, or inadequate therapy where a strain may temporarily be undetectable in the samples but re-emerge after treatment end. Studies of drug efficacy must make this distinction between environmental reacquisition of the organism after successful eradication of organisms versus recrudescence indicating inadequate initial therapy. Methods of detection of intraspecific variability are therefore crucial to assessment of the cause of reinfection in the Canadian onychomycosis population, and this study is providing data which can help to answer this vital question.

Commercial Support: None Identified

P1506

Onychomycosis therapy: Past, present, future

Aditya K Gupta, PhD, MD, Sunnybrook Health Sciences Center and the University of Toronto, Toronto, Canada; Elizabeth A Cooper, Mediprobe Research Inc, London, Canada; Michael Uro, DPM, Foot Doctor Laser Center, Sacramento, California, United States

Since their development, oral antifungal therapies have represented the gold standard for onychomycosis treatment over other methods. However efficacy with oral therapies remains limited and safety may be an issue, leaving many patients requiring alternative treatments. With the advance of science, topical therapies as alternatives for onychomycosis are being investigated in greater numbers than in the past, as new technologies are overcoming previous limitations of topical treatments such as lack of nail

penetration. New device-related topical therapy methods are particularly interesting, as they may allow for shorter, more convenient treatments for patients, reducing issues with topical compliance, and in the case of non-drug light-based therapies they will avoid potential for drug reactions. An Iontophoresis device increases drug concentration in the nail plate above the levels possible with ordinary diffusion methods using a terbinafine patch applied to a toenail under mild electric current (100 microamperes/cm²). Several laser devices using non-ultraviolet (UVA, UVB, UVC) light spectrums are currently being tested for efficacy and safety in onychomycosis. A combination 870nm/930nm laser system has been shown to produce photoinactivation of *Trichophyton rubrum* at physiologic temperatures in vitro. Additionally, seven patients received laser treatment for toenail infections at days 1, 7, 14 and 60 (4 exposures of 870nm/930nm for 240s with energy density of 408J/cm² with 1.5cm spot, followed by 930nm for 120s with an energy density of 204 J/cm²). All 7 patients were mycologically negative at day 60. Evaluation of the safety and efficacy of a prototype Nd:YAG antifungal laser was performed in 17 subjects. The treatment was tolerated by all subjects without anesthesia and there were no occurrences of serious adverse effects. Eleven out of 14 (79%) treated toes improved. Improvement ranged from 2.1 to 6.1 mm over 90 days following a single treatment. A further study of efficacy and safety of this laser has been performed for 71 patients who had received either a 1-pass (255 J/cm²) or 2-pass (510 J/cm²) single treatment. At 6 months post treatment, 65% of all patients treated showed improvement with a statistically significant mean improvement in lesion-free area of 9.8% (p<0.001). Research in these fields remains preliminary and the impact these methods may have on the future of onychomycosis remains to be seen.

Commercial Support: Sponsored by Patholase Inc

P1507

Iontophoretic delivery of terbinafine for the treatment of onychomycosis

Aditya K Gupta, PhD, MD, Sunnybrook Health Sciences Center and the University of Toronto, Toronto, Canada; Frank J McCaney, Nitric BioTherapeutics Inc., Bristol, Pennsylvania, United States

Introduction: Onychomycosis is a common disease with increasing prevalence, and high relapse rates after cessation of therapy. Presently oral terbinafine is the gold standard antifungal treatment, however it presents with the potential for harmful adverse events and/or potential drug interactions.. Topical terbinafine formulations typically do not provide sufficient penetration to be suitably effective in onychomycosis. To address this penetration issue, an iontophoretic device has been developed to aid in the penetration of existing drugs such as terbinafine through the nail plate to the site of infection.

Methods: A device delivering a 10 mA/min electric current was employed to assist the penetration of a liquid formulation of terbinafine into and through the nail plate. Pharmacokinetic testing was performed to determine terbinafine levels in the nail plate/bed, and systemically, before and after drug application.

Results: After a 20 minute treatment the amount of terbinafine far exceeded (1.6×10^5) the MIC for terbinafine in the nail plate as well as that achieved during oral terbinafine therapy (1.9×10^3). Terbinafine was gradually released from the nail plate for more than 7 weeks after treatment. All tissue in contact with or surrounding the nail plate contained levels of terbinafine between 500- 6000 times the MIC.

Conversely, no terbinafine was detectable in plasma out to 8 hours after treatment. Drug delivery with iontophoresis was approximately equal in normal and diseased nails.

Discussion and conclusion: Although antifungal agents in theory are capable of treating onychomycosis the reality of the situation is that drug delivery to infected tissue is troublesome. Iontophoretic delivery of terbinafine is capable of overcoming this shortcoming in present treatment protocols.

Commercial Support: Sponsored by NitricBio Therapeutics Inc

INFECTION (VIRAL)

P1600

Herpes zoster duplex bilateralis: A case report and review of the literature

Sang-Seok Kim, MD, Dept. of Dermatology, Kangdong Sacred Heart Hospital, Hallym University, Seoul, South Korea; Ju Hyuk Park, MD, Dept. of Dermatology, Kangdong Sacred Heart Hospital, Hallym University, Seoul, South Korea; Min Seong Kil, MD, Dept. of Dermatology, Kangdong Sacred Heart Hospital, Hallym University, Seoul, South Korea

Herpes zoster is characterized by unilateral distribution of the painful rash as the result of reactivation of latent varicella-zoster virus within sensory ganglia. Cases of bilateral involvement are rare, and moreover, simultaneous involvement of two noncontiguous dermatomes is even rarer in both immunocompetent and immunosuppressed persons. And the latter has been referred to as zoster duplex unilateralis or bilateralis, depending whether one or both halves of the body are involved. It's well known that the patients with a malignancy or immunosuppressed states are more likely to develop zoster than their age-matched counterpart, but it's uncertain whether zoster duplex could be diagnostic clue for latent immunodepressed state of the patients. We report a 69-year-old woman with zoster duplex bilateralis. At that time there was no evidence that she was immunodeficient, but 6 years later she was diagnosed with malignant lymphoma. And, in conclusion, we suggest that the patients with zoster duplex be examined for the immunodeficiency and close follow-up be needed.

Commercial Support: None Identified

P1601

Genital wart affecting labia minora

Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Francisco O`Valle, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Genital warts are a common manifestation of venereal disease caused by viral transmission. Typically, they affect the mucocutaneous surfaces of the external genitalia or perianal region. We describe a woman with multiple warts on labia minora.

CASE PRESENTATION: A 64-year-old woman presented with a 10-months history of lesions affecting labia minora which had been present for eight months. Lesions were asymptomatic and grew up slowly. She did not attend to her medical center and lesions never were treated. She was no taking any current medications and there was no history of an immunodeficiency. Examination of the skin revealed multiple, soft, filiform warts of variable size on left labium minus. Warts occurred widely in the whole left labium. No lesions were found in the anal margins or rectum. Histopathological findings of lesional skin biopsy showed characteristic features of verruca vulgaris. The patient refused both surgical excision and laser therapy. Therefore, treatment with combination Imiquimod and 40% salicylic acid cream was initiated. After two months, the response has been partial.

CONCLUSION: Viral warts remain a therapeutic challenge for dermatologist and general practitioners. Patients are often frustrated by their large or multiple warts and suffer for major cosmetic, functional and social discomfort.

Commercial Support: None Identified

P1602

Human papillomavirus type 27 in epidermodysplasia verruciformis

Joyce Castillo, MD, Makati Medical Center, Makati, Philippines; Ma. Lourdes De Veyra, MD, Makati Medical Center, Makati, Philippines

Epidermodysplasia verruciformis (EV) is a rare genodermatosis associated with the human papillomavirus (HPV). Most cases display an autosomal recessive inheritance, but X-linked and sporadic mutations have also been reported. Malignant transformation of skin lesions, particularly squamous cell carcinoma is observed in more than half of these patients after the age of 30. We report a 37-year-old Filipino male seen at a medical mission in Antique, southern Philippines with severe fungating hyperkeratotic plaques on his right hand. At 19 years old, the patient developed erythematous, scaly macules localized on the trunk and lower legs. At the same time, reddish-brown verrucous papules on the dorsa of both hands were also noted. Over the years, the verrucous papules slowly appeared on the face, trunk and limbs. His right hand was eventually covered with large vegetating verrucous plaques causing an almost complete loss of function. No significant systemic symptoms were noted. Laboratory tests (complete blood count, urinalysis, bleeding and clotting time and chest radiographs) were normal. Radiograph of the right hand revealed multinodular soft tissue densities with disuse osteoporosis. A clinical diagnosis of EV was made. Surgical shaving of the verrucous plaques was done under regional and local anesthesia. Histopathology confirmed our diagnosis. No evidence of cutaneous malignancy was seen. Tissue samples were sent for HPV detection by polymerase chain reaction (PCR). HPV was detected and genotype identification by sequence analysis showed HPV-type 27. Such genotype, unlike types 5 and 8 detected in most cases of EV, is not associated with malignancy. This report establishes a probable association of HPV-27 and EV or a possible variant that may have little or no potential for malignant transformation.

Commercial Support: None Identified

INTERNAL MEDICINE DERMATOLOGY

P1700

Schonlein-Henoch purpura on legs aggravated after depilation

Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; María Sierra Girón Prieto, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

BACKGROUND: Schonlein-Henoch purpura is a systemic vasculitis characterized by deposition of immune complexes containing the antibody IgA in the skin and kidney. We report a case of a young lady with Schonlein-Henoch purpura which aggravated after depilation.

CASE PRESENTATION: A 16-year-old female was admitted to our hospital because of bilateral lower limb swelling with skin rash for 2 days. She was healthy and was not under medications. She got bilateral knee and ankle joint pain not relieved by oral analgesics 2 weeks before admission and symptoms of upper respiratory tract infection 2-3 days prior to presentation. Patient noticed skin lesions abruptly increased in size and color after depilation. Nonblanchable, maculopapular purpuric skin rashes ranging from 1 mm to few cm were noted over both lower limbs. No lesion was found on mucosa or trunk. Laboratory tests showed normochromic normocytic anemia, elevated erythrocyte sedimentation rate (85 mm/hr) and proteinuria (2.1 gr/d). Diagnosis of Schonlein-Henoch purpura was made based on nonthrombocytopenic purpuric skin rash with biopsy confirmed leucocytoclastic vasculitis, markedly elevated Ig A level, proteinuria and microscopic haematuria. Therapy with prednisone 45 mgr/day controlled symptoms, proteinuria disappeared and skin lesions recovered completely.

CONCLUSION: Local trauma should be avoid in Schonlein-Henoch purpura patients in order to prevent recurrence or disseminated disease.

Commercial Support: None Identified

P1701

The terminology used by non-dermatologists in consults for potentially malignant lesions: What is predictive of skin cancer?

Whitney Tolpinrud, Yale University School of Medicine, New Haven, Connecticut, United States; Cary Gross, Yale University College of Medicine, New Haven, Connecticut, United States; Kate Viola, Yale University School of Medicine, Robert Wood Johnson Clinical Scholars Program, New Haven, Connecticut, United States; Robert Kirsner, Yale University School of Medicine, New Haven, Connecticut, United States; Suguru Imaeda, Yale University School of Medicine, New Haven, Connecticut, United States

Background: Skin cancer is frequently suspected by non-dermatologists. Dermatology practices triage referrals from non-dermatologists based on the terminology used. Little is known how non-dermatologists describe lesions of concern when making referrals.

Objective: To assess the descriptive terminology used by non-dermatologists when referring patients with potential cutaneous malignancies.

Methods: We completed a retrospective chart review of 400 patients referred by non-dermatologists for skin lesions suspicious of malignancy at the VA Connecticut Health Care System between 2006-2009. We collected both specific descriptive terminology used to characterize the lesion of concern by the referring health care clinician as well as the final diagnosis.

Results: General concern for malignancy without specific descriptors was used in 78 patients, of which 23% (n=18) were found to be malignant. Specific descriptive terminologies used most frequently by non-dermatologists to describe suspicious lesions were hyperpigmented (n=71), changing size (n=69), non-healing (n=55), irregular border (n=52), irritated and/or scaly (n=40), and raised (n=33). All descriptions predicted cancer 9-13% of the time except for non-healing, which demonstrated a positive predictive value of 44%. The following were the most frequently used general concerns: rule out melanoma, rule out basal cell carcinoma, and personal history. Of the 31 rule out melanoma, 10% (n=3) were malignant. Two of these 3 were melanoma. Rule out basal cell carcinoma was utilized 57 times and had a positive predictive value of 30%. Lastly, personal history was listed as a concern for 31 patients, none of which were diagnosed with skin cancer.

Conclusion: The descriptive terminology of potential cutaneous malignancies utilized by non-dermatologists may provide important clues to aid dermatologists in triage decisions. Specifically, non-healing and rule out basal cell carcinoma may be key terminology that indicate the patient should be seen by the dermatologist in a timely manner.

Commercial Support: None Identified

P1702

Outcomes of referral to dermatology for “suspicious” lesions: Implications for teledermatology

Kate Viola, Yale University School of Medicine, New Haven, Connecticut, United States; Cary Gross, Yale University School of Medicine, New Haven, Connecticut, United States; Robert Kirsner, Yale University School of Medicine, New Haven, Connecticut, United States; Suguru Imaeda, Yale University School of Medicine, New Haven, Connecticut, United States; Whitney Tolpinrud, Yale University School of Medicine, New Haven, Connecticut, United States

Background: Skin cancer is the most common malignancy worldwide and it is uncertain whether non-dermatologists are accurate in referring worrisome lesions. Some have proposed teledermatology as an approach to increase prompt access to dermatologic expertise, by sharing digital photographs of lesions and obviating the need for in-person evaluation. It is not known how often other malignancies are incidentally detected by dermatologists at the time of consultation.

Objective: To determine the proportion of suspicious lesions referred by non-dermatologists that are found to be malignant and the number of incidental skin cancers identified at the time of dermatology referral.

Methods: A retrospective cohort study of 400 patients referred to the VA Connecticut Healthcare System by non-dermatologists for skin lesions deemed suspicious for malignancy was conducted between 2006

and 2009. Data were collected including the type and accuracy of referring provider, the final diagnosis by the dermatologist, and the number and type of incidental lesions.

Results: Only 22% of index lesions (i.e. lesions that prompted the referral) were found to be cancerous. The proportion of lesions found to be malignant was similar across all clinician types including primary care physician (22%), resident (30%), other physician type (22%), and mid-level practitioner (19%). In aggregate, 149 cancerous lesions were noted in 98 patients (sensitivity 59%; specificity 78%). However only 88 (59%) were identified in the index lesion; an additional 111 incidental lesions were biopsied by the consulting dermatologist with 61 additional skin cancers identified. Ten of the 61 incidental cancers were found in patients whose primary referred lesion was clinically benign and not biopsied.

Conclusion: Non-dermatologists may benefit from focused educational initiatives on skin cancer detection. A substantial proportion of malignancies were incidentally identified by the consulting dermatologist in addition to the primary lesion of concern. Teledermatology to assess a specific lesion of concern may be associated with underdiagnosis of clinically significant lesions which are not appreciated by the referring physician, and therefore must not be used as a substitute for a total body skin examination.

Commercial Support: None Identified

P1703

Biologics treatments for sapho syndrome: Report of three cases

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Norberto Ortego-Centeno, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: SAPHO syndrome is a rare condition of unknown pathogenesis originally described by Charmot et al in 1987. Onset usually occurs in young adults, with no differences between sexes and it is manifested by Synovitis, Acne, Pustulosis, Hyperostosis and Osteitis. Of paramount importance is the finding of a non-infectious, inflammatory osteitis associated with skin lesions.

CASE REPORT: Three patients with SAPHO syndrome and good response with infliximab and adalimumab therapy are presented in this study. Many treatments were tried before biologics without an appropriate response. A 49 year-old woman with plantar pustulosis and osteoarticular inflammation of her anterior chest wall and right shoulder, presented good response to adalimumab therapy. A 39 year-old woman with personal history of hypertension and dyslipidaemia, presented with pustular lesions in palms and plants of her feet and sternoclavicular and manubriosternal joints inflammation with good response to infliximab therapy. A 45-year-old man with plantar pustulosis and chest wall osteitis had good response to infliximab.

DISCUSSION: Being the knowledge regarding the pathogenesis of SAPHO syndrome so limited, a wide range of therapies has been used, mostly in order to relief symptoms, such as NSAIDs, steroids, antibiotics, biphosphonates (pamidronate and zolendronic acid) and different immunosuppressive and immunomodulators (methotrexate, leflunomide, sulfasalazine, cyclosporine A). The results of the uses of these therapies are quite varied, too. The usage of a new group of drugs, the TNF- α blocking agents – infliximab and etanercept-, has been reported with good response. Also adalimumab may present as an excellent alternative to control both skin and osteoarticular lesions in patients with SAPHO syndrome unresponsive to other treatments.

Commercial Support: None Identified

LYMPHOMA, CUTANEOUS/MYCOSIS FUNGOIDES

P1800**Clonal T-cell receptor γ -chain gene rearrangements in differential diagnosis of metastatic anaplastic large cell lymphoma versus lymphomatoid papulosis**

Oleg Akilov, PhD, MD, University of Pittsburgh, Pittsburgh, Pennsylvania, United States; Jeffrey Kant, PhD, MD, University of Pittsburgh, Pittsburgh, Pennsylvania, United States; Larisa Geskin, MD, University of Pittsburgh, Pittsburgh, Pennsylvania, United States; Lisa Grandinetti, MD, University of Pittsburgh, Pittsburgh, Pennsylvania, United States; Raju Pillai, MD, University of Pittsburgh, Pittsburgh, Pennsylvania, United States

Background: Lymphomatoid papulosis (LyP) type C manifesting after anaplastic large cell lymphoma (ALCL) may present a significant diagnostic challenge not only because they belong to the same group of CD30+ lymphoproliferative disorders, but they can also have very similar histopathological features.

Objectives: Reliable diagnostic methods would be of benefit in the differential diagnosis of metastatic ALCL versus LyP when clinical and histologic features are very similar.

Case report: A 54-year-old Caucasian male presented with a history of ALK-1 negative ALCL in the right inguinal lymph node 6 years ago. The cells lacked expression of epithelial membrane antigen and ALK-1, but were positive for CD4, CD3, CD2, and CD43. A PET scan showed an abnormal right external iliac lymph node suspicious for involvement with lymphoma with a SUV measuring 3.6 (with tumor being greater than 2.5). He received six cycles of CHOP chemotherapy. A complete response to chemotherapy was achieved as judged by negative PET scan. For optimal management, field radiation therapy to the right inguinal and pelvic region was administered, delivering 3060 cGy in 17 fractions. Three and ½ years after achieving remission, the patient developed a nodular lesion over the right clavicle. The lesion was biopsied, and a dense CD30+ lymphocytic infiltrate was detected. Diminished expression of CD8, CD4, CD5, CD7, and negative CD20, EMA, ALK1, CD56, CD57, granzyme and TIA-1 was demonstrated. A PET scan done at the same time did not find any evidence of malignancy. For the next 2 years, the patient observed waxing and waning papules and nodules appearing on different parts of the body. They regressed without scarring after application of topical steroids within 2 to 3 months of treatment. The lesions never grew to a diameter more than 3 cm and never became ulcerated. While clinically the presentation was consistent with LyP, metastatic ALCL had to be ruled out. Clonal T-cell receptor γ -chain gene rearrangement (TCR-GR) PCR was performed on original tissue samples from the lymph node and new skin lesions using 4 primer sets (V1-8, V9, V10 and V11). TCR-GR was positive in both lesions. However, the TCR-GR was observed with different V γ primer sets in ALCL (V γ 9) and LyP (V γ 1-8), which were consistent with separate clonal processes. Demonstration of different clones by TCR-GR in the two lesions ruled out metastatic ALCL and confirmed clinical findings of LyP.

Conclusion: TCR-GR PCR is a useful method in distinguishing different clonal processes and should be used when differentiation of primary and secondary lymphoproliferative disorders is required.

Commercial Support: None Identified

P1801**Unilateral, progressive facial swelling: Extranodal NK T-cell lymphoma – nasal type**

Steven Nelson, MD, Mayo Clinic - Scottsdale, Scottsdale, Arizona, United States; David DiCaudo, MD, Mayo Clinic - Scottsdale, Scottsdale, Arizona, United States

A 23 year-old Native American man presented for evaluation of extensive right facial swelling, which had progressed slowly over the last 2 years. The patient attributed the initial swelling to minor trauma to the face, which occurred during an altercation. Over the last several months, the patient noticed recent ulceration of the right buccal mucosa, episodes of epistaxis from the right naris, and significant deformity of the nose and lips due to swelling. He lost 15 pounds over the previous month due to difficulty and pain while eating. Prior to his current evaluation, the patient had been seen by an outside otolaryngologist, dermatologist, and internist. Three biopsies with tissue cultures had been performed during the course of his illness without definitive diagnosis. The patient had been treated with isotretinoin, prednisone, and multiple courses of antibiotics without improvement prior to his evaluation. Physical exam revealed

significant swelling of the right face causing partial closure of the eye and deformity of the nose. Ulcerations were noted on the lower lip and right buccal mucosa MRI demonstrated right-sided facial soft tissue swelling and edema with right-sided lymphadenopathy. Review of the biopsy of the right buccal mucosa showed ulcerated mucosa with a dense, sheet-like infiltrate composed of small lymphocytes, atypical large mononuclear cells with mitoses, and plasma cells. Immunohistochemical stains revealed expression of CD56 and the cytotoxic markers (TIA-1 and granzyme B) in the atypical cell population, without expression of T-cell markers, CD30, or CD138. Epstein Barr virus RNA was detected in the atypical cells by in situ hybridization. Extranodal NK/T-cell lymphoma, nasal type (ENKTCL) is a rare Epstein-Barr virus-associated non-Hodgkin lymphoma. This tumor, previously referred to as lethal midline granuloma, most commonly affects the nasal cavity and upper aerodigestive tract but can also present in the skin and other organ systems. ENKTCL preferentially affects middle-aged males and is most prevalent in Asians and in the Native American populations of Central and South America. Even the United States, ENKTCL should be considered for a slowly growing facial mass, especially in patients of Asian or Native American descent. Unfortunately, prognosis is poor with a 5 year survival ranging from 40-45%.

Commercial Support: None Identified

P1802

CD4+/CD56+ hematodermic neoplasm: Case presentation and review of the literature

Jing Liu, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, United States; Anna K. Haemel, MD, Departments of Medicine and Dermatology; University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, United States; B. Jack Longley, MD, Department of Dermatology; University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, United States; Gary S. Wood, MD, Department of Dermatology; University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, United States

An 81 year old man presented with an asymptomatic violaceous nodule measuring 2 by 3 cm with a surrounding golden contusiform rim on the left deltoid. The duration of the lesion was unknown, and the patient denied systemic symptoms. Hematology survey and liver panels were within normal limits. CT chest showed a 5 by 2 cm right chest lesion not palpable on exam and a 1.7 cm splenic mass, both of which were felt to represent possible additional foci of disease. Skin biopsy showed a dense infiltrate of uniform medium sized mononuclear cells filling the papillary and reticular dermis with a Grenz zone. There was no epidermotropism, necrosis, or angioinvasion. Immunostains were positive for CD4, CD56, CD43, CD31, and CD45 and negative for CD2, CD3, CD5, CD7, CD8, TIA-1, CD20, PAX-5, Lysozyme, Myeloperoxidase, CD30, CD1a, CD68, and TdT, suggesting the diagnosis of CD4+/CD56+ hematodermic neoplasm. Bone marrow biopsy was within normal limits. CD4+/CD56+ hematodermic neoplasm, previously known as blastic NK-cell lymphoma, is a rare malignancy that was designated as a separate entity from the NK lymphomas in the 2005 WHO-EORTC classification. Recent advances in immunohistochemical staining have suggested that CD4+/CD56+ hematodermic neoplasm may be derived from a plasmacytoid dendritic cell precursor. This tumor can present with one or more cutaneous nodules, which may generalize with progression. The contusiform appearance in this case may be related to the expression of platelet endothelial adhesion molecule or CD31 by the tumor, possibly interfering with platelet or endothelial cell binding leading to hemorrhage. CD4+/CD56+ hematodermic neoplasm is an extremely aggressive tumor. About half the patients also have bone marrow or lymph node involvement at diagnosis, and some authors believe this is a form of aleukemic leukemia originating in the bone marrow and secondarily involving the skin. The median survival is 14 months and is minimally impacted by currently available therapies. This patient decided not to pursue further treatment and suffered a rapid decline over the next few months.

Commercial Support: None Identified

P1803**Regulatory T-cell phenotype in aggressive mycosis fungoides**

David Wada, MD, Mayo Clinic, Rochester, Minnesota, United States; Lawrence Gibson, MD, Mayo Clinic, Rochester, Minnesota, United States; Nneka Comfere, MD, Mayo Clinic, Rochester, Minnesota, United States; Ryan Wilcox, PhD, MD, Mayo Clinic, Rochester, Minnesota, United States

FOXP3 is regarded as the most reliable marker for regulatory T-cells (Tregs). Our group and others have previously demonstrated that the in vivo expression of FOXP3 by the neoplastic population in cutaneous T-cell lymphoma (CTCL), particularly mycosis fungoides, is highly uncommon. Limited numbers of positive cases have been reported in the literature, with the vast majority of cases represented by Sezary syndrome. We present a case of FOXP3+ CTCL clinically characterized by a relatively rapid evolution of plaques and subsequent tumor formation. The tumor cells were found to be positive for CD3, CD4, CD25, and FOXP3 by immunohistochemistry, a phenotype characteristic of Tregs. The patient was negative for HTLVIII. Previously reported cases of CTCL expressing Treg markers have also been associated with an aggressive clinical course, although cases with a clinical phenotype consistent with mycosis fungoides are highly unusual.

Commercial Support: None Identified

MELANOMA AND PIGMENTED LESIONS**P1900****The changes of nevi dimensions during and after pregnancy**

Alin Laurentiu Tatu, PhD, MD, University Dunarea de Jos-Faculty of Medicine -Galati, Galati, Romania

INTRODUCTION: Some nevi may change in aspect, shape, margins, colors and dimensions during pregnancy. We are seeing in pregnancy the darkening of some areas like linea nigra, mammal areolas and also some nevi. It is important to observe that some nevi could also change in size during pregnancy related to their location.

OBJECTIVES: To determine if there is a relationship between location and dimensions of nevi during pregnancy.

METHODS: Study design: It was a prospective comparative open labeled trial. I studied and compared from clinical and dermoscopic point of view the dimensions of two cohorts of nevi during pregnancy: one situated on distended cutaneous areas (abdominal, breasts) and the other on non distended cutaneous areas. During 8 years, I followed up 420 pregnant women with 1642 nevi in first, the third trimester and at six months after birth. I measured the nevi clinically and with the dermoscopic scale.

RESULTS. 1) From 357 nevi situated on distended areas 49 (13, 72%) were enlarged in diameter between first and the third trimester of pregnancy (2, 9% of all 1642 nevi). At six months postpartum 38 (77, 5%) of nevi are coming back in dimensions, 8 (16, 3%) are stable and 3 (6, 2%) are smaller than in the first trimester. 2) From 1285 nevi situated in areas without cutaneous distension just 28 (2, 18%) of nevi are enlarged between first and the third trimester (1,7% of all 1642 nevi). At six months postpartum 60,7% of those nevi are stable.

CONCLUSIONS: In pregnancy just a small number of nevi (4, 6%) are enlarged between first and the third trimester. When they are situated on distended areas a larger proportion of nevi (13, 72 %) are enlarged comparative to the nevi situated on non expanded skin areas (2, 18 %). The expanded skin could thin the deep of the nevus under the pressure of the nevocitic nests to the basal membrane. This phenomena may be partially reversible, 77, 5% of the nevi that enlarged between first and the third trimester decreased dimensions at six months postpartum.

Commercial Support: None Identified

P1901

Crown of thorns: A dermoscopic pattern of lichenoid keratosis

Christine Cole, MD, Mayo Clinic Arizona, Scottsdale, Arizona, United States; David Dicaudo, MD, Mayo Clinic Arizona, Scottsdale, Arizona, United States; David Swanson, MD, Mayo Clinic Arizona, Scottsdale, Arizona, United States

Lichenoid keratoses have been proposed to represent a regressive response to a variety of pre-existing epidermal proliferations, such as solar lentigines or seborrheic keratoses. Histologically, lichenoid keratoses may demonstrate marked lichenoid inflammation or an interface pattern with lymphocytes arrayed along the dermoepidermal junction, accompanied by melanin incontinence. It has been reported that melanoma in situ with lichenoid regression may histologically mimic a lichenoid keratosis. Therefore, it would be helpful to use additional tools, such as dermoscopy, to assist in distinguishing a benign lichenoid keratosis from a regressing melanoma. Dermoscopic patterns for lichenoid keratoses have been described most commonly as a localized granular pattern and a diffuse granular pattern, whereas on the face they may demonstrate a pseudoreticular pattern. This latter pattern can be indistinguishable from the pattern seen in lentigo maligna, in which short fine streaks are distributed asymmetrically around hair follicles prior to the formation of characteristic rhomboid structures. The pseudoreticular pattern has been reported in a lesion which histologically showed regression from a seborrheic keratosis to a lichenoid keratosis. We report a unique dermoscopic finding which we call crown of thorns observed in four cases of benign keratoses with lichenoid inflammation seen in separate patients. These lesions are from the right lateral arm of an 81-year-old man, the left lower back from a 72-year-old woman, the left forehead of a 66-year-old man, and the left posterior shoulder of an 89-year-old man and all clinically represented atypical pigmented macules. All four lesions reveal a series of peripheral black spikes resembling a crown of thorns around the perimeter. Histologically, two of these lesions represent seborrheic keratoses with lichenoid inflammation and two of these lesions represent benign lichenoid keratoses arising in association with lentigines. These four cases illustrate a specific dermoscopic pattern, which is not seen in melanocytic lesions, and which thereby may represent a distinguishing feature in clinically suspicious pigmented lesions. (This pattern has been seen in warts. Personal communication, Ash Marghoob.) However, for lesions of concern, a biopsy is necessary to confirm the diagnosis.

Commercial Support: None Identified

P1902

A puzzling pink papule: Amelanotic melanoma with reflectance confocal microscopy features of basal cell carcinoma

Larisa Speetzen, MD, Mayo Clinic Arizona, Scottsdale, Arizona, United States; David Swanson, MD, Mayo Clinic Arizona, Scottsdale, Arizona, United States

A 66-year-old man with a history of nonmelanoma skin cancer presented with a 1-cm, nonulcerated, pearly pink papule on the mid back consistent with a basal cell carcinoma. No pigmentation was noted. On dermoscopy, the lesion had blue grey nests and polymorphous blood vessels. The differential diagnosis for this pink lesion favored basal cell carcinoma, but included amelanotic melanoma, squamous cell carcinoma, and inflamed seborrheic keratosis. In vivo reflectance confocal microscopy (RCM) showed tumor islands and silhouettes, peritumoral dark clefts, cytologic streaming and dilated and tortuous blood vessels. The suspected diagnosis of basal cell carcinoma was supported by these confocal findings. Pathology showed malignant melanoma, no ulceration, no mitoses, at least 1.65 mm in depth. The histogenetic type was nodular, spindled and epithelioid. Radial and vertical growth phases were present. Immunostains were performed on paraffin sections. The tumor cells strongly expressed melan A and S100 and did not express cytokeratin AE1/AE3. These findings were consistent with malignant melanoma and excluded the diagnosis of basal cell carcinoma. RCM is a relatively new technique that can aid in the diagnosis and treatment of skin neoplasms. To date, the RCM features of melanoma and basal cell carcinoma are thought to be very different. RCM features of melanoma include atypical melanocytes with attenuated brightness, polymorphic and irregularly shaped cells with coarse branching dendritic processes, and atypical cells seen in several layers of the epidermis representing pagetoid spread. Melanoma also shows architectural disarray and unevenly distributed pigment. The typical honeycomb

pattern of keratinocyte cell borders is absent. Contrastingly, RCM features of basal cell carcinoma include dark silhouettes surrounded by dense stromal collagen, occasional bright tumor islands with peritumoral dark clefts, polarization of tumor nuclei along same axis, small bright cells, and dilated and tortuous blood vessels. Amelanotic melanomas are difficult to diagnose clinically due to their similarity to a variety of other benign and malignant skin neoplasms. Dermoscopic diagnostic algorithms for pigmented lesions cannot be applied to amelanotic melanoma, as many of the characteristic features (eg: pigment network) are absent. The presence of atypical vessels on dermoscopy may suggest a diagnosis of amelanotic melanoma but is not definitive. Previous case reports have reported that amelanotic melanoma can be more definitively recognized by RCM. RCM has also been previously described as a noninvasive method to make the diagnosis of amelanotic melanoma and in monitoring the response to imiquimod therapy for in situ residual disease. This case is unique in that it presents a pink lesion that had clinical, dermoscopic, and RCM features of basal cell carcinoma. Final pathology demonstrated invasive malignant melanoma. This has potentially far-reaching consequences as RCM is increasingly adopted into clinical practice and used as a tool in both diagnostic and treatment decisions. It may be that amelanotic melanoma has a different confocal "signature", and that current definitions require revision.

Commercial Support: None Identified

P1903

X-linked inhibitor of apoptosis (XIAP) and XIAP-associated factor-1 (XAF1) expressions in human malignant melanoma

Sang-Seok Kim, MD, Dept. of Dermatology, Kangdong Sacred Heart Hospital, Hallym University, Seoul, South Korea; Chul Woo Kim, MD, Dept. of Dermatology, Kangdong Sacred Heart Hospital, Hallym University, Seoul, South Korea; Young Her, MD, Dept. of Dermatology, Kangdong Sacred Heart Hospital, Hallym University, Seoul, South Korea

The X-linked inhibitor of apoptosis (XIAP) belongs to the inhibitor of apoptosis protein (IAP) family, and the action of XIAP is inhibited by XIAP-associated factor-1 (XAF1). In the present study, XIAP and XAF1 protein expressions and their relationships to apoptosis were investigated respectively in malignant melanoma. We examined immunohistochemical expressions of XIAP and XAF1, and the number of apoptotic epidermal melanocytes by terminal deoxynucleotidyl transferase-mediated dUTP-biotin nick end labeling (TUNNEL) assay in surgically resected tissues of 27 primary malignant melanomas and 9 intradermal nevi. Our result showed that XIAP expression in melanoma tissues was significantly increased compared with in intradermal nevi. And XAF1 was opposed to that. An XIAP and XAF1 expressions showed significant positive correlation each other. In TUNNEL staining, the intensity of XIAP and XAF1 staining were not correlated with number of apoptotic cells. Other clinicopathologic characteristics including age, gender, tumor thickness also showed no significant relationship with XIAP and XAF1 staining. Further study is required to examine whether or not Smac/DIABLO as well as XIAP and XAF1 expression could be clinically useful marker for the predication of survival. In addition, quantitative analysis techniques with large samples are needed to predict the accurate outcome of malignant melanoma.

Commercial Support: None Identified

P1904

Balloon cell malignant melanoma

Jose Aneiros-Fernandez, MD, San Cecilio Hospital (Department of Pathology), Granada, Spain; Francisco O`Valle, PhD, MD, San Cecilio Hospital (Department of Pathology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, MD, San Cecilio Hospital (Department of Pathology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: There are wide variations in the architecture, cytomorphology and stromal components of cutaneous malignant melanoma.

CASE REPORT: A 58-year-old-man was referred with a two-month history of a pruritic lesion on abdomen. Physical examination showed a raised, non-ulcerated tumor of 1.2 x 1.3 cm with irregular limits and homogeneous pigmentation. Digital dermoscopy showed a multicomponent pattern with central pigmented spot. The microscopic findings revealed malignant melanoma with clear cells.

DISCUSSION: Balloon cell melanoma is a histologic variant composed predominantly or entirely of large cells with abundant, vacuolated cytoplasm. It shares the cytologic features of the other subcategories of malignant melanoma, such as discohesion, nuclear pleomorphism and intranuclear cytoplasmic pseudoinclusions, but generally lacks melanin pigment and, as the name would suggest, is characterized by the presence of numerous cytoplasmic vacuoles.

Commercial Support: 100 % DAKO DIAGNOSTICOS SA.

P1905

Regression of spitz nevus

Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Husein Husein-ElAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, PhD, Department of Pathology, Granada, Spain; Maria Antonia Fernandez Pugnaire, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

INTRODUCTION: The Spitz nevus with intense inflammatory reaction is an uncommon condition that leads to misdiagnosis with melanoma.

CASE REPORT: A 16 years old male without a history of interest in consultation lesion in the right leg of months of development, was seen in the emergency department with a diagnosis of angiokeratoma. It features a raised lesion with dark red-black well-defined edge and discreetly pigmented 0.8 cm in diameter located in the back of the right leg, soft to the touch. With clinical diagnosis of hemangioma vs. angiokeratoma excision biopsy is decided. The histopathological study shows a symmetrical and well circumscribed lesion. The epidermis shows hyperplasia pseudoepiteliomatous with nests of melanocytes located epithelioid comprehensive look at the dermo epidermal deep nests are smaller and conclude isolated cellular elements which extend into the reticular dermis. Tumor cells show eosinophilic cytoplasm with large and voluminous nucleus with nucleolus, with no evidence of mitotic activity. The stroma shows intense inflammatory infiltrate separating and isolating the tumor nests. Immunohistochemistry shows positivity for Melan A, CD117, and more focally for HMB-45. The proliferative activity assessed by Ki-67 is low (<5%). The inflammatory component correspond mostly to T8 lymphocytes (CD8 +) and less frequently to T4 lymphocytes (CD4 +) and B cells (CD 20 +). The CD 34 has abundant vascular structures.

DISCUSSION: - Halo Nevus Spitz with changes are rare and pose a clinical differential diagnosis with melanoma and atypical nevi (38%) cases. Our case was diagnosed clinically angiomatous process would be justified by the abundance of vascular structures in the tumor stroma. - In 11% of the spitz nevus with intense inflammatory reaction present clinically halo reaction, that could be detected better with Wood's light. - The presence of intense inflammatory reaction spitz nevus could be related to phenomena of regression

Commercial Support: None Identified

NON-MELANOMA SKIN CANCER

P2000

Two 'near synchronous' cutaneous neuroendocrine (Merkel cell) carcinomas at distant cutaneous sites: A second primary or a single cutaneous metastatic lesion?

Iris Ahronowitz, Department of Dermatology, University of California San Francisco, San Francisco, California, United States; Boris Bastian, MD, Department of Dermatology and UCSF Helen Diller Family Comprehensive Cancer Center, University of California San Francisco, San Francisco, California, United States; Siegrid Yu, MD, Department of Dermatology, University of California San Francisco, San Francisco, California, United States; Timothy McCalmont, MD, Departments of Dermatology and Pathology, University of California San Francisco, San Francisco, California, United States

Merkel cell carcinoma (MCC) is an aggressive neuroendocrine carcinoma of the skin with a higher mortality rate than melanoma, whose incidence has nearly tripled over the past two decades due to a growing at risk population from advanced age, extensive ultraviolet exposure, and immunosuppression. Disease progression usually occurs via lymphatic spread to regional lymphatic draining basins, followed by distant metastatic sites. Although the rare occurrence of a second primary MCC has been reported, confirmatory genetic analysis usually was not utilized to verify this phenomenon. We report the clinical course, histopathology, and genetic analysis of a 69-year old woman with rapid hematogenous spread of neuroendocrine carcinoma of the skin, manifesting as a single metastatic lesion to a distant cutaneous site. Given the near-synchronous appearance of her right cheek and left leg nodules, the initial impression was of two distinct primary tumors. The microscopical appearance of both lesions was typical of neuroendocrine carcinoma, consisting of coalescing collections of compact cells with hyperchromatic nuclei and scant cytoplasm. There was "dot" positive expression of both CK20 and neurofilament, as is commonplace in cutaneous neuroendocrine (Merkel cell) carcinoma. Array comparative genomic hybridization (CGH) identified identical distal amplification of the short arm of chromosome 12, and loss of chromosomes 8p and 17p, effectively ruling out the possibility of independent primary tumors. We propose that this most likely represents a primary cheek MCC with rapid, isolated cutaneous metastasis to the contralateral ankle via hematogenous spread. Although it is possible that these two cutaneous lesions could represent metastasis from an occult primary tumor, we find this scenario unlikely given the consistently negative comprehensive imaging studies on 22 months of follow-up (the great majority of regional and distant metastases in MCC appear within 2 years of diagnosis). The distinction between a second primary MCC versus a distant cutaneous metastasis clearly has important implications with regard to staging, treatment, and prognosis. To our knowledge, this represents the first report of the use of CGH to clarify the relationship of multiple synchronous cutaneous MCCs and the first report of a single distant cutaneous focus of hematogenous spread. Our data calls into question prior reports alleging multiple cutaneous primaries of this very rare tumor.

Commercial Support: None Identified

P2001

Age adjusted incidence and histological types of actinic keratosis in Qatar

Amina Alobaidaly, HMC, Doha, Qatar; Hassan Riad, HMC, Doha, Qatar

Abstract Background: Actinic Keratoses are proliferations of transformed neoplastic keratinocytes confined to the epidermis induced by cumulative exposure to sunlight probably to UV spectrum. Mostly on exposed part of the body, Actinic Keratosis quantifies as in-situ malignant neoplasm.

Objective: The aim of the study is to calculate the age adjusted incidence of Actinic Keratosis and to study the different histological types from collected skin biopsies of the new patient in Qatar 2003. Epidemiological studies from Gulf region are sluggish. We are first reporting the incidence of the condition in Qatar.

Patient & methods: The study was done in the Dermatology OPD of Hamad Medical Corporation; the major hospital in Doha. All patients with Actinic Keratoses in the year 2003 from January 2003 to December 2003 were registered. Patients enrolled in this study were newly diagnosed as Actinic Keratosis on the basis of clinical and pathological correlation. Descriptive statistics was done using Statistical Package for Social Sciences SPSS version 14. The crude incidence equals the number of

patients with Actinic Keratosis in Qatar divided by total number of population in Qatar in 2003. Age adjusted incidence equals the crude incidence multiplied by population weight.

Results: Out of 19,000 patients, 16 patients were diagnosed as Actinic Keratosis. The calculated crude incidence was 1.95 per 100,000 per year. The age adjusted incidence was 3.29 per 100,000 per year. In conclusion, we concluded that the incidence of Actinic Keratosis is quite low in Qatar compared to reports from other regions. We need to continue reporting and registering patients with Actinic Keratosis and to update calculation for incidence. We recommend that it would be prudent for physicians to have a lower threshold to biopsy suspected lesions rather than repeatedly treating them with liquid nitrogen or other method.

Commercial Support: None Identified

P2002

Skin cancer in African Americans and Hispanics

Wayne A. I. Frederick, MD, Howard University College of Medicine, Washington, District of Columbia, United States; Leybelis Padilla, Howard University College of Medicine, Washington, District of Columbia, United States; Rebat M. Halder, MD, Howard University College of Medicine, Washington, District of Columbia, United States; Stephanie R. Downing, MD, Howard University College of Medicine, Washington, District of Columbia, United States

Background: Despite skin cancer's increasing incidence amongst African-American (AA) and Hispanic populations, limited descriptive literature exists.

Objective: To accurately describe the presentation, management, and survival of AA and Hispanic skin cancer patients at Howard University Hospital and compare using the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) registry.

Methods: Howard University's Cancer Center Registry (HUCCR) was queried for AA and Hispanic patients diagnosed with squamous cell carcinoma (SCC), basal cell carcinoma (BCC) and malignant melanoma from 1956 to March 2009. Patients from the SEER registry were selected to match our demographics and compared with the HUCCR for differences in survival, age at diagnosis, staging, ethnicity, and management.

Results: Of the total 101 patients from the HUCCR, 94% were AAs and 6% were Hispanics. The most frequently presenting skin cancer was BCC comprising 49% of all cases. All melanomas found in the AA population presented on non sun-exposed skin, and 83% of Hispanics presented with BCC on the face. SCC lesions tended to be smaller in females than in males ($p < 0.05$). The mean size was 5.7 cm in males and 2.3 cm in females. Out of the 1,359 SEER melanoma cases, 73% occurred on non sun-exposed skin. Interestingly, SEER cases were diagnosed at a younger age than Howard ($p < 0.05$), 55 years old versus 64 years old respectively. Limitations: The small study population and limited available staging and pathology data.

Conclusions: BCC is the most prevalent type of skin cancer in African American patients in the Howard University Hospital population, contrary to accepted epidemiology. BCC was also the most prevalent skin cancer in the observed Hispanic population. Possible reasons for the differences in presentation may be a wide spectrum of melanin content and rising genetic diversity of mixed race individuals, making strict racial classifications less reliable. Based on the findings in this study, we believe that a genetic classification system for patients is becoming increasingly necessary.

Commercial Support: None Identified

P2003

Preventing ultraviolet light scalp injury: Scalp cancer awareness and protective behaviors

Douglas Heiner, University of Texas Medical Branch, Galveston, Texas, United States; Donnie Warren, University of Texas Medical Branch, Galveston, Texas, United States; Richard Wagner, MD, University of

Texas Medical Branch, Galveston, Texas, United States; Tatsuo Uchida, MS, University of Texas Medical Branch, Galveston, Texas, United States

Background: Ultraviolet light (UVL) exposure is a known risk factor for developing skin cancer. However, while UVL is a major risk factor for scalp cancer, the types of protective measures taken to avoid UVL scalp damage remains less studied.

Objective: Evaluation of the impact of hair loss and other factors on UVL protective behaviors and the development of cutaneous cancer of the scalp.

Methods: A cross-sectional survey was designed to compare the awareness and protective behaviors of beachgoers in regards to skin and scalp cancer in an environment with high natural UVL exposure. Data were collected about subjects' age, gender, Fitzpatrick skin type (FST), hair loss, UVL skin and scalp protection behaviors, and baseline knowledge about the causes of skin and scalp cancer.

Results: A total of 248 questionnaires were completed and analyzed. These questionnaires included data from 153 (62%) participants with no reported hair loss and 95 (38%) participants with self-reported hair loss. When scalp protection was compared with skin protection there was a significant difference ($p < .001$) in rates of UVL skin protection (50%) and UVL scalp protection (16%). There also exists significant association ($p < 0.0001$) between hair loss and sun protection factor (SPF) use on the scalp. That is, subjects with mild hair loss (2A to 3V on questionnaire) are more likely and subjects with advanced hair loss (4 or greater on questionnaire) are even more likely to use sunscreen on their scalp than those who do not have hair loss (21% and 38%, respectively, vs. 7%). Significant association ($p = 0.0008$) also exists between hair loss and hat use, as well as significant association ($p = 0.0035$) between visibility of scalp and hat use. Sixty-eight percent of 248 survey respondents scored high (two correct answers) for awareness of UVL damage to skin. However, only 48% of 248 respondents scored high for awareness of the influence of UVL on hair loss/scalp damage. A high degree of awareness of UVL damage to skin is more likely than a high degree of awareness of the influence of UVL on hair loss and scalp damage ($p < 0.0001$).

Conclusion: This study demonstrates a low rate of SPF scalp (16%) protection. In addition, this study shows that subjects become increasingly likely to use sunscreen or a hat on their scalp as they lose more hair. However, even with advanced hair loss, only 38% of subjects used SPF on their scalp. More public education focused on UVL scalp protection is needed.

Commercial Support: None Identified

PHOTOBIOLOGY, PHOTOTHERAPY AND PHOTOSENSITIVITY DISEASES

P2100

Extensive pigmented purpuric dermatoses treated with phototherapy

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Maria Antonia Fernandez-Pugnaire, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain

Introduction: Pigmented purpuric dermatoses are a group of dermatoses of unknown etiology characterized by not palpable purpuric and petechial lesions distributed primarily in the lower limbs. We present a patient with very extensive lesions resistant to multiple therapies, who responded favorably to narrowband UVB radiation.

Case report: A 27-yr-old women, without relevant medical history, presented with purpuric lesions of 3 years of evolution. The lesions started on the legs and then spread to trunk and upper limbs causing a significant cosmetic problem. Blood count, basic biochemistry, ANA and ESR were normal. After testing multiple oral and topical treatments, we decided to start phototherapy with UVB narrow-band starting dose of 200 mJ / day 3 times weekly which was increased progressively. There was a significant improvement after six months of initiating treatment.

Discussion: The pigmented purpuric dermatoses are classified into 5 entities that are considered within the same spectrum with a similar histopathology: purpuric progressive pigmentary dermatosis (Schamberg's disease), annular and telangiectoid purpuric disease (Majocchi disease), lichen aureus, pigmentary and purpuric lichenoid dermatosis of Gougerot-Blum and eczematid like-purple Doucas and Kapetanakis. While there are many alternative therapies (corticosteroids, antihistamines, pentoxifylline, vitamin C ...) the results are unsatisfactory and the course of the disease becomes chronic and recurrent. Phototherapy (PUVA and narrow-band UVB) has been used successfully in some cases as in the case presented with significant clinical and quality of life improvement.

Commercial Support: None Identified

P2101

Comparative study of the efficacy of antioxidant formulations in the protection against UV-induced DNA damage

Jean-Philippe Therrien, PhD, Stiefel, a GSK company, Palo Alto, California, United States; Edward Hsia, PhD, Stiefel, a GSK company, Palo Alto, California, United States; Elizabeth Millerman, Stiefel, a GSK company, Palo Alto, California, United States; Hans Hofland, PhD, Stiefel, a GSK company, Palo Alto, California, United States

Antioxidants scavenge reactive oxygen species generated by endogenous oxidative stress or ultraviolet (UV) exposure, and are thought to prevent photo-aging. CoffeeBerry® extract (CBE) is derived from the fruit of the coffee plant, *Coffea arabica*, and contains potent polyphenols, such as chlorogenic acid, condensed proanthocyanidins, quinic acid, caffeic acid and ferulic acid. Other commercially available antioxidants include vitamin C, idebenone, coenzyme Q10, kinetin, zeatin, phloretin, α -tocopherol, and ferulic acid. The purpose of this study was to assess the photoprotective effects of antioxidant-containing formulations using reconstructed human epidermis (RHE) cultures. In comparison to other antioxidant activity assays such as the oxygen radical absorbance capacity assay, the RHE model is a more accurate representation of in vivo conditions, i.e. antioxidant activity in human skin upon acute UV exposure. Formulations containing either CBE, vitamin C, idebenone, coenzyme Q10, kinetin + zeatin, phloretin, or α -tocopherol + ferulic acid were applied topically to RHE cultures in triplicate 1 hour before exposure to 150 mJ/cm² UV type B (UVB). Cultures were harvested at 2 hrs post-UVB and evaluated by histology and gene expression for changes in skin morphology, DNA damage, and pro-inflammatory cytokine induction. Disruption of skin integrity was observed only in cultures treated with ferulic- and phloretin-containing formulations, whereas skin morphology in all other groups was normal. Levels of 8-hydroxy-2-deoxyguanosine, a marker of oxidative DNA damage, was lower in all groups when compared to untreated control, but non-specific cytoplasmic staining was observed in cultures treated with CBE- and idebenone-containing formulations. The highly mutagenic DNA damage cyclobutane pyrimidine dimer (CPD) was detected in all groups, with the exception of those treated with CBE- and phloretin-containing formulations. Gene expression analysis by real-time quantitative PCR showed that the CBE formulation prevented UVB-induced upregulation of TNF- α , suggesting that CBE has anti-inflammatory properties. In conclusion, a formulation containing CBE was found to have the most complete photoprotective properties: including preservation of skin integrity, reduction of oxidative DNA damage, and prevention of UVB-induced CPD formation and inflammation.

Commercial Support: None Identified

P2102

Examining dermatophyte inactivation by aminolevulinic acid (ALA)

Sonya Kenkare, University of Chicago Medical Center, Chicago, Illinois, United States; Bernhard Ortel, MD, University of Chicago Medical Center, Chicago, Illinois, United States; Keyoumars Soltani, MD,

University of Chicago Medical Center, Chicago, Illinois, United States; Lawrence Chan, MD, University of Illinois at Chicago Medical Center, Chicago, Illinois, United States

The management of onychomycosis can be frustrating and there is a need for additional treatment options. Pilot studies have indicated that (1) dermatophytes form porphyrins when exposed to ALA (Kamp et al.) and (2) onychomycosis may be treatable by ALA PDT (Piraccini et al., Donnelly et al.) However, at present we know little about ALA induced protoporphyrin IX formation in dermatophytes. A better understanding of these processes may lead to improved photosensitizing protocols and potentially a viable clinical treatment strategy. While optimal conditions for porphyrin formation are being established we aim to quantify porphyrin formation and perform photosensitization experiments using red light exposure. While optimal conditions for porphyrin formation are being established we aim to quantify porphyrin formation and perform photosensitization experiments using red light exposure. In our pilot study we exposed *T. rubrum*, the most common causative agent in onychomycosis, in vitro to ALA. Porphyrin formation was studied qualitatively by Woods' lamp and fluorescence microscopy. Fluorescence was observed following three hour incubation with 2% and 20% ALA. After ALA incubation and 30 minutes of light exposure 20-30% dermatophyte inhibition of growth and 15-20% dermatophyte inactivation of previously recorded cultures were noted. Preliminary data suggests that ALA may inhibit and possibly also inactivate dermatophytes.

Commercial Support: None Identified

PIGMENTARY DISORDERS AND VITILIGO

P2200

Skin brightening cream with hydroquinone free complex

Michael Gold, MD, Gold Skin Care Center, Tennessee Clinical Research Center, Nashville, Tennessee, United States; Julie Biron, Tennessee Clinical Research Center, Nashville, Tennessee, United States

Melanogenesis is the result of a cascade of events and processes involving (1) transport of melanin precursors phenylalanine and tyrosine into melanocyte and melanosome, (2) enzymatic transformation of tyrosine to dopamine, dopaquinone and later melanin by tyrosinase, which is enhanced after sun exposure via α -MSH, (3) melanosome maturation, and (4) melanosome transfer from melanocyte to keratinocyte. Currently, hydroquinone at prescription strength is considered the gold standard for effective skin whitening. Since hydroquinone's safety continues to be debated and the FDA aims to ban hydroquinone without NDA, alternatives to hydroquinone are researched. Kojic acid or the hydroquinone derivative arbutin seem little promising due to low efficacy and safety concerns. Whereas most alternatives focus only on the inhibition of tyrosinase, this study describes a novel skin brightening complex comprising four actives inhibiting several key processes involved in melanogenesis. The complex consists of leucine, disodium glycerophosphate, phenylethyl resorcinol and undecylenoyl phenylalanine. Leucine competes with tyrosine transport into melanocyte and melanosome what may limit availability of tyrosine needed for melanin formation. Disodium glycerophosphate binds calcium and therefore potentially influences calcium dependent processes in melanogenesis including phenylalanine uptake into melanosomes, and melanosome transfer. Unlike hydroquinone, phenylethyl resorcinol strongly inhibit tyrosinase (i.e., about 10-times more efficiently than kojic acid) without any significant melanocytotoxicity. In addition, in vitro data indicates that undecylenoyl phenylalanine acts as an antagonist of α -MSH. Safety and efficacy of an oil-in-water emulsion containing the skin brightening complex (provided by Neocutis, San Francisco) was studied in ten females with mild to moderate facial melasma. The subjects applied the cream twice daily in conjunction with a SPF30+ sunscreen during day time for 12 weeks after a one month wash-out period with the sunscreen. Efficacy was assessed by photography, investigator global assessment, MASI and age spot count and intensity evaluation. MASI score significantly decreased from 5.2 ± 1.4 to 2.1 ± 1.1 after the treatment period. Total number of age spots significantly decreased from 19 ± 16 to 9 ± 9 . As judged from the wash-out period, the sunscreen affected severity of melasma and age spots insignificantly. The cream was well tolerated.

Commercial Support: 100% sponsored by Neocutis

PSORIASIS AND OTHER PAPULOSQUAMOUS DISORDERS

P2300

Finding the optimal PASI association with physician- and patient-reported outcomes

Girish Aras, PhD, Amgen Inc., Thousand Oaks, California, United States; Gregory Kricorian, MD, Amgen Inc., Thousand Oaks, California, United States; Juan Li, PhD, Amgen Inc., Thousand Oaks, California, United States; Paul Klekotka, PhD, MD, Amgen Inc., Thousand Oaks, California, United States

Background: To investigate the association between the Psoriasis Area and Severity Index (PASI) score and clinical outcomes, we identified the percentage improvements in PASI that were most accurately associated with the static Physician Global Assessment (sPGA), the Subject Global Assessment (SGA), and the Dermatology Life Quality Index (DLQI).

Methods: A total of 1737 patients were studied from 3 randomized, phase 3, placebo-controlled etanercept trials using etanercept 25 mg twice weekly (BIW), 25 mg once weekly, 50 mg BIW, or placebo. Week 12 data (observed cases) were analyzed. For sPGA, patients were grouped according to scores of clear (0), clear/almost clear (0/1), or mild to severe (2–5). For SGA, patients were grouped according to scores of zero (0), 0 or 1 (0/1), or 2–5. For DLQI, patients were grouped as responders (5-point improvement in total DLQI score or a total score of 0) vs non-responders. Receiver operating characteristic (ROC) curves were generated to identify the percentage PASI improvements matching the highest sensitivity and highest specificity for each outcome measure. For sPGA, a false positive rate would be the percentage of incorrectly predicted clear/almost clear patients out of all true clear/almost clear patients, using the percentage PASI improvement score as a cutoff. Similarly, a false negative rate would be the percentage of incorrectly predicted patients with sPGA mild to severe out of all true patients with sPGA mild to severe. The optimal percentage PASI improvement was identified by choosing the minimal overall inaccuracy, defined as the sum of the square of the false positive rate and false negative rate.

Results: Our findings indicate that a 65% PASI improvement was best associated with the sPGA clear/almost clear category (sensitivity [S]=90%; specificity [Sp]=86%); a 90% PASI improvement was best associated with the sPGA clear category (S=94%; Sp=92%). For SGA, a 61% PASI improvement was best associated with the SGA category of zero (0) or 1 (S=80%; Sp=85%); a 77% PASI improvement was best associated with the SGA category of zero (0) (S=87%; Sp=80%). For DLQI, a 42% PASI improvement was best associated with achieving responder status (S=75%; Sp=74%).

Conclusion: A 65% improvement in PASI was best associated with a sPGA clear/almost clear response. Patient satisfaction as measured by SGA 0/1 and DLQI responder status was reported at lower percentage improvements in PASI scores.

Commercial Support: Research funded by Immunex Corporation, a wholly owned subsidiary of Amgen Inc.

P2301

Safety update from OBSERVE-5, a long-term safety surveillance registry of etanercept therapy for psoriasis

Alexa Kimball, MD, Massachusetts General Hospital, Boston, Massachusetts, United States; David Pariser, MD, Eastern Virginia Medical School and Virginia Clinical Research, Inc., Norfolk, Virginia, United States; Gregory Kricorian, MD, Amgen Inc., Thousand Oaks, California, United States; Joel Gelfand, MD, University of Pennsylvania Health System, Philadelphia, Pennsylvania, United States

Background: OBSERVE-5 is a phase 4, prospective, multicenter, 5-year observational registry to collect and evaluate safety data from the real-world use of etanercept (ETN) for psoriasis (PsO) as part of an FDA post-marketing commitment.

Methods: The study includes 2500 patients with plaque PsO for whom ETN is indicated, per prescribing information. Patients initiate (or re-initiate) ETN at baseline (BL); interim visits must occur at least twice yearly thereafter. Patients are followed for up to 5 years, and may discontinue ETN at any time or use other anti-psoriatic therapy. Serious adverse events (SAEs), including serious infectious events (SIEs) are being collected. Efficacy outcomes include Dermatology Life Quality Index (DLQI), percent Body Surface Area (BSA) affected by PsO, and Patient Global Assessment (PtGA).

Results: As of March 2009, 2513 patients have been enrolled and 2512 patients received at least 1 dose of ETN; 48% (n=1194) were female, 82% (n=2054) were white/Caucasian, and mean age (SD) was 46.3 (13.6) years. Mean (SD) disease duration at BL was 15.7 (12.7) years. Among patients who received at least one dose of ETN, 409 (16.3%) discontinued from the study. Most frequent reasons for discontinuation were withdrawal of consent (n=176, 7.0%), ineligibility (n=63, 2.5%), and lost to follow-up (n=53, 2.1%). The most common comorbidities in the study population were arterial hypertension (27.5%), psoriatic arthritis (18.0%), and hypercholesterolemia/hyperlipidemia (17.2%). SAEs and SIEs were reported in 171 and 53 subjects, respectively. Pneumonia (n=13, 0.5%) and cellulitis (n=10, 0.4%) were the most common SIEs. Malignant events were reported in 47 subjects (1.9%) with basal cell carcinoma (n=17, 0.7%) and squamous cell carcinoma of skin (n=12, 0.5%) being the most common. Improvements in mean DLQI scores from BL (10.76, n=2449) were observed at 6, 12, and 18 months (mo) (4.41, n=2037; 4.27, n=1778; 4.21, n=1230). Similar improvements were also observed in percent BSA affected by PsO (21.12% at BL, n=2492; 8.21% at 6 mo, n=2085, 7.74% at 12 mo, n=1812, 6.88% at 18 mo, n=1249). The proportion of subjects reporting a PtGA score of 0/1 at 6, 12, and 18 mo was 20.5%/28.7% (n=2039), 21.6%/29.6% (n=1779), and 21.9%/28.2% (n=1229).

Conclusion: Accumulating safety data from the ongoing OBSERVE-5 registry will complement safety data from randomized, controlled trials of ETN in patients with moderate to severe plaque PsO.

Commercial Support: Amgen Inc.

P2302

Cost-effectiveness of continuous adalimumab vs. continuous or intermittent etanercept for the treatment of psoriasis

James Signorovitch, Analysis Group, Inc., Boston, Massachusetts, United States; Parvez Mulani, Abbott Laboratories, Abbott Park, Illinois, United States; Shiraz Gupta, Abbott Laboratories, Abbott Park, Illinois, United States; Yanjun Bao, Abbott Laboratories, Abbott Park, Illinois, United States

Objectives: Compare the cost-effectiveness of continuous adalimumab (ADA) vs. continuous or intermittent etanercept (ETN) for 1 year of treatment of moderate to severe psoriasis from the United States payer perspective.

Methods: Data reporting drug usage, utility outcomes, and the Physician's Global Assessment (PGA) of psoriasis severity were obtained from the REVEAL and CRYSTEL trials of moderate to severe plaque psoriasis. In REVEAL, a 52-week trial with a 24-week open-label extension (M03-658), patients were treated with ADA 80 mg at Week 0 and ADA 40 mg at Week 1 and every other week thereafter for up to 52 weeks; non-responders withdrawing from REVEAL were followed into open-label treatment with ADA (M03-658). In CRYSTEL, patients were randomized to 54 weeks of open-label ETN continuously (25 mg twice weekly [BIW]) or intermittently (50 mg BIW to Week 12, followed by 25 mg BIW that was paused after achieving a PGA score ≤ 2 and restarted if PGA was ≥ 3). To adjust for differences between trial populations, data from ADA-treated patients were reweighted so that mean baseline characteristics matched those of ETN-treated patients in age, weight, disease duration, Psoriasis Area and Severity Index score, Dermatology Life Quality Index score, PGA, and prior systemic therapy. Hospitalization risk was linked to percentage of nonresponders during follow-up via a literature review, and outpatient visit frequencies were estimated from treatment protocols. Service costs were obtained from the Nationwide Inpatient Sample. Drug costs (40 mg ADA, \$762; 50 mg ETN, \$388) were obtained from the 2009 Red Book and were prorated per mg to account for intermittent use or dose escalation. A 1-year treatment period was studied.

Results: Continuous ADA was associated with the greatest average utility gain per patient compared to continuous or intermittent ETN (0.22 vs. 0.17 or 0.13, both $p < 0.01$) and with the lowest total costs per

patient (including drug, inpatient, and outpatient costs: \$23,205 vs. \$25,504 or \$24,903, both $p < 0.01$). Continuous ADA was also associated with the greatest average number of days per patient with PGA ≤ 1 compared to continuous or intermittent ETN (210 vs. 145 or 69 days, both $p < 0.01$), and annual drug costs per patient were \$18,887, \$19,503 and \$16,695, respectively.

Conclusions: Continuous ADA treatment was dominant over continuous or intermittent ETN, with lowest total costs and greatest gains in utility.

Commercial Support: This study was funded by Abbott Laboratories.

P2303

Effect of baseline characteristics on the efficacy of ABT-874 for the treatment of moderate to severe psoriasis

Richard Langley, Dalhousie University, Halifax, Canada; Alan Menter, Baylor Research Institute, Dallas, Texas, United States; Alexa Kimball, Mass General Hospital, Boston, Massachusetts, United States; Joaquin Valdes, Abbott Laboratories, Abbott Park, Illinois, United States

Aim: Explore how baseline characteristics of moderate to severe psoriasis patients impact the efficacy of ABT-874, an interleukin-12/23 monoclonal antibody.

Methods: 12-week, randomized, double-blind, placebo-controlled, multi-center study (NCT00292396).

180 adult patients with psoriasis affecting $\geq 10\%$ body surface area and a Psoriasis Area and Severity Index (PASI) score ≥ 12 were randomized to: one 200-mg dose ABT-874 at Week 0, 100 mg ABT-874 every other week (eow) for 12 weeks, 200 mg ABT-874 weekly for 4 weeks, 200 mg ABT-874 eow for 12 weeks, 200 mg ABT-874 weekly for 12 weeks, or placebo. We examined the effects of the following baseline characteristics on week 12 PASI 75 response rates: weight, PsA history, PASI score, previous psoriasis treatments and PGA score (severe/very severe). PGA score was a post-hoc analysis. Results are presented for all ABT-874 dosage groups combined following 12 weeks of treatment.

Results: At week 12, the percentage of patients achieving PASI 75 in the ≤ 100 kg or > 100 kg groups was 71.7% vs. 73.3% respectively. PASI 75 responses for patients with and without previous PsA were 83.7% vs. 86.9% respectively. A majority of patients (85.5%) with a PGA score of severe or very severe at baseline achieved PASI 75. For patients with baseline PASI scores of ≤ 20 or > 20 , 87.0% vs. 84.0% achieved PASI 75 responses at week 12, respectively. In addition, prior psoriasis therapies such as systemic or biologic agents, topicals or phototherapy did not appear to effect PASI 75 response rates. Conclusions: A majority of patients receiving ABT-874 therapy for the treatment of moderate to severe psoriasis are able to achieve PASI 75, regardless of baseline weight, PGA and PASI scores, PsA history, or prior psoriasis treatment.

Commercial Support: This study was funded by Abbott Laboratories.

P2304

Effects of topical calcipotriol/betamethasone (C/B) on adalimumab efficacy for moderate to severe psoriasis — subanalysis of BELIEVE

Diamant Thaçi, Goethe University Frankfurt, Frankfurt, Germany; Eric Sasso, Abbott Laboratories, Abbott Park, Illinois, United States; Georg Stingl, University of Vienna, Vienna, Austria; Kristina Unnebrink, Abbott GmbH & Co. KG, Ludwigshafen, Germany

Aims: To elucidate results from BELIEVE, where adalimumab (ADA) plus C/B provided greater psoriasis improvement than ADA alone to Week 4, and less improvement from Weeks 8 to 16.

Methods: In BELIEVE, a 16-week phase IIIb study, patients with moderate to severe psoriasis and failure/intolerance/contraindication for ≥ 2 systemic therapies (≥ 1 being CsA, MTX, or oral PUVA) received subcutaneous ADA (80 mg at Week 0, 40 mg biweekly Weeks 1–15) plus either: vehicle ointment (N=364) or C/B ointment (N=366), applied once daily for 4 weeks then PRN. ITT post hoc analyses

grouped patients by usage of topical therapy or pattern of clinical response. Missing values were imputed by NRI (categorical) or LOCF (continuous).

Results: ADA+C/B vs. ADA+vehicle PASI 75 response rates (%) were: 15/6 ($p<0.001$) and 41/32 ($p<0.05$) at Weeks 2 and 4; and 53/60 (NS), 58/73 ($p<0.001$) and 65/71 (NS) at Weeks 8, 12 and 16, respectively. Similar response profiles were observed for PASI 50, 90, and 100; PASI component scores; PGA responses; and PASI 75 responses among patients who used no C/B or any C/B after Week 4. Although relatively uncommon in both groups, loss of PASI 75 response after Week 4 was more frequent with ADA+C/B, whereas sustained PASI 75 responses starting after Week 4 were common overall, and were more frequent with ADA+vehicle. In contrast, while improvements in DLQI, pain, and pruritus were also greater at Week 4 for ADA+C/B vs. ADA+vehicle, they were similar thereafter.

Conclusions: ADA+C/B resulted in lower PASI response rates than ADA+vehicle from Weeks 8 to 16 in BELIEVE predominantly due to reduced onset, rather than loss, of efficacy. Nevertheless, improvements in patient-reported outcomes were similar between treatments from Weeks 8 to 16.

Commercial Support: This study was funded by Abbott Laboratories.

P2305

the effects of adalimumab on c-reactive protein in an open-label study of moderate to severe psoriasis following suboptimal responses to etanercept, methotrexate, or phototherapy

Bruce Strober, New York University School of Medicine, New York, New York, United States; Orin Goldblum, Abbott Laboratories, Abbott Park, Illinois, United States; Yihua Gu, Abbott Laboratories, Abbott Park, Illinois, United States; Yves Poulin, Centre Dermatologique du Québec Métropolitain, Québec City, Canada

Objective: To evaluate the effects of adalimumab on high sensitivity C-Reactive Protein (hs-CRP) concentrations in moderate to severe psoriasis patients with suboptimal responses to other systemic therapies.

Methods: Data were analyzed from a 16-week, multicenter, open-label, Phase IIIb trial that enrolled chronic plaque psoriasis patients with suboptimal responses to etanercept (ETN), methotrexate (MTX), or narrow-band ultraviolet B (NB-UVB) phototherapy. Patients discontinued therapy 2 weeks (ETN) or 1 week (MTX, NB-UVB) before initiating adalimumab (80 mg at week 0, then 40 mg every other week from week 1). The primary endpoint was the proportion of patients who achieved PGA of clear or minimal at Week 16. Concentrations of hs-CRP were determined at baseline and Weeks 4, 8 and, 16. Post-hoc analyses assessed hs-CRP for patients grouped by baseline history of psoriatic arthritis (PsA) and body-mass index (BMI). Results were analyzed overall and for each prior-therapy group.

Results: The study enrolled 152 patients (ETN, N=82; MTX, N=41; NB-UVB, N=29). At week 16, PGA of clear or minimal was achieved in 52.0% (95% CI: 43.7, 60.1) of all patients and 48.8% (37.6, 60.1), 61.0% (44.5, 75.8), and 48.3% (29.4, 67.5) in the ETN, MTX, and NB-UVB groups, respectively. At baseline, the mean hs-CRP concentrations for all/ETN/MTX/NB-UVB patients were 5.0/6.1/2.8/4.6 mg/L (n=142/77/38/27). Median hs-CRP changes from baseline to final value for all/ETN/MTX/NB-UVB patients were -0.3/-0.4/-0.3/-0.3 mg/L (n=142/77/38/27). Median changes in hs-CRP from baseline to final value for all/ETN/MTX/NB-UVB patients were -0.4/-0.5/-0.3/-2.3 mg/L (n=69/46/17/6) for those with PsA; and -0.3/-0.1/-0.3/-0.3 mg/L (n=73/31/21/21) for those without PsA. Median changes in hs-CRP from baseline to final value for all/ETN/MTX/NB-UVB patients were -0.1/-0.2/-0.1/-0.2 mg/L (n=18/8/5/5) for those with normal BMI, -0.3/-0.2/-0.5/-0.2 mg/L (n=49/21/18/10) for those overweight by BMI and -0.6/-0.5/-0.5/-1.3 mg/L (n=75/48/15/12) for those obese by BMI.

Conclusions: Transition to adalimumab reduced CRP concentrations for patients with suboptimal responses to systemic therapy. CRP reductions occurred regardless whether patients had PsA or were obese.

Commercial Support: This study was funded by Abbott Laboratories.

P2306

Patient reported assessment of psoriasis disease severity and affected body surface area before and after biologic treatment

Chureen Carter, PharmD, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Deborah Freedman, MBA, KantarHealth, New York, New York, United States; Marco DiBonaventura, PhD, KantarHealth, New York, New York, United States; Silas Martin, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States

Objective: To examine patient-reported assessments of psoriasis (PsO) severity and affected body surface area (BSA) after receiving biologic treatment (BIO).

Methods: Cross-sectional data were collected in the Psoriasis Patient Study Project conducted March–April 2009. Study participants were aged ≥ 18 yrs and self-reported a physician diagnosis of PsO.

Demographics, self-reported PsO severity (mild, moderate, severe), and BSA (1-2%-low, 3-10%-medium, or $>10\%$ -high) were assessed. Patients with either moderate/severe disease or BSA 3-10%/ $>10\%$ at the time of initial PsO diagnosis (baseline) were asked to assess PsO severity and BSA prior to taking BIO (pre-BIO) and after taking BIO (post-BIO) based on recall of their condition.

Results: A total of 127 patients diagnosed with PsO and using BIO completed the survey. There were 96 patients with baseline moderate PsO (n=68; 46% female; mean age=44 yrs) or severe PsO (n=28; 61% female; mean age=49 yrs). There were 98 patients with baseline BSA 3-10% (n=52; 42% female; mean age=43 yrs) or BSA $>10\%$ (n=46; 48% female; mean age=46 yrs). The distribution of PsO severity and affected BSA changed from the pre- to post-BIO time periods for each group (percentages may total >100 due to rounding). Baseline moderate PsO (pre-BIO: 6% mild, 69% moderate, 25% severe; post-BIO: 15% mild, 71% moderate, 15% severe). Baseline severe PsO (pre-BIO: 7% mild, 11% moderate, 82% severe; post-BIO: 25% mild, 36% moderate, 39% severe). Baseline BSA 3-10% (pre-BIO: 10% low BSA, 67% medium BSA, 23% high BSA; post-BIO: 29% low BSA, 62% medium BSA, 10% high BSA). Baseline BSA $>10\%$ (pre-BIO: 2% low BSA, 11% medium BSA, 87% high BSA; post-BIO: 11% low BSA, 41% medium BSA, 48% high BSA).

Conclusions: Based on patient recall of their disease, BIO appeared to have a positive impact on patient-reported PsO severity and BSA, most notably for patients who were severe or had BSA $>10\%$ when initially diagnosed. Due to the limitations of cross-sectional data, these findings need to be validated by longitudinal analyses. However, these findings highlight the plausible need for novel biologic treatment options that may yield greater impact on PsO disease severity and BSA.

Commercial Support: Centocor Ortho Biotech Services, LLC

P2307

Efficacy of treatment with ABT-874, an interleukin-12/23 monoclonal antibody, across body regions of patients with moderate to severe psoriasis

Alan Menter, Baylor Research Institute, Dallas, Texas, United States; Joaquin Valdes, Abbott Laboratories, Abbott Park, Illinois, United States; Kenneth Gordon, Northwestern University, Evanston, Illinois, United States; Richard Langley, Dalhousie University, Halifax, Canada

Aim: To examine the efficacy of ABT-874, an interleukin-12/23 monoclonal antibody, in 4 specific body regions (head and neck, upper and lower extremities and trunk) of patients with moderate to severe psoriasis.

Methods: 12-week, randomized, double-blind, placebo-controlled, multi-center study (NCT00292396). 180 adult patients with psoriasis affecting $\geq 10\%$ body surface area and a Psoriasis Area and Severity Index (PASI) score ≥ 12 were randomized to: one 200-mg dose ABT-874 at Week 0, 100 mg ABT-874 every other week (eow) for 12 weeks, 200 mg ABT-874 weekly for 4 weeks, 200 mg ABT-874 eow for 12 weeks, 200 mg ABT-874 weekly for 12 weeks, or placebo. The primary endpoint was \geq PASI 75 response by week 12. Individual PASI scores in the four body regions utilized for PASI evaluation were also assessed.

Results: The percentage of patients achieving \geq PASI 75 or \geq PASI 90 at Week 12 was greater for all ABT-874 dosage groups combined vs. the placebo group (86.0% vs. 3.3% and 43.9% vs. 0.0%,

respectively). For all ABT-874 dosage groups combined, a greater percentage of patients achieved $\geq 75\%$ and $\geq 90\%$ improvements in PASI scores as compared to placebo patients for all body regions examined: head and neck (PASI 75, 83.3% vs. 13.3%; PASI 90, 72.0% vs. 13.3%), upper extremities (PASI 75, 81.3% vs. 3.3%; PASI 90, 57.3% vs. 3.3%), trunk (PASI 75, 82.0% vs. 3.3%; PASI 90, 68.0% vs. 3.3%), lower extremities (PASI 75, 78.0% vs. 3.3%; PASI 90, 48.0% vs. 0.0%).

Conclusion: ABT-874 treatment resulted in clinically meaningful improvements in all four body regions comprising the PASI score, including traditionally resistant areas in patients with moderate to severe psoriasis, such as head and neck and lower extremities.

Commercial Support: This study was funded by Abbott Laboratories.

P2308

Efficacy and safety results from a phase III, randomized controlled trial comparing two dosing regimens of ABT-874 to placebo in patients with moderate to severe psoriasis

Kenneth Gordon, NorthShore University Health System, Evanston, Illinois, United States; Joaquin Valdes, Abbott Laboratories, Abbott Park, Illinois, United States; Richard Langley, Dalhousie University, Halifax, Canada; Yihua Gu, Abbott Laboratories, Abbott Park, Illinois, United States

Aims: To assess the efficacy and safety of 2 dosing regimens of the fully human interleukin 12/23 monoclonal antibody, ABT-874, compared to placebo in adult patients with moderate to severe chronic plaque psoriasis.

Methods: In a Phase III, 52-week, double-blind, placebo-controlled, two-phase (Induction and Maintenance) trial, patients were randomized 2:1 to receive ABT-874 (200 mg at Weeks 0 and 4, followed by 100 mg at Week 8) or placebo (Induction Phase). Patients achieving a PGA score of "clear" or "minimal" (PGA 0/1) at Week 12 were then re-randomized 2:2:1 to receive either ABT-874 100 mg every 4 weeks (q4 wk), 100 mg every 12 weeks (q12 wk), or placebo q4 wk up to Week 52 (Maintenance Phase). Primary efficacy endpoints were PGA 0/1 and PASI 75 at Week 12, and PGA 0/1 at Week 52, with analysis using nonresponder imputation (NRI). Safety was assessed throughout the study and up to 45 days following the last dose of study drug.

Results: 1,465 patients were randomized (ABT-874, N = 981; placebo, N = 484) in the Induction Phase. At Week 12, PGA 0/1 response rates were significantly higher with ABT-874 vs. placebo (76.0% [746/981] vs. 4.3% [21/484], respectively, $P < .001$); PASI 75 responses at week 12 were 80.7% (792/981) for ABT-874 vs. 4.5% (22/484) for placebo ($P < .001$). Of 981 patients randomized to ABT-874 at baseline, 745 patients with PGA 0/1 at Week 12 entered the Maintenance Phase and were re-randomized to ABT-874 100 mg q4 wk (N = 298), ABT-874 100 mg q12 wk (N = 298), or placebo q4 wk (ABT-874-to-placebo, N = 149). Percentages of patients maintaining PGA 0/1 at Week 52 were 79.2% (236/298) for ABT-874 q4 wk, 41.6% (124/298) for ABT-874 q12 wk, and 6.0% (9/149) for ABT-874 to-placebo ($P < .001$ between ABT-874 groups, and for each ABT-874 group vs. ABT-874-to-placebo). During the Induction Phase, more adverse events of infection and malignancy occurred in patients receiving ABT-874 vs. placebo (22.3% [219/981] vs. 19.8% [96/484] and 0.6% [6/981] vs. 0, respectively). A total of 7 major adverse cardiac events (MACE) occurred in patients treated with ABT-874 while none were observed in the placebo group.

Conclusions: ABT-874 treatment for moderate to severe psoriasis resulted in higher efficacy responses compared to placebo at week 12, with dosing every 4 weeks resulting in better maintenance of response than every 12 weeks up to week 52. A higher incidence of infection, malignancy and MACE events were observed in ABT-874 vs. placebo treated patients.

Commercial Support: This study was funded by Abbott Laboratories.

P2309

Adalimumab for treatment of moderate-to-severe chronic plaque psoriasis of the hands and/or feet: Efficacy and safety results from a placebo-controlled, double-blind study

Craig Leonardi, Central Dermatology, S. Louis, Missouri, United States; Alan Menter, Baylor Research Institute, Dallas, Texas, United States; Kristina Unnebrink, Abbott GmbH & Co. KG, Ludwigshafen, Germany; Wendell Valdecantos, Abbott Laboratories, Abbott Park, Illinois, United States

Aims: To determine the efficacy and safety of adalimumab compared with placebo in adults with chronic psoriasis involving hands and/or feet, and to examine sustainability of response.

Methods: A 16-week randomized, double-blind, placebo-controlled study of adalimumab in patients with chronic, moderate-to-severe plaque psoriasis involving the hands and/or feet (active: placebo allocation 2:1), followed by a 12-week, open-label extension (OLE) during which all patients received adalimumab. Adalimumab was administered 80 mg SC at Week 0, followed by 40 mg every other week at Week 1. Primary endpoint was percentage of patients achieving Physician's Global Assessment (PGA) of clear or almost clear at Week 16, analyzed with non-responder imputation.

Results: A total of 81 patients were enrolled: 72 patients (49 adalimumab:23 placebo) were analyzed (one center with 9 patients was excluded due to protocol violations). Baseline percentages of patients with PGA moderate: PGA severe were 75.5:24.5 and 73.9:26.1 for adalimumab and placebo groups, respectively. At Week 16, 30.6% of patients randomized to adalimumab and 4.3% of patients randomized to placebo achieved PGA of clear or almost clear (P=0.014). At Week 28, 80% of the PGA clear or almost clear response was maintained from Week 16 (24.5% for patients randomized to adalimumab). Adverse events in both groups were generally mild to moderate: nasopharyngitis (26.5% and 13.0% for adalimumab- and placebo-treated patients, respectively), was most frequently reported. One placebo-treated patient was diagnosed with breast cancer. During OLE, one patient had GI hemorrhage and one had congestive heart failure. **Conclusions:** Adalimumab is efficacious for treatment of chronic plaque psoriasis of the hands and/or feet, with efficacy largely maintained to 28 weeks. Safety profile is consistent with results from other adalimumab psoriasis clinical trials.

Commercial Support: This study was funded by Abbott Laboratories.

P2310

Serious infections in global clinical trials of adalimumab in moderate to severe psoriasis

Richard Langley, Dalhousie University, Halifax, Canada; Bruce Strober, New York University School of Medicine, New York, New York, United States; Stephen Rozzo, Abbott Laboratories, Abbott Park, Illinois, United States; Yihua Gu, Abbott Laboratories, Abbott Park, Illinois, United States

Aims: To examine serious infections occurring in all clinical trials of adalimumab in patients with moderate to severe psoriasis.

Methods: Cumulative treatment emergent adverse event (AE) data from all patients administered ≥ 1 dose of adalimumab in 11 global clinical trials in moderate to severe psoriasis were included in this analysis.

Two overlapping safety data sets were created by pooling all data collected through April 15, 2007 and through November 6, 2008, respectively. AE were described using MedDRA preferred terms.

Results: The 2007 and 2008 data sets included 1819 and 2197 patients with total adalimumab exposures of 2424.7 and 4351.9 patient-years (PYs), respectively. Mean per-patient exposure in the 2008 data set was 23.8 months. Incidence rates for AE overall were 2.977 and 2.757 events/PY for the 2007 and 2008 data sets, respectively. Incidence rates were 0.840 and 0.802 for infections; 0.013 and 0.014 for serious infections; 0.002 and 0.003 for opportunistic infections; 0.065 and 0.072 for serious AE. The 6 total cases of tuberculosis were classified as: disseminated (1 case), pulmonary (3), and tuberculosis (2), with an incidence of <0.001 event/PY for both data sets. Opportunistic infections were: candidiasis (6 cases), coccidioidomycosis (1), oral candidiasis (4), and oropharyngeal candidiasis (1); none were serious AE. Serious infections occurring in ≥ 2 patients were: cellulitis (9 cases), pneumonia (4), pulmonary tuberculosis (3), and 2 cases each of appendicitis, tuberculosis, lobar pneumonia, sepsis, and staphylococcal abscess. No chronic hepatitis B reactivation, lymphomas, or deaths due to infections were observed.

Conclusions: Pooled data from adalimumab clinical trials of patients with moderate to severe psoriasis, with average adalimumab exposure of nearly two years, showed that rates of serious infections and other infections of interest were generally low and stable with increased exposure.

Commercial Support: This study was funded by Abbott Laboratories.

P2311

Time to and duration of psoriasis clearance with biologic treatment: the patient perspective

Chureen Carter, PharmD, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Deborah Freedman, MBA, KantarHealth, New York, New York, United States; Heidi Waters, MS, MBA, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Marco DiBonaventura, PhD, KantarHealth, New York, New York, United States; Silas Martin, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States

Objective: To evaluate patient-reported time to and duration of psoriasis (PsO) clearance among PsO patients receiving biologic treatment.

Methods: An internet-based cross-sectional survey of PsO patients using biologic treatments (adalimumab, alefacept, efalizumab, etanercept, infliximab) was conducted from March to April 2009. Patients included in the study were aged ≥ 18 yrs and had a self-reported physician diagnosis of PsO. Demographics, self-reported disease severity (mild, moderate, severe), and measures of PsO clearance were assessed by the patient. Measures of PsO clearance included the length of time for the biologic to clear PsO to the patient's satisfaction, percentage of clearance experienced, and the length of time clearance lasted before symptoms returned.

Results: A total of 127 PsO patients receiving biologic treatment (adalimumab=48, alefacept=4, efalizumab=10, etanercept=55, infliximab=10) completed the survey (48% female; mean age=45.3 yrs; mean time diagnosed with PsO of 14.1 years; mean duration of biologic use = 27.4 months). Of all PsO biologic users, 21% (n=27) reported no clearance to their satisfaction with use of a biologic and 79% (n=100) reported some clearance to their satisfaction (mean time to clearance 4.2 weeks; mean of 59% clearance experienced per patient). The mean reported length of time clearance lasted until symptoms returned was 7.1 weeks. The majority (72%; n= 92) of biologic users reported moderate or severe PsO severity, with less than one-third reporting mild severity (28%; n=35). Although not statistically significant, there were numerical differences in reported measures of PsO clearance by PsO severity. Mean time to patient-reported clearance was 2.6, 5.0, and 4.6 weeks for mild, moderate, and severe PsO patients using biologics, respectively. Biologic users with moderate or severe PsO also reported a numerically lower mean percentage of clearance (59% and 55%, respectively) compared to those with mild disease (63%).

Conclusions: Nearly 1 in 5 PsO patients using biologics (mostly adalimumab or etanercept) reported no symptom clearance to their satisfaction. Of those with clearing to individual satisfaction, the average length of time to clearance was just over one month. While initially there was evidence of some response, patients reported symptoms returning within 2 months. There is a need for newer biologic treatment options that can address improvements in the time to and duration of PsO clearance.

Commercial Support: Centocor Ortho Biotech Services, LLC

P2312

Adalimumab treatment improves work productivity and activity in patients with psoriasis affecting the hands and/or feet: Results from a double-blind, placebo-controlled study

Jerry Bagel, Psoriasis Treatment Center of Central New Jersey, East Windsor, New Jersey, United States; Hongbo Yang, Analysis Group, Inc., Boston, Massachusetts, United States; Martin Okun, Abbott Laboratories, Abbott Park, Illinois, United States; Parvez Mulani, Abbott Laboratories, Abbott Park, Illinois, United States

Objectives: We assessed the effects of adalimumab (ADA) on work productivity and activity impairment among patients with psoriasis affecting the hands and/or feet.

Methods: Patients with moderate to severe psoriasis affecting the hands and/or feet were randomized to 16 weeks of double-blind treatment with ADA (40 mg every-other-week dosing starting at Week 1, after an initial 80-mg dose at Week 0) (n=54) or placebo (n=27). Measured Work Productivity and Activity Impairment Questionnaire (WPAI) outcomes included percentages of absenteeism, presenteeism, total work productivity impairment (TWPI), and total activity impairment (TAI). The score ranges from 0-100% for each outcome with greater scores indicating greater impairment. Psoriasis severity was measured using the Physician's Global Assessment (PGA) of the hands/feet. Longitudinal models were used to assess the effects of ADA vs. placebo on changes in WPAI from baseline to Week 16. Correlations between changes in WPAI and hand/foot psoriasis severity were assessed using Pearson correlation coefficients.

Results: Average baseline WPAI and PGA scores were similar between the ADA and placebo groups. Patients in both treatment groups reported significant baseline impairment in WPAI (TWPI and TAI >30%). Longitudinal regression analyses indicated that compared with placebo, ADA treatment was associated with greater average score improvement from baseline in presenteeism (-14.07; p=0.023), TWPI (-14.58; p=0.023), and TAI (-13.24; p=0.011), corresponding to improvements of 43.0%, 46.9% and 34.0% relative to the mean adalimumab baseline score. No significant difference was observed in absenteeism (0.43; p=0.931). Compared with placebo, ADA treatment was significantly more likely to result in patients' achievement of a PGA response of "Clear" or "Almost Clear" (30.6% vs. 4.3%; p=0.014). Improvements in all WPAI outcome scores were significantly and positively associated with improvements in hand/foot symptom scores assessed by the PGA (absenteeism, r=0.35; presenteeism, r=0.49; TWPI, r=0.49; TAI, r=0.47; all p<0.020).

Conclusions: For patients with moderate to severe psoriasis affecting the hands and/or feet, ADA treatment substantially improved work productivity and activity compared with placebo. These improvements were significantly associated with reductions in hand/foot symptom severity.

Commercial Support: This study was funded by Abbott Laboratories.

P2313

Documentation of comorbidities, psoriasis assessment instruments, and reasons for biologic discontinuation among biologic-experienced patients with plaque psoriasis: Results from a chart review study of U.S. dermatology practices

Heidi Waters, MS, MBA, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Chureen Carter, PharmD, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Michael Ropacki, PhD, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Paul Yamauchi, PhD, MD, Dermatology Institute & Skin Care Ctr, Inc Clinical Science Institute, Div of Derm, David Geffen Sch of Med, Santa Monica, California, United States; Vickie Andros, Total Therapeutic Management, Inc, Kennesaw, Georgia, United States

Objectives: To assess documented comorbidities, utilization of psoriasis severity measures and validated health-related quality of life instruments, and reasons for biologic discontinuation among patients with plaque psoriasis (PsO) treated with a biologic in the dermatology clinical setting.

Methods: A retrospective medical chart review was conducted September-November 2008 at 5 community dermatology offices in different geographic regions of the United States (Northeast, Southeast, Midwest, and West). Patients were required to be ≥18 years of age, diagnosed with PsO and receiving current treatment with a biologic (adalimumab, alefacept, efalizumab, etanercept, infliximab) for ≥3 months. Patients were excluded if they were receiving a biologic for a condition other than PsO, or enrolled in a randomized biologic clinical trial at the time of data collection.

Results: A total of 279 patients, representing 3,496 dermatology office visits, were included in the sample for analysis. The mean (SD) age was 48.9 (13.1) years, 33.7% were female, and the mean (SD) duration of time with a PsO diagnosis was 16.9 (11.4) years. The top three documented comorbidities were psoriatic arthritis (44.1%), hypertension (31.2%), and diabetes (13.3%). Familial history of PsO was documented in 17.2% of the sample. Documentation of assessment instruments was recorded for only 7.5% of total visits. The body surface area (BSA; 4.9%; n=170 visits) and Dermatology Life Quality Index (DLQI; 1.7%; n=58 visits) were most often used. Upon initiation of a biologic, use of assessment

instruments was documented for 35% (n=97/279) of all patients. BSA, DLQI, Psoriasis Area and Severity Index (PASI), and Physician Global Assessment (PGA) were recorded for 28%, 3.2%, 2.9%, and 0.7% of all patients, respectively. The most common documented reasons for biologic discontinuation were lack of/inadequate efficacy (29.5%), patient dissatisfaction (8.6%), and completion of course of therapy (8.4%).

Conclusions: Biologic-experienced PsO patients had multiple comorbidities and reasons for biologic discontinuation documented in the dermatology office medical chart. Documentation of PsO assessment instruments was more likely at the start of the biologic, but in the minority of patients. While documentation of qualitative assessments, such as presence of comorbidities and BSA, was common, there remains an opportunity for improved documentation of quantitative assessments, including validated instruments.

Commercial Support: Centocor Ortho Biotech Services, LLC

P2314

Types of healthcare professionals involved in the diagnosis and treatment of concomitant psoriatic arthritis or rheumatoid arthritis in psoriasis patients

Chureen Carter, PharmD, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Deborah Freedman, MBA, KantarHealth, New York, New York, United States; Silas Martin, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Susan Bolge, PhD, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States

Objectives: To determine the percentage of patients diagnosed with psoriasis (PsO) and concomitant psoriatic arthritis (PsA) or rheumatoid arthritis (RA) in the United States. To evaluate the types of healthcare professionals (HCPs) involved with the diagnosis and treatment of PsO and concomitant PsA or RA.

Methods: Cross-sectional data were collected through self-administered, web-based questionnaires from March–April 2009. Study participants were aged ≥ 18 yrs and had a self-reported physician diagnosis of PsO. Patient-reported information on demographics, concomitant PsA or RA, and type of healthcare professional [general/family practitioner (GP/FP), internist (INT), dermatologist (DERM), pediatrician, rheumatologist (RHEUM), others] responsible for diagnosing and treating PsO, PsA, and RA was collected.

Results: A total of 1,003 respondents (59% female; mean age=50 yrs; mean 17 years diagnosed with PsO) completed the survey. Concomitant PsA or RA was reported by 17% (N=168) and 8% (N=81) of PsO patients, respectively. Patients reported receiving a concomitant PsA diagnosis approximately 5 years after the PsO diagnosis. PsO patients with concomitant RA had been diagnosed with RA for a mean of 13 years. DERM represented the majority of HCP types responsible for PsO diagnosing (61%) and treating (33%), followed by GP/FP (24%/28%) and RHEUM (10%/21%), respectively. RHEUM represented the majority of concomitant PsA diagnosing (43%) and treating (34%), followed by GP/FP (27%/30%) and DERM (18%/14%), respectively. Concomitant RA was mostly diagnosed and treated by RHEUM (52%/41%), followed by GP/FP (33%/33%) and INT (10%/7%), respectively. DERM was not reported as a diagnosing HCP in concomitant RA, but represented 3% of the HCPs treating RA in PsO. A portion of patients reported not receiving any current care from any HCP for PsO (12%), concomitant PsA (14%), or concomitant RA (11%).

Conclusions: The published prevalence of concomitant PsA in PsO patients in the United States ranges from 10%-30%. This study determined a patient-reported prevalence rate of PsA/RA in PsO consistent with the reported range in the literature. Concomitant PsA/RA was most often diagnosed and treated by a RHEUM HCP. However, there was evidence of some DERM HCP involvement in the treatment of PsA/RA in PsO patients. Further research on PsA/RA in PsO is necessary to contribute to the body of real-world evidence needed by multiple types of HCPs treating these concomitant diseases.

Commercial Support: Centocor Ortho Biotech Services, LLC

P2315**Patient reported symptoms of psoriasis: Results from the psoriasis select patient study**

Jie Zhang, PhD, Novartis Pharma, East Hanover, New Jersey, United States; Andrine Swensen, PhD, Novartis Pharma, East Hanover, New Jersey, United States; Judit Nyirady, MD, MBA, Novartis Pharma, East Hanover, New Jersey, United States; Macro DiBonaventura, PhD, Health Sciences Practice, Kantar Health, New York, New York, United States

Objectives: In order to better understand the needs of psoriasis patients, a survey was conducted to assess the frequency, severity and otherness of patient reported psoriasis symptoms.

Methods: Potential respondents were identified through the 2009 U.S. National Health and Wellness Survey, Lightspeed Research Ailment panel, and other Internet panel partners. Only those patients who self-reported a severe (>10% body surface area) diagnosis of psoriasis and were 18 years or older were asked to participate. Psoriasis symptoms were reported over the past 24 hours by patients. Severity was reported on a scale of 0-10, 0 = no symptoms, 10=symptoms as bad as you can imagine. Botherness was reported on a scale of 0-10, 0 = no bother, 10=bother as bad as you can imagine.

Results: Total 251 responders with severe plaque psoriasis completed the survey. The mean age was 49 (20-78) years and 63% were female. Itch and scaling were reported by greater than 90% patients with average scores of 5.1 to 5.3 for both severity and botherness. Stinging, skin cracking and pain were reported by greater than 80% patients with average scores of 3.8 to 4.0 for both severity and botherness. In addition, psoriasis-affected skin color was reported by all patients with 28% pink, 16% light red or brown, 20% bright red or purple, 4% deep dark red, purple or brown, and 31% grey, white or silver. Among them, 94% stated that their psoriasis-affected skin was noticeable.

Conclusion: A large percent of patients reported psoriasis symptoms with a severity and botherness score of 3.6-5.2 on a scale of 10. Patient reported psoriasis symptoms are important and should be assessed in evaluation of treatment benefit in clinical trials.

Commercial Support: 100% was sponsored Novartis Pharmaceutical

P2316**Erosive lichen planus: Role of topical tacrolimus**

Swetha Kandula, MD, Indiana University School of Medicine, Indianapolis, Indiana, United States; Gerald S Lazarus, MD, Johns Hopkins Medical Institutions, Baltimore, Maryland, United States; Sofia M Shea, MD, Johns Hopkins Medical Institutions, Baltimore, Maryland, United States

A 60 year old Caucasian male with unremarkable past medical history presented with a nine year history of bilateral heels ulcerations. They initially started as erythematous patches with overlying scale. Two years later, he spontaneously lost all finger and toenails. Previous biopsies were consistent with lymphomatoid allergic contact dermatitis. He underwent multiple debridements and treatment for psoriasis with minimal improvement. Physical examination was notable for 7 x 11 cm ulcer on right plantar heel and 5 x 8 cm ulcer on the left plantar heel with beefy red hypertrophic granulation tissue and serosanguineous drainage. There was an annular violaceous lesion with overlying scale on his lateral right calf. Oral and genital mucosa were uninvolved. All nails were absent. Laboratory workup including CBC, CMP and rheumatoid factor, ANA, HCV antibodies and serum immunoglobulins were unremarkable. Biopsy of the new lesion on his calf was remarkable for lichenoid lymphocytic infiltrate extending into the epidermis with dyskeratosis and squamatization of the basal layer. IgM positive cytooid bodies were seen on Immunofluorescence. Dense fibrillar fibrinogen was noted along the basement zone extending into the dermis. Stains were negative for Ig A, IgG and C3. He was diagnosed with lichen planus, erosive type. Oral corticosteroids and silver dressings were initiated. The ulcers flared as the prednisone was tapered. We initiated tacrolimus 0.1% ointment which has improved the ulcerations leading to a successful steroid taper. Later Hydroxychloroquine 200 mg twice a day was added to the regimen.

Discussion: Lichen planus (LP) is a relatively uncommon disorder of unknown cause, affecting middle-aged adults. It has been associated with drugs and hepatitis C virus infection. LP typically affects the skin, nails, and mucous membranes. LP presents as violaceous polygonal papules commonly over the flexor

surface of the extremities. Erosive LP, an uncommon variant is characterized by painful hypergranulated ulcers on palmar and plantar surfaces, loss of the toenails, and cicatricial alopecia. These lesions are disabling and resistant to conventional treatment. Corticosteroids remain the mainstay of treatment. Alternative therapies implemented for erosive LP are oral acitretin, photochemotherapy and steroid-sparing agents like thalidomide, cyclosporine, and azathioprine. Our patient had worsening of his ulcers on steroids taper. Topical tacrolimus was initiated leading to improvement.

Commercial Support: None Identified

P2317

The impact of psoriasis body surface area on psychological functioning, physical functioning, and disease-related quality of life

Chureen Carter, PharmD, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Deborah Freedman, MBA, KantarHealth, New York, New York, United States; Heidi Waters, MS, MBA, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Marco DiBonaventura, PhD, KantarHealth, New York, New York, United States; Silas Martin, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States

Objective: To assess the impact of psoriasis (PsO) body surface area (BSA) on psychological functioning, physical functioning, and disease-related quality of life outcomes in patients with PsO.

Methods: Data were collected from the Psoriasis Patient Study Project, a cross-sectional survey of PsO patients, conducted March-April 2009. Invitations were sent to a sample of Internet panel participants aged 18 years and above who self-reported a physician diagnosis of PsO, and were stratified by BSA (1-2%-low, 3-10%-medium, or >10%-high). Demographic information and self-reported PsO disease severity (mild, moderate, severe) was collected. Psychological and physical functioning was assessed by the Skindex-16 (scale 0-100 with 0= no effect; 100= effect experienced all the time). Disease-specific quality of life was assessed by the Dermatology Quality of Life Index (DLQI) (scale 0-30 with higher scores indicating increased impairment in patient's life).

Results: A total of 1,003 respondents diagnosed with PsO (59% female; mean age=50 yrs) completed the survey. When asked about their current disease severity, 51% reported mild disease, 42% moderate, and 7% severe. The majority of patients (48%) had low BSA involvement, followed by medium BSA (38%) and high BSA (14%). Based on the Skindex-16 emotions and functioning subscales, those with high BSA reported their PsO bothering them significantly more emotionally (30.9) and physically (17.2) than those with medium BSA (24.5/11.2) and with low BSA (15.8/5.2), respectively (all $p < 0.05$). In addition, disease-specific quality of life, as measured by the DLQI, worsened as BSA increased (2.8 low BSA, 6.8 medium BSA, 11.8 high BSA; $p < 0.05$ for all differences).

Conclusions: In patients with PsO, greater self-reported BSA involvement was associated with lower psychological functioning, physical functioning, and disease-related quality of life. Moreover, psychological and physical functioning worsens as BSA increases. Appropriately and aggressively treating PsO may help alleviate some of the psychological and physical burden of the disease, especially in those patients with $\geq 3\%$ BSA involvement.

Commercial Support: Centocor Ortho Biotech Services, LLC

P2318

The value to patients of reducing lesion severity in plaque psoriasis

A Brett Hauber, PhD, RTI Health Solutions, Research Triangle Park, North Carolina, United States; Brad Schenkel, MS, Johnson & Johnson Pharmaceutical Services, LLC, Horsham, Pennsylvania, United States; Jennifer Lofland, PhD, PharmD, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States; Juan Marcos Gonzalez, PhD, RTI Health Solutions, Research Triangle Park, North

Carolina, United States; Silas Martin, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States

OBJECTIVE: To quantify the value to patients of reducing the severity of plaque psoriasis (PsO) skin lesions.

METHODS: Individuals with a self-reported diagnosis of PsO were recruited from a nationally representative household panel. Individuals completed a web-based conjoint survey in which they were asked to choose between 2 hypothetical PsO treatments in each of a series of choice questions. Each choice alternative was defined by lesion severity (redness, thickness, and texture), percentage of body surface area (BSA) covered by the lesions, type of treatment (oral agent, subcutaneous injection, or phototherapy), injection discomfort or pain (if treatment included injections), risk of serious lung infection, and monthly out-of-pocket cost. Preference weights were estimated for all levels of each attribute using mixed logit methods. Conjoint preference weights were used to calculate willingness-to-pay (WTP) for reductions in lesion severity.

RESULTS: Of the 28,200 panel members invited to participate, 18,330 individuals responded, and 503 qualified to participate. 419 PsO patients completed the survey; mean age was 54.5 years and 52% were female. 64% of patients self-reported their PsO severity as mild or mild-to-moderate. 12%, 12%, 7% and 3% of patients self-reported their PsO severity as moderate, moderate-to-severe, severe, and very severe, respectively. Overall, patients were willing to pay the highest amount on a monthly basis to eliminate very severe lesions. The highest WTP for incremental improvements through the range of severity levels appeared as changes from severe to moderate, and from mild to none. Patients were willing to pay lesser amounts to reduce lesion severity from very severe to severe or moderate to mild. For example, patients initially with lesions covering 10% of BSA on the arms and legs were willing to pay \$395.50/month to eliminate very severe lesions, \$146.39/month to reduce the severity from severe to moderate, and \$201.78/month to eliminate mild lesions. WTP to reduce severity from very severe to severe was \$47.33/month. This pattern was consistent across different levels of BSA covered by the lesions and whether the lesions covered the arms and legs or the torso.

CONCLUSIONS: In this WTP study, individuals with PsO value reductions in lesion severity differently across the spectrum of severity levels, placing the highest value on eliminating lesions completely, followed by reducing severity from severe to moderate.

Commercial Support: Centocor Ortho Biotech Services, LLC

P2319

Real-world dosing of tumor necrosis factor (TNF) blockers in us psoriatic disease patients

Charles Makin, MS, MBA, IMS Health, Falls Church, Virginia, United States; David Harrison, PhD, Amgen Inc., Thousand Oaks, California, United States; Seth Goodman, IMS Health, Falls Church, Virginia, United States; Vernon Schabert, PhD, IMS Health, Falls Church, Virginia, United States

BACKGROUND: TNF blockers are commonly used biologic therapies for plaque psoriasis (PsO) and psoriatic arthritis (PsA). US labels for etanercept (ETN) and adalimumab (ADA) recommend a higher initial dose for PsO, but not for PsA. It is important to understand whether varied dosing regimens influence the cumulative dosing that PsO and PsA patients receive relative to US label recommended dosing.

OBJECTIVE: To compare real-world dosing of TNF blockers to US label recommendations for PsO and PsA.

METHODS: IMS's LifeLink Health Plan Claims database was used to obtain ADA and ETN patients who initiated treatment between 01/01/2003 and 03/31/2009 and after approval for the indication (first ADA/ETN claim defined as index date); and were enrolled for 360 days pre- and ≥ 180 days post-index. Based upon ICD-9 CM codes, patients were classified as PsO only, PsA only or PsO+PsA. Patients with other inflammatory disorders within 360 days pre- or post-index or who received a TNF blocker or other biologic within 360 days pre-index were excluded. Patients were followed until the end of the study period (03/31/2009) or health plan disenrollment; whichever came first. A dosing ratio for each patient was calculated by dividing the total dose (mg) of TNF blocker received while persistent with therapy by the

recommended amount of drug (USPI dosing) for that period. Persistence was defined as the number of days from index date to discontinuation (the beginning of any gap >6.5 weeks between the end of supply and the next fill) or the end of the study period, whichever came first.

RESULTS: Analyzable data was obtained for 2,763 ETN and 302 ADA patients. Mean age was 44.5 years; 44.2% were female. For PsO, ETN patients received a mean ratio [95% CI] of 82% [81, 83] of recommended dosing while persistent, compared to 91% [88, 95] for ADA. For PsA, mean [95% CI] dosing ratios were 87% [85, 89] and 101% [97, 105] for ETN and ADA. Dosing for patients with both PsO+PsA was 71% [69, 73] (ETN) and 87% [83, 92] (ADA) when compared to PsO dosing; 98% [95, 100] (ETN) and 103% [98, 107] (ADA) when compared to PsA dosing. Persistence for ETN patients ranged from 337-397 days depending upon indication, and 207-302 for ADA patients.

CONCLUSIONS: Overall, the amount of the TNF blocker received was similar to the amount recommended in the USPI for both agents; 81-86% for ETN patients and 94-98% for ADA patients depending on the dosing recommendations used to evaluate PsO+PsA patients.

Commercial Support: This poster and its underlying research are sponsored by Amgen Inc.

P2320

Peripheral corneal melting syndrome and psoriasis

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain; Miguel Gonzalez-Andrades, MD, San Cecilio Clinical Hospital, Granada, Spain

Introduction: The ocular affection in patient with psoriasis is frequently bilateral and usually takes place when an exacerbation of the psoriasis occurs. Approximately 10% of psoriatic patients have some form of ocular signs. Psoriasis can affect the lids, conjunctiva, cornea and anterior uveal tract. Peripheral corneal melting syndrome is a rare disease consisting of marginal corneal thinning that can progress to perforation.

Case report: A 39 year-old man presented with superior marginal corneal infiltrates in the right eye which did not heal after topical applications of antibiotic ointments. Latter on and during psoriasis exacerbation, conjunctival hyperaemia and conjunctiva follicles appeared, together with the development of a superior pannus in response to peripheral infiltrates and marginal corneal thinning that presented negative culture. The corneal infiltrates improved after three weeks using ocular corticosteroids and tacrolimus.

Discussion: Corneal melting syndrome is most often described in association with rheumatoid arthritis, Sjögren's syndrome, polyarteritis nodosa and Wegener's granulomatosis, and can progress to ulceration. It is crucial for dermatologists to have a high index of suspicion for this condition in a patient with psoriasis presenting with a red eye. An urgent ophthalmology consultation should be requested to establish the diagnosis and institute treatment.

Commercial Support: None Identified

P2321

Comorbidities in patient with lichen planus: Dyslipidaemia

Salvador Arias-Santiago, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Agustin Buendía-Eisman, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Husein Husein-EIAhmed, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Cachaza, MD, San Cecilio Clinical Hospital (Department of Dermatology), Granada, Spain; Jose Aneiros-Fernandez, MD, San Cecilio Clinical Hospital (Department of Pathology), Granada, Spain

Introduction: Cardiovascular risk factors have been assessed with some skin diseases such as androgenetic alopecia and psoriasis. Recently a case control study found that lichen planus (LP) was associated with dyslipidaemia in a large series of patients. However no data were presented about lipid values in patients and controls. The objective of this case control study was to evaluate lipid levels in men and women with lichen planus and in controls, excluding lichenoid drug eruption and treatment for LP such as systemic corticosteroids, retinoid acid or methotrexate.

Methods: This case-control study included 160 patients, 80 with LP (40 males and 40 females) and 80 controls consecutively admitted to the outpatient clinic in Dermatology department of San Cecilio Hospital, Granada, Spain.

Results: Patients with LP presented higher significant triglycerides values (145.9 vs. 101.5 mg/dl $P=0.0018$), total cholesterol values (197.6 vs. 178.4 mg/dl $P=0.001$) LDL-C values (120.8 vs. 100.96 mg/dl $P<0.001$) and lower HDL-C values (55.25 vs. 61.94 mg/dl $P=0.004$) versus controls. Adjusted OR for dyslipidaemia in patients with LP was 3.10 (95% confident interval 1.51-6.34, $P=0.002$).

Conclusion: The results obtained indicate an association between LP in males or females and dyslipidaemia. Lipid levels screening in males or females with LP may be useful to detect individuals at risk and start preventive treatment against the development of cardiovascular disease.

Commercial Support: None Identified

P2322

Ustekinumab safety update: Cumulative experience from longer term follow-up of patients treated in the ustekinumab psoriasis clinical development program

Kenneth Gordon, MD, University of Chicago Pritzker School of Medicine/NorthShore University Health System, Skokie, Illinois, United States; Christopher Griffiths, MD, University of Manchester, Salford,, United Kingdom; Craig Leonardi, MD, St. Louis University, Dept of Dermatology,, St. Louis, Missouri, United States; Kristian Reich, MD, Dermatologikum Hamburg, Hamburg, Germany; Philippe Szapary, MD, Centocor Research & Development, Inc, Malvern, Pennsylvania, United States

Objective: The objective is to analyze the cumulative safety experience and select adverse events observed across psoriasis clinical trials in patients treated with ustekinumab(UST), a first in class, human monoclonal antibody against interleukin 12/23p40.

Methods: This analysis pooled safety data across Phase 2 and 3 psoriasis trials including 152wks (3yrs) from PHOENIX 1, 100wks (2yrs) from PHOENIX 2, and 64wks (1yr) from ACCEPT ($n=903$). UST 45mg and 90mg dosing were studied in each trial (Phase 2: 1 injection or 4wky injections; PHOENIX 1 and 2: injections at wk 0, 4, and q12wk thereafter. Placebo-treated patients crossed over to UST at wk20 (Phase 2) or wk12 (PHOENIX 1 and 2). In ACCEPT, patients received injections at wk 0, 4 and at variable intervals thereafter. All analyses are adjusted for follow up and expressed as rates per 100 patient-years (PY) of exposure.

Results: This analysis included 3117 patients (4782 PY of follow-up), with 1247 patients treated for at least 2yrs (median follow-up, 1.7yrs). Overall AE rates per 100 PY were 287.75 and 280.29 for the UST 45mg and UST 90mg groups, respectively. The most common reported AE's (occurring in at least 5%) included nasopharyngitis, upper respiratory tract infection, arthralgia, sinusitis, headache, and back pain. The rates of serious AEs per 100 PY were 6.78 and 8.24 for each group, respectively. Serious infection rates per 100 PY in the UST 45mg and UST 90mg groups were 0.82 and 1.50, respectively; rates of infections requiring treatment were 34.9 and 34.7 per 100 PY, respectively. The incidence of non-melanoma skin cancers (NMSC) per 100 PY of follow-up in UST 45mg and UST 90mg groups were 0.64 and 0.77, respectively. Rates of non-cutaneous malignancies were 0.69 and 0.46 for the respective UST dose groups. Rates of major cardiovascular events (cardiovascular death, myocardial infarction, or stroke), per 100 PY in the UST 45mg and UST 90mg groups were 0.41 and 0.35, respectively. Rates of serious infections, malignancies, and major cardiovascular events were stable over time and were consistent with rates previously described and with observations in the general and/or psoriasis population.

Conclusions: The safety profile of continued UST exposure in the most recent pooled analysis is favorable and is consistent with previous reports. Ongoing Phase 3 studies with a total of 5yrs of follow-up will continue to define the safety profile of UST in the psoriasis population.

Commercial Support: Centocor Ortho Biotech Services, LLC

P2323

Characterization of infections associated with ustekinumab in moderate to severe psoriasis patients

Craig Leonardi, MD, St. Louis University, Dept of Derm, St. Louis, Missouri, United States; Kristian Reich, MD, Dermatologikum Hamburg, Hamburg, Germany; Lynn Guenther, MD, The Guenther Dermatology Research Centre, London, Canada; Newman Yeilding, MD, Centocor Research & Development, Inc, Malvern, Pennsylvania, United States; Norman Wasel, MD, Stratica Medical, Edmonton, Canada

Background: Ustekinumab(UST), a human IgG1k monoclonal antibody against the p40 subunit of IL-12 and IL-23, is approved for treatment of moderate to severe psoriasis. The median half-life is approximately 21 days, consistent with that of endogenous IgG.

Objective: To explore the theoretical impact of half-life on infections in patients treated with UST, we evaluated the characteristics of infections that occurred early in a dosing interval when drug concentrations are highest vs late, when drug concentrations are lowest.

Methods: Rates and characteristics of infections occurring in PHOENIX1(n=766) and PHOENIX2(n=1230) Phase 3 trials, through wk 12(common PBO-controlled period) and up to 3yr follow-up, were determined. Patients were randomized to SC UST45mg or 90mg at wks 0 and 4 and then q12wks or PBO with crossover to UST at wk12.

Results: 1965 patients were treated with UST in these trials with an average follow-up and exposure duration of 103.9 and 92.7wks, respectively. Through wk12, respective rates in the PBO, UST45mg, and 90mg groups of serious infections(1.0%, 1.0%, and 2.0%), overall infections(22.6%, 25.5%, and 23.9%), infections requiring treatment(7.8%, 6.2%, and 8.4%) and discontinuation of treatment due to infection(0.2%, 0.0%, and 0.5%) were similar. The respective rates of infection were generally comparable at different time points in the dosing interval(wks 0-4: 12%, 13%, 12%; wks 4-8: 7%, 8%, 7%; wks 8-12: 6%, 9%, 8%). The median time to infection from last injection was 19 days(range: 11.0, 28.5) for placebo vs. 22 days(range: 12.0, 33.0) for UST-treated patients. Infection severity was similar, with the majority considered mild. The median duration of infection was similar (11 days[range: 6.0, 16.0] for PBO, 10 days[range: 6.0, 15.0] for UST 45mg, 9 days[range: 6.0, 16.0] for UST 90mg). Through to the end of the longest observation period, the median duration and severity of infections did not increase and a dose response relationship was not apparent. There was no difference in duration or severity of infections occurring early or late during a dosing interval.

Conclusions: Rates, severity, and duration of infection were comparable between the UST and PBO groups. Infections that occurred early in a dosing interval did not have a longer duration and were no more severe than infections occurring at the end. These observations do not suggest a relationship of infections to peak UST serum concentration and do not support an adverse impact of UST half-life on infection characteristics.

Commercial Support: Centocor Research & Development, Inc

P2324

Malignancies in ustekinumab-treated moderate-to-severe psoriasis patients: Observations with up to 3 years of follow-up and comparisons to the general United States population

Kim Papp, MD, Probitry Medical Research, Waterloo, Canada; Kristian Reich, MD, Dermatologikum Hamburg, Hamburg, Germany; Newman Yeilding, MD, Centocor Research & Development, Inc, Malvern,

Pennsylvania, United States; Richard Langley, MD, Dalhousie University, Halifax, Canada; Vincent Ho, MD, University of British Columbia, Vancouver, Canada

Background: Ustekinumab(UST) is a fully human monoclonal antibody directed against interleukins (IL)-12 and -23 developed for the treatment of moderate-to-severe psoriasis.

Objective: To assess the longer term impact of IL-12 and IL-23 blockade on malignancy risk, the incidence of malignancies in psoriasis patients treated with UST for up to 3yrs in clinical trials, was compared with malignancy rates expected in the general US population.

Methods: The incidences of basal and squamous cell cancers or nonmelanoma skin cancers(NMSCs) and all other malignancies were evaluated in patients with moderate-to- severe plaque psoriasis treated in Phase 2 and 3 trials. For all other malignancies except NMSC, standardized incidence ratios(SIRs) compared observed malignancy rates in UST-treated patients to rates expected in the US population adjusting for age, sex and race based on data available in the National Institutes of Health Surveillance, Epidemiology, and End Results (SEER) database(2000-2004).

Results: 3117 patients were treated with UST for 4774 patient-yrs of follow-up(P-Y) for up to 3yrs(median follow-up of 1.7yrs with 1247 patients treated for 2yrs). The incidence of NMSC(per 100P-Y) for the UST45mg and UST90mg groups was 0.64(95%CI:0.35, 1.08) and 0.77(95%CI:0.47,1.19), respectively; 34 cases were observed and included 28 basal cell and 9 squamous cell skin cancers(basal to squamous cell ratio, 3:1).The incidence(per 100P-Y) of NMSC occurrence by year evaluated for the UST combined group was 0.94(95%CI:0.61,1.41), 0.44(95%CI:0.18,0.90) and 0.47(95% CI:0.10,1.36) for Yrs 1,2 and 3, respectively; the respective rates of other malignancies were 0.39 (95%CI:0.19,0.72), 1.00(95%CI:0.57,1.63), and 0.16(95%CI:0.00,0.86). The incidence(per 100P-Y) of other malignancies for the UST45mg and UST90mg groups was 0.69(95% CI:0.39,1.13) and 0.46(95%CI:0.24,0.81), respectively; 27 cases were observed and included (≥ 2 cases) prostate, breast, melanoma, colorectal, renal, head and neck. The rate of these malignancies reported in UST-treated patients was comparable to the rate expected in the general population (SIR = 1.05[95% CI:0.69,1.53]).

Conclusions: Malignancy rates remained low and stable with no observed UST dose effect. The observed malignancy rate was consistent with the expected rate in the general US population in the SEER database. Additional analyses with 5yrs of follow-up are planned to continue examining the impact of IL-12/23 blockade on malignancy rates.

Commercial Support: Centocor Research & Development, Inc

P2325

Infection rates in ustekinumab-treated psoriasis patients: Observations with up to 3 years of follow-up and comparisons to a large health care claims database

Kenneth Gordon, MD, University of Chicago Pritzker School of Medicine/NorthShore University Health System, Chicago, Illinois, United States; Alan Menter, MD, Baylor Research Institute, Dallas, Texas, United States; Lynn Guenther, MD, The Guenther Dermatology Research Centre, London, Canada; Philippe Szapary, MD, Centocor Research & Development, Inc, Malvern, Pennsylvania, United States; Richard Langley, MD, Dalhousie University, Halifax, Canada

Objective: Ustekinumab(UST) is a first in class monoclonal antibody that blocks IL-12 and IL-23.

Theoretical risks of pharmacological blockade of IL-12 and -23 include a potential increased risk of infection, though previous reports have not substantiated an increased risk of infection with up to 1.5yrs of UST treatment. We describe infections observed in Phase 2 and 3 psoriasis clinical trials with up to 3yrs of UST treatment.

Methods: Infections were evaluated in data pooled across UST psoriasis trials [Phase 2 trial(n=320), PHOENIX1(n=766), PHOENIX2(n=1230), and ACCEPT(n=903)]. Rates of serious infections(SI) were compared to expected rates based on psoriasis patients treated with systemic agents in the MarketScan Claims Database, adjusted by age-sex distribution.95% confidence intervals were calculated assuming number of events following Poisson distribution.

Results: 3117 patients(4782 patient-years of follow-up [PY]) were treated with UST; 1247 patients were treated for ≥ 2 yrs(1.7 median yrs of follow-up). At least one infection was reported in 71.7% and 61.9% in

the UST45mg and UST90mg groups, respectively; the number of infections per 100-PY were 113.68 and 111.21, respectively. Rates of overall infections in UST-treated patients per 100-PY were 134.6, 91.06, and 77.04 in Yrs 1,2 and 3, respectively. The number of infections per 100-PY requiring treatment was 34.9 and 34.7 for the UST45mg and UST90mg groups, respectively. 1.3% and 1.7% of pts had ≥ 1 SI, respectively; SI per 100-PY(95%CI) for the UST45mg and UST90mg group were 0.82(0.49, 1.30) and 1.50(1.07, 2.05), respectively. Based on the MarketScan Claims Database analysis, the expected rates (95%CI) of SI were 1.48(1.01, 2.09) and 1.54(1.10, 2.10) per 100-PY for the UST45mg and UST90mg groups, respectively. The rates of SI in UST-treated patients per 100-PY were 1.41, 1.00, and 0.78 in Yrs 1, 2 and 3, respectively. No specific patterns of infections emerged with the majority of SI caused by common pathogens. One potential opportunistic infection of disseminated, cutaneous herpes zoster was observed. No cases of TB, atypical mycobacterial disease, systemic fungal infections, or salmonellosis were observed.

Conclusions: Overall rates of infections remained stable with up to 3yrs of follow-up and did not appear to increase with cumulative exposure. Rates of SI in this analysis are comparable to the expected rates observed in the general psoriasis patient population who were treated with other systemic agents.

Commercial Support: Centocor Research & Development, Inc

P2326

Cost per responder of ustekinumab versus etanercept in patients with moderate-to-severe plaque psoriasis: Analysis from the ACCEPT trial

Steven Feldman, PhD, MD, Wake Forest University School of Medicine, Winston-Salem, North Carolina, United States; Bradley Schenkel, MS, Johnson & Johnson Pharmaceutical Services, LLC, Horsham, Pennsylvania, United States; Matthias Augustin, MD, University Clinics of Hamburg, Hamburg, Germany; Philippe Szapary, MD, Centocor Research & Development, Inc, Malvern, Pennsylvania, United States; Silas Martin, MS, Centocor Ortho Biotech Services, LLC, Horsham, Pennsylvania, United States

Objective: To compare the cost per responder of ustekinumab (UST) versus etanercept (ETN) based on head-to-head data from the ACCEPT trial, which demonstrated greater efficacy of two doses of UST, 45mg and 90mg at weeks 0 and 4, versus ETN, 50mg twice weekly through week 12, in patients with moderate-to-severe plaque psoriasis (PsO).

Methods: Efficacy results (proportion of patients achieving at least 75% improvement in the Psoriasis Area and Severity Index [PASI75]) were obtained from the ACCEPT trial (n=903). Given the unique dosing of UST (weeks 0, 4, 16, and q12 weeks thereafter), we determined the cost per PASI75 response at week 16, the appropriate decision point for determining whether to proceed with a third dose. Week 16 PASI75 results were assumed to be equal to week 12 efficacy from ACCEPT; previously published randomized controlled trials have reported similar observations for both drugs. Dosing through week 12 was per ACCEPT. Dosing for weeks 13-16 was assumed to be per labeled indication in PsO. US wholesale acquisition cost (WAC) was used for calculating costs. The analyses used weight-based efficacy results for UST (45mg ≤ 100 kg and 90mg > 100 kg) and overall efficacy for ETN to align with the respective approved labels for each drug.

Results: In ACCEPT, 209 patients received UST 45mg, 347 received UST 90mg, and 347 received ETN. Baseline demographics and disease characteristics were comparable between groups. Twenty-eight percent of patients were > 100 kg. The PASI75 responses at week 12 were 72% for UST 45mg in patients ≤ 100 kg and 65% for UST 90mg in patients > 100 kg, compared with 57% for the ETN group. At week 16, the WAC per PASI75 response was \$17,009 for UST-treated patients and \$19,140 for ETN-treated patients.

Conclusion: WAC per PASI75 response was lower for UST relative to ETN through 16 weeks in PsO patients.

Commercial Support: Centocor Research & Development, Inc

P2327**Efficacy of ustekinumab is sustained through 3 years of treatment for patients with moderate-to-severe psoriasis maintained on q12 week dosing based on body weight**

Alexandra Kimball, Mass General Hospital, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, United States; Bernard Goffe, Dermatology Associates, PLLC, Seattle, Washington, United States; Kim Papp, Probit Medical Research, Waterloo, Canada; Newman Yeilding, Centocor Research & Development, Inc., Malvern, Pennsylvania, United States; Robert Bissonnette, Innovaderm Research, Montreal, Canada

Background: Ustekinumab (UST) has demonstrated significant efficacy for moderate-to-severe psoriasis (PsO). Patients (pts) ≤ 100 kg on 45mg and pts > 100 kg on 90mg show comparable, high level responses in short term analyses, establishing dosing parameters that optimize efficacy while minimizing drug exposure.

Objective: To assess long-term efficacy of UST in PsO pts maintained on q12wk dosing based on body weight.

Methods: Pts in the PHOENIX 1 trial were randomized to receive UST 45mg or 90mg at Wk0 and Wk4 followed by q12wk dosing, or placebo. Placebo pts crossed over to UST 45mg or 90mg at Wk12. Wk28 nonresponders ($< \text{PASI } 50$) discontinued UST; partial responders with $< \text{PASI } 75$ at Wk28 or Wk40 had dosing adjusted to q8wks. After Wk40, PASI 75 responders originally receiving UST were re-randomized to continue or withdraw from treatment. Pts included in these analyses were limited to pts ≤ 100 kg on UST 45mg (n=246) and pts > 100 kg on UST 90mg (n=133). Pts who discontinued due to lack of efficacy or started a prohibited therapy were considered nonresponders. All pts were included in Wk12 analyses; subjects with missing data were considered nonresponders.

Results: Baseline clinical characteristics were comparable among both grps. PASI 75 rates were 74% and 69% at the 12wk primary endpoint for the ≤ 100 kg/45mg and > 100 kg/90mg grps, respectively. Peak PASI 75 rates for these respective grps were observed at Wks20-24 (83% and 80%) and were stable through Wk36 (81% and 75%), the last time point all pts were on q12wk dosing. For Wk40 PASI 75 responders continuing q12wk therapy (≤ 100 kg/45mg, n=55 and > 100 kg/90 mg, n=28), response rates showed modest variation in both grps, but remained relatively stable. At Wk148, 96% and 92% of pts had PASI 50, 88% and 72% had PASI 75, and 48% and 44% had PASI 90 responses for the ≤ 100 kg/45mg and > 100 kg/90 mg grps, respectively. Median percent improvement for Wk40 responders continuing therapy ranged between 90-96% and 86-100% for these respective grps through Wk148. Response in withdrawal pts progressively decreased with time. Rates of adverse events (AEs), AEs leading to discontinuation, and serious AEs were 89.2%, 6.0%, and 2.4% for pts on maintenance dosing, and 95.1%, 7.4%, and 9.9%, for pts with interrupted therapy, respectively.

Conclusion: High level clinical responses were largely sustained and comparable for pts ≤ 100 kg receiving UST45 mg and pts > 100 kg receiving UST 90mg on a q12wk dosing schedule through up to 3 years.

Commercial Support: Centocor Research & Development, Inc.

P2328**Meta-analysis of biologic therapies for the treatment of moderate to severe psoriasis**

Neil Hawkins, PhD, MMSc, Oxford Outcomes Ltd, Oxford, United Kingdom; James Eaton, MMSc, Oxford Outcomes Ltd, Oxford, United Kingdom

Objective: To assess the comparative efficacy of biologics for the treatment of moderate to severe psoriasis.

Methods: A systematic literature review was conducted to identify all randomized, controlled trials (until October 2008) evaluating the efficacy of approved biologics (adalimumab, efalizumab, etanercept, and infliximab) for the treatment of moderate to severe psoriasis. As regulatory approval of ustekinumab in this indication is anticipated shortly, three Phase 3 trials of ustekinumab were also included in this review. A network meta-analysis (NMA) conducted on the ordered probit scale was conducted to evaluate the comparative efficacy of the biologics based on the Psoriasis Area and Severity Index (PASI) responder endpoints. The absolute probability of PASI 50, 75 and 90 responses were estimated.

Results: A total of 20 studies enrolling 10,108 psoriasis patients, including 1 head-to-head trial of etanercept and ustekinumab, were identified and included in the NMA. 13 studies evaluated TNF-alpha inhibitors (adalimumab =3, etanercept =6, infliximab =4), 5 studies evaluated T-cell modulators (efalizumab =5), and 3 studies evaluated ustekinumab. Baseline patient characteristics were comparable across the trials. The estimated mean PASI 75 responses were as follows: infliximab (mean 80%; 95% CI 70-87%), ustekinumab 90mg (74%; 68-80%), ustekinumab 45mg (69%; 62-75%), adalimumab (58%; 49-68%), etanercept 50mg biw (52%; 45-59%), etanercept 25mg biw (39%; 30-48%), efalizumab (26%; 21-32%), and supportive care/placebo (4%; 3-4%).

Conclusions: Based on this analysis, all of the active treatments produced a greater response rate than placebo. Ustekinumab and infliximab had the highest mean response rates followed in order by adalimumab, etanercept and efalizumab. However, there was considerable overlap in the 95% confidence intervals.

Commercial Support: None Identified

P2329

Clinical trial on the efficacy of turmeric extract plus ultraviolet-A phototherapy for the treatment of patients with moderate to severe plaque psoriasis

Manuel Asin Llorca, MD, Centro Dermatologico Estetico, Alicante, Spain; Ana Ramirez-Bosca, PhD, MD, Centro Dermatologico Estetico, Alicante, Spain; Asuncion Martinez Andres, MD, Centro Dermatologico Estetico, Alicante, Spain; Jose Francisco Horga de la Parte, MD, Instituto de Bioingenieria, Elche, Spain

Background: Several experimental models and topical administration studies in humans strongly support the potential usefulness of systemic administration of curcumin in the treatment of psoriasis. However, curcumin alone, without ultraviolet phototherapy, have not showed any therapeutic benefits over those expected from placebo.

Objectives: A pilot clinical trial was designed to assess the efficacy of turmeric extract associated with ultraviolet-A phototherapy (UVA) in patients with moderate-to-severe chronic plaque-type psoriasis.

Methods: This was a phase IV, single arm, single dose, non-controlled, open-label, unicenter clinical trial of orally administered 600mg/d Curcuma Longa extract ZCL4 in patients with moderate-to-severe chronic plaque psoriasis. UVA phototherapy treatment (two sessions per week) started within 48-72 hours after the first dose of turmeric extract ZCL4. Physician's global assessment (PGA) and Psoriasis Area and Severity Index (PASI) scores were assessed at each visit. Treatment was administered up to 8 weeks or until a PASI reduction >90% from baseline was achieved.

Results: Twenty-two patients were included in the trial (74% males and 36% females). At the end of study, 80% of patients achieved the PGA category of "clear" or "almost clear", in some cases after only 5 treatment sessions. The median time to achieve a PASI reduction >75% was 30 days (95% CI 23-37 days). At 45 and 65 days after started treatment 80% and 100% of patients, respectively, achieved a PASI reduction >75% (treatment responders). Twenty-five percent of the patients were considered as responders within 15 days of the treatment initiation. Most of the treatment-related adverse events were mild. Limitations: The study was relatively small and non-controlled. Further studies that involve head-to-head comparison with other treatment modalities are needed.

Conclusions: The results of this pilot clinical trial suggest that Curcuma Longa extract ZCL4 in association with UVA phototherapy induces a relevant therapeutic response in patients with moderate to severe chronic plaque psoriasis. Turmeric extract effect is rapid in onset and its efficacy seems at least comparable to recommended first-line treatments.

Commercial Support: 100% is sponsored by Asac- Pharma Laboratory

P2330

Efficacy and safety of ustekinumab in the treatment of moderate and severe psoriatic patients: An open-label study

Rafael Jiménez Puya, MD, Reina Sofia University Hospital, Córdoba, Spain; Francisco Gómez García, MD, Reina Sofia University Hospital, Córdoba, Spain; José Carlos Moreno Giménez, MD, Reina Sofia University Hospital, Córdoba, Spain; Rafael Salido Vallejo, MD, Reina Sofia University Hospital, Córdoba, Spain

Objective: To evaluate the efficacy and safety of the treatment of ustekinumab in the treatment of moderate to severe in plaque psoriasis.

Methods: A total of 12 patients with moderate to severe psoriasis have been treated with adalimumab during a period between 1 and 3 months (open-label study). Patients received an induction with a subcutaneous dose of 45 mg (in patients with a weight <220 pounds) or 90 mg (if > 220 pounds) and a second dose one month after the first. The dose of maintenance (45 or 90 mg according to the weight) is every three months. In the basal visit were collected: demographic data (age, gender), Psoriasis severity index (PASI) and Dermatology Life Quality Index (DLQI). Concomitant disease and adverse events were collected during the treatment period.

Results: 12 patients were included (91,6% male and 8,4% female), mean age 46,0 years. Initial results show both PASI50 and 75 at week 4 in a 37,5% and 62,5%, respectively. 37,5% show a PASI90. Mean basal DLQI is 8, mean DLQI at week 4 is 2. We have not observed any concomitant adverse events so far.

Conclusion: Ustekinumab provided clinically meaningful benefit to patients with chronic plaque psoriasis in the clinical setting. Ustekinumab was well tolerated and not present severe adverse effects directly related with the drug in this period of time.

Commercial Support: None Identified

P2331

ICD solution improves scalp psoriasis and quality of life over 8 weeks of home use: Results from a self-assessment survey

Barbara Green, MS, NeoStrata Company, Inc., Princeton, New Jersey, United States; Brenda Edison, NeoStrata Company, Inc., Princeton, New Jersey, United States; Irina Brouda, NeoStrata Company, Inc., Princeton, New Jersey, United States

BACKGROUND: Scalp psoriasis affects 50-80% of psoriasis sufferers. Its symptoms include mild to severe scaling, flaking, and itching. Shampoos containing coal tar or liquor carbonis distillate (LCD) are commonly used to treat scalp psoriasis but may provide limited effectiveness due to the short contact time afforded by a wash off formulation. A new over-the-counter (OTC) medication containing 15% LCD solution was found to be more effective in treating body psoriasis than the leading non-steroid prescription topical, was shown not to stain hair, and was now tested in scalp psoriasis.

OBJECTIVE: To determine the effectiveness of LCD solution in adult scalp psoriasis through user self-assessment.

METHODS: Adults with self-reported scalp psoriasis were recruited using an online questionnaire. Interested volunteers were interviewed by clinical personnel and mailed a consent form. Upon its return, they were emailed a baseline questionnaire. Participants who returned the baseline questionnaire were mailed LCD solution (NeoStrata Company, Inc.). For 8 weeks, participants applied LCD solution to psoriasis lesions on the scalp once daily for 30 minutes prior to washing their hair. Participants completed additional questionnaires at weeks 4 and 8.

RESULTS: 137 adults responded online, but 128 were excluded because they couldn't be reached, declined to participate, did not return documents, or were ineligible. Nine participants received LCD solution, 1 participant withdrew due to difficulty with application routine, and 8 participants completed the study. Participants who completed 8 weeks of therapy reported almost clearance (4/8), marked improvement (1/8), or moderate improvement (3/8) in scalp psoriasis. Participants also reported significant improvements in appearance and quality of life as well as in self-graded disease parameters such as scalp area involvement (45% improvement), flaking (55%), itching (53%), overall severity (46%), and discomfort (56%). Finally, they reported that the treatment worked, was easy to use, cosmetically acceptable, and preferable to previously used OTC steroid solution and/or tar shampoo.

DISCUSSION: Although internet-based recruitment was a challenge in this study, the success of the participants who completed therapy indicates that LCD solution is a good option for individuals who seek an effective and cosmetically acceptable OTC medication for scalp psoriasis.

Commercial Support: 100% sponsored by NeoStrata Company, Inc.

P2332

Pityriasis rubra pilaris treated successfully with adalimumab

Adriana Lombardi, UMDNJ RWJ Department of Dermatology, Somerset, New Jersey, United States; Babar Rao, MD, UMDNJ RWJ Department of Dermatology, Somerset, New Jersey, United States; Cindy Wassef, UMDNJ RWJ Department of Dermatology, Somerset, New Jersey, United States

Pityriasis rubra pilaris is a chronic papulosquamous disorder characterized by follicular hyperkeratosis on an erythematous base, reddish orange scaly plaques, and palmoplantar keratoderma. Known treatments, systemic and topical, are rarely effective. Our patient, a 62 year old male with a two year history of pityriasis rubra pilaris failed to improve with topical, retinoids, and ultra violet therapy. Biologics have rarely proven effective. Our patient improved drastically after eight weeks of adalimumab. This case report suggests that biologic therapies should be considered as a viable treatment for PRP provided that there are no contraindications.

Commercial Support: None Identified

SURGERY (COSMETIC)

P2400

Time to onset of response to treatment of glabellar lines: A subset analysis of phase III clinical trials of a new botulinum toxin type A

Joel Schlessinger, MD, MD, Advanced Skin Research Center, Omaha, Nevada, United States; Gary Monheit, MD, Total Skin & Beauty Dermatology Center, Birmingham, Alabama, United States; Michael Kane, MD, The New York Eye and Ear Infirmary, New YorkNew York, United States

BACKGROUND: A new formulation of botulinum neurotoxin type A (BoNTA-ABO; abobotulinumtoxinA, Medicis Aesthetics Inc., Scottsdale, AZ) was approved in 2009 in the United States. BoNTA-ABO is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age.

OBJECTIVE: To determine time to onset of treatment response.

METHODS & MATERIALS: Time to onset was a secondary endpoint for 4 multicenter, double-blind, placebo-controlled, randomized phase III trials to evaluate the efficacy of BoNTA-ABO. Patients received a total dose of 50 to 80 units of BoNTA-ABO or placebo (n=1160 and 580 patients, respectively) administered at 5 injection sites in the glabellar region. Patients used a diary card to record their self-assessment of onset of treatment response on days 1 through 7 of each treatment cycle. Kaplan-Meier estimates were employed for the 4 individual study analyses and an integrated analysis of time to onset data from 3 of the 4 phase III studies (1 study was conducted on product from a different manufacturing source and was not part of the integrated analysis).

RESULTS: Response was documented by day 1 in individual studies for 13.4% to 32.5% of BoNTA-ABO patients and for 3% to 11% of placebo patients. Integrated analysis from 3 studies showed 19.7% of patients responded to BoNTA-ABO by day 1. Median time to onset was 2 to 4 days for the individual studies and 3 days for the integrated analysis.

CONCLUSIONS: BoNTA-ABO treatment demonstrates significant reduction in glabellar lines. In individual studies, up to 32.5% of patients experienced improvement within 24 hours, with a median time to onset

between 2 and 4 days. Median time to onset for placebo was 15 days. This study and poster were funded by Medicis Pharmaceutical Corporation.

Commercial Support: This study and poster were funded by Medicis Pharmaceutical Corporation.

P2401

Safety and efficacy of LIPO-102 (salmeterol xinafoate (SX) + fluticasone propionate (FP) for injection) for the reduction of abdominal subcutaneous fat

Stacy Smith, MD, Therapeutics Clinical Research, San Diego, California, United States; John Dobak, MD, Lithera, Inc., San Diego, California, United States; Kenneth Locke, PhD, Lithera, Inc., San Diego, California, United States; Murray Maytom, MBChB, Lithera, Inc., San Diego, California, United States

Objective: LIPO-102 is an injectable aqueous combination of salmeterol xinafoate (SX) and fluticasone propionate (FP) for selective, non-ablative fat reduction. This Phase 2a clinical study evaluated the safety and efficacy of 3 doses of LIPO-102 injected SC one or two times per week for 4 weeks in subjects with measurable abdominal SC fat.

Methods: Sixty male and female subjects, aged 18-65, with anterior abdominal skin-fold thickness of 30-50 mm measured with pinch calipers and a Body Mass Index ≥ 22 kg/m² and < 30 kg/m² were randomized to receive 1 mL injections of LIPO-102 (0.5 μ g SX + 1.0 μ g FP, 5.0 μ g SX + 1.0 μ g FP or 10.0 μ g SX + 1.0 μ g FP) 2 cm to the right or left of the umbilicus once or twice per week for four consecutive weeks. All subjects also received placebo injections on the contralateral side to the LIPO-102 injection site at the same frequency as LIPO-102. Safety and efficacy were evaluated weekly for 4 weeks and at 1 and 4 weeks post-treatment. Efficacy was assessed by waist circumference measurements, skin-fold pinch calipers, as well as 2D-ultrasound imaging.

Results: LIPO-102 was well-tolerated when administered either once or twice weekly SC into the abdominal subcutaneous fat of healthy subjects. The most commonly reported adverse events were mild, transient injection site pain (20%) and irritation (15%), most of which resolved spontaneously within five minutes. There was no inflammation, nodularity or skin atrophy on physical examination of the injected sites. There were also no clinically significant changes in blood pressure, heart rate, respiratory rate or temperature measurements. LIPO-102 was associated with reductions in waist circumference when administered once weekly. The 0.5 μ g SX + 1.0 μ g FP once-weekly treatment group experienced the greatest reductions in full waist circumference at 8 weeks (-3.47 cm, $p = 0.017$). LIPO-102 was also associated with reductions in abdominal skin-fold thickness when administered either once or twice weekly. The 5.0 μ g SX + 1.0 μ g FP once-weekly treatment group experienced the greatest reductions in skin-fold thickness at 8 weeks (-3.21 mm, $p < 0.001$). No change in weight was observed over the 8-week trial that might explain the reduction in abdominal adiposity.

Conclusions: Subcutaneous injections of LIPO-102 were well tolerated and produced significant reductions in measures of abdominal fat. LIPO-102 may offer a novel, minimally-invasive, non-ablative approach to localized fat reduction.

Commercial Support: 100% is sponsored by Lithera, Inc.

P2402

Ultrasound and radiofrequency for body contouring: Brazilian experience

Rafael Nunes, MD, Slim Clinique Laser Center and Bonsucesso Hospital - Dermatology Department, Rio de Janeiro, Brazil; Daniela Nunes, MD, Slim Clinique Laser Center, Rio de Janeiro, Brazil; Guilherme Nunes, MEd, Slim Clinique Laser Center, Rio de Janeiro, Brazil; Renata Marques, MD, Slim Clinique Laser Center And Bonsucesso Hospital - Dermatology Department, Rio de Janeiro, Brazil; Taissa Novis, MD, Slim Clinique Laser Center, Rio de Janeiro, Brazil

Background: In Brazil, the desire for body contouring improvements is more frequent than ever in everyday practice. The use of ultrasound and radiofrequency technology has become a common modality in the aesthetic market for non-invasive body contouring.

Study: 24 subjects, 22 females, 2 males, 19-60 years old (avg 34), body mass index 23-30 (avg 26,3), treated area: abdomen – 2 areas of 15cmx10cm during the same session. Subjects were submitted to 4 sessions, spaced 2 weeks apart. Treatment protocol comprised alternate ultrasound shear wave followed by unipolar radiofrequency.

Results: Photographs and circumference measurements were made at fixed reference points (upper, middle and lower abdomen) before and 2 weeks after the final treatment. Improvement in body contouring was noticed on all subjects. No adverse side effects were recorded during or after the treatment.

Conclusion: In the Brazilian experience the combination of ultrasound and radiofrequency has proven to be safe and effective for the purpose of body contouring and with a high subject satisfaction.

Commercial Support: None Identified

P2403

OnabotulinumtoxinA dose-ranging study for vertical lip muscle columns

Joel Cohen, MD, University of Colorado, Department of Dermatology, Denver, Colorado, United States; Steven Dayan, MD, University of Illinois, Chicago, Illinois, United States; Sue Ellen Cox, MD, University of North Carolina, School of Medicine, Chapel Hill, North Carolina, United States

Background: Physicians increasingly incorporate use of botulinum toxin into lower face regions and the vertical lip muscle columns are frequently treated. Despite the growing popularity of treating vertical lip muscle columns, there are few clinical data on onabotulinumtoxinA dosing in this field. Studying the safety and effectiveness of onabotulinumtoxinA in a controlled setting is beneficial to understanding treatment of hyperfunctional lines within the orbicularis oris, which lead to etched-in vertical lip lines.

Objective: To compare the safety, efficacy, and dose-response relationship of 2 doses of onabotulinumtoxinA in females with vertical lip muscle columns.

Methods: Female subjects (N=60) were randomized 1:1 to receive equivalent injection volumes of onabotulinumtoxinA at 4 sites (2 per lip) totaling 7.5U (5U upper lip; 2.5U lower lip) or 12.0U (8U upper lip; 4U lower lip). After the baseline visit, subjects returned for follow-up at weeks 2, 4, 8, 12, 16, and 20. Perioral Line Severity (POL) and Total Lip Satisfaction (a composite of 7 dimensions of satisfaction) were assessed by investigators and subjects at all visits. Responders were subjects who achieved a reduction of ≥ 1 point on the Investigator Assessment of Perioral Line Severity (maximum contraction) at week 4.

Results: Investigator-assessed mean POL severity was significantly reduced from baseline through week 20 for 12U ($P < .01$). Significant POL reduction for 7.5U persisted until week 16 ($P < .05$). Responder rates between the 2 groups were not significantly different until week 12 (12U, 79%; 7.5U, 36%; $P = .003$).

Subject-assessed Total Lip Satisfaction was significantly improved from baseline ($P < .05$) at all timepoints for both groups, except week 20 (12U; $P = .06$). Most adverse events (AEs) were mild to moderate in severity and resolved without sequelae. AEs were typical for onabotulinumtoxinA treatment in the lips, and the incidence was dose dependent.

Conclusion: OnabotulinumtoxinA provides significant reductions from baseline in POL severity and high levels of subject satisfaction. Lack of dose response and fewer AEs suggests that treatment of the upper and lower lip vertical muscle columns with 7.5U appears adequate for up to 14 weeks. A total dosage of 12U may provide a longer duration of correction, but carries potential for greater adverse events. These data will likely facilitate decisions on onabotulinumtoxinA dose and interval for combination or multimodal facial treatments.

Commercial Support: 100% supported by a grant from Allergan, Inc.

SURGERY (LASER)

P2500

Acne treatment with possible long term benefits in Asian patients

Jong Hee Lee, PhD, MD, Seoul National University Boramae Hospital, Seoul, South Korea

BACKGROUND: Various light based treatment modalities for acne can lead good results but often fail to maintain those effects.

OBJECTIVE: This study shows a comparative result between combining long pulsed Nd:YAG/KTP laser and long pulsed KTP laser alone in Asian patients with mild to moderate acne.

METHODS: Total of 25 Korean female patients with mild to moderate acne (skin type III to IV) were enrolled. Fifteen patients were treated with long pulsed Nd:YAG/KTP laser together and ten patients with long pulsed KTP laser alone. Each patient was treated twice a week for 3 weeks and no additional topical or oral treatment was allowed during and 8 weeks after the last treatment. Photographs were taken and lesion counts as well as patient's and physician's assessment surveys were performed.

RESULTS: Both group showed remarkable improvement (over 50% reduction of lesion counts) during the treatments. At 8 week follow-up after the last treatment, long pulsed Nd:YAG/KTP treated group showed statistically significantly less recurrences than in long pulsed KTP alone treated group and sustained the effect during treatment free period. No serious adverse effects were reported.

CONCLUSION: Combining Nd:YAG/KTP treatment may be excellent in acne controlling. It can be safely applied in Asian patients with possible long term benefits.

Commercial Support: None Identified

P2501

924nm, 975nm laser device: New approach to treat contour deformities produced by traditional liposuction

Rafael Nunes, MD, Slim Clinique Laser Center - Bonsucesso Hospital: Dermatology Department, Rio de Janeiro, Brazil; Daniela Nunes, MD, Slim Clinique Laser Center, Rio de Janeiro, Brazil; Guilherme Nunes, MEd, Slim Clinique Laser Center, Rio de Janeiro, Brazil; Leticia Silva, MD, Slim Clinique Laser Center, Rio de Janeiro, Brazil; Luciana Camara, MD, Slim Clinique Laser Center, Rio de Janeiro, Brazil

Background: Body Sculpting has been the objective of several procedures. Traditional liposuction can produce contour deformities as a complication. 924nm, 975nm laser device represents a new option of treatment for these deformities.

Study: 1 subject, male, 32 years old, severe contour deformity produced by cannula during a traditional liposuction in flanks was submitted to a 1 treatment with 924nm, 975nm laser device.

Results: The combination of 2 wave lengths (924nm, 975nm) in a laser lipolysis device allowed the correction of the contour deformity with no adverse effect. Subject referred high level of satisfaction.

Conclusion: Laser lipolysis device with 924nm, 975nm wave lengths showed to be an efficient and safe technique for the treatment of body contouring deformity.

Commercial Support: None Identified

P2502

Use of an 800nm diode laser for the treatment of facial telangiectasias

Otavio Macedo, MD, Clínica Dr. Otávio Macedo Ltda, São Paulo, Brazil; Melissa Fuzaro, MD, Clínica Dr. Otávio Macedo, São Paulo, Brazil

Background: Facial telangiectasias have been treated with a variety of laser wavelengths. Diode lasers, with appropriate skin cooling systems, are efficient light sources available and particularly well suited for clinical purposes. An 800nm wavelength laser (Light sheer Diode Laser System, Lumenis Inc., Santa Clara, CA) was evaluated to determine its effectiveness in clearing facial telangiectasias.

Objective: The primary objective is to evaluate the safety and effectiveness of pulsed 800nm diode laser for facial telangiectasias.

Materials and Methods: 40 female and 10 male patients, aged 30 to 70 years, with Fitzpatrick skin types I to IV with diffused facial telangiectasias, were submitted to a three-month treatment with 800nm diode laser, fluence rate varying from 30 to 45 J/cm², pulse durations of 10 – 100 ms and pulse frequencies of 1-5 Hz. Were excluded patients with previous history of photosensitivity and herpes virus infection.

Patients were advised to avoid sun exposure and to use sunscreen for 1 month before and after laser treatment. Close-up photographs were taken with a Canfield Visia CR System before the first procedure and 1 month after the last session. Patient's satisfaction surveys were also obtained at each follow-up visit (after 1 and 3 months post-procedure) on a 0 to 3 point scale (0- no clearing, 1-5 to 25% clearing, 2-25 to 50% clearing and 3-more than 50% clearing). The photographs were analyzed by three independent physicians and the facial telangiectasias were measured. Diode laser treatment was performed without anesthesia and was well tolerated.

Results: In the post-laser period a minor swelling and erythema are normally found and gradually faded within 1-2 days. All 50 patients cleared 25 to 50% or more than 50% of facial telangiectasias, and reported an overall subjective improvement in the quality of their skin without side effects. There were 5% of hyperpigmentation and no hypopigmentation in the study.

Conclusion: In this current study, the 800nm laser provided safe and effective treatment for facial telangiectasias with minimal downtime, no side effects and also improved the signs of photodamage.. It can be an alternative of non-ablative rejuvenation treatment

Commercial Support: None Identified

P2503

Q/S Nd YAG laser in pigmented lesions an egyptian experience

Abd Elaziz Eltaweel, MD, MSD, Cairo, Egypt

A variety of lasers can be used to treat pigmented lesions of the skin. These can be categorized into lasers that are pigment nonselective, those that are somewhat pigment selective, and those that are highly selective for pigment removal. Pigment nonselective lasers such as the carbon dioxide (10,600 nm) and erbium:YAG (2940 nm) lasers can be used to eliminate epidermal pigment because of their ability to target water and remove the entire epidermis, including melanocytes and melanized keratinocytes, in a traumatic fashion. Pigment is removed as a secondary event. Numerous clinical studies have confirmed the efficacy and safety of Q-switched lasers in the treatment of various epidermal pigmented lesions, including ephelides, lentiginos , cafe-au-lait macules , seborrheic keratoses, nevi spilus, and Becker's nevi . Pigment in epidermal lesions is located superficially, so shorter wavelength devices can be used effectively. This is an Egyptian experience in treatment of some pigmented lesions by Q/S ND YAG LASER. 15 patients of different color and different site of tattoo were treated in the period between July 1908 to May 1909 and the sessions were repeated each month, for about 6 sessions for each patient, and after the treatment by 3 months. And they were photographically taken before and after each session.

Commercial Support: None Identified