EADV CONGRESS
AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 243

A case of indeterminate cell histiocytosis treated with a topical Janus kinase (JAK) inhibitor

Hiroyuki Miura*[1], Yuya Nakanishi[1], Rai Fujimoto[1], Mayumi Takata[1], Sakuhei Fujuwara[1]

[1]Osaka Minato Central Hospital , Dermatology Department, Osaka, Japan

Introduction & Objectives:

Indeterminate cell histiocytosis (ICH) is a rare CD207-/CD1a+ histiocytes proliferating disease with clinical and histopathologic overlap with both Langerhans cell histiocytosis (LCH) and non-LCH. Clinically the lesions present as papules and/or nodules on the face, neck, trunk, or extremities. Langerin (CD207), which is used to identify Langerhans cells, is negative in ICH, and is a critical marker to distinguish ICH from LCH.

We report a case of ICH treated with a topical Janus kinase (JAK) inhibitor.

Materials & Methods:

Results:

A 50-year-old man presented with a 20-year history of plaques and papules with pruritus on his face. Histological examination demonstrated dermal infiltration of histiocytes immunohistochemically positive for CD1a and S-100 and negative for CD207, consistent with a diagnosis of indeterminate cell histiocytosis. After unsuccessful topical steroid and ultraviolet phototherapy, 0.5% delgocitinib ointment, a topical Janus kinase inhibitor, applied once daily was effective after 4 weeks. The treatment was continued for 24 months without recurrence.

Conclusion:

Delgocitinib, a novel topical small-molecule JAK inhibitor, has been used for atopic dermatitis, and it is also effective for ICH, a rare CD207-/CD1a+ histiocyte proliferative disease. It suggests the possibility of JAK-STAT pathway activation in ICH and effect of the drug on ICH by suppressing some pathogenetic interleukins.

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Abstract N°: 252

"Tri-Blend Triumph: Investigating a novel triple combination injection for recurrent keloids"

Dr Kalyani Deshmukh*[1]

[1]Dr. Deshmukh's The Skin Clinic, Nashik, India

Introduction & Objectives:

Introduction: Keloids are not only symptomatically distressing and aesthetically disfiguring, but also difficult to treat. Several therapeutic agents have been used to treat with moderate success. Hence, we introduce a novel triple combination injection treatment here – (bleomycin sulfate , triamcinolone acetonide, and hyaluronidase) in the hope of further symptomatic relief and preventing recurrence of these hard- to-treat lesions. To date, this is the first report of concomitant use of these three agents for treatment of recalcitrant keloids with noteworthy promising results. **Objectives:** To study the efficacy of a novel triple combination injection treatment (bleomycin sulfate ,triamcinolone acetonide, and hyaluronidase) in recalcitrant keloids in the hope of further symptomatic relief and preventing recurrence of these hard- to-treat lesions.

Materials / method: Twenty patients with recalcitrant and symptomatic keloids with were enrolled in this study. During this study, a novel triple combination injectable treatment constituting three active ingredients that are well known for treating keloids, i.e. triamcinolone acetonide, bleomycin sulfate, and hyaluronidase. A total 1 mL solution was reconstituted in 1mL of insulin syringe with all the drugs in in 1:1:1 proportion with one proportion of 2% lignocaine, and injected into the lesions at monthly intervals. Evaluation was performed using "Patient and Observer Scar Assessment Scale"(POSAS) score.

Results: All patients tolerated the triple combination injection well. The clinical improvement in our study as assessed by the POSAS was statistically significant as indicated in with more than 50% of the patients showing significant flattening and 30% showing complete flattening just after single treatment which is the highlight of this study. After two injection treatments, the percentage of

complete flattening increased remarkably from 30% to 55 %. Functional symptoms, like pruritus and pain subsided within one session. In the study, no patients developed recurrences 3 months post treatment.

Conclusion: This novel triple medicine cocktail therapy for keloids has been shown in this clinical evaluation to be quick in action with long lasting symptomatic relief. This treatment is rather inexpensive, easily available, with less duration and an effective treatment option that can be offered in the consulting/treatment room. The most hallmark of this study is that this combination offers promising results with one –two months of treatment. To date, this is the first report of using these three agents together with promising results.

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Abstract N°: 500

Micro-needling of irradiated amniotic collagen in the treatment of stretch marks

Nashwa Radwan[1]

[1]Egyptian Atomic Energy Authority, Radiation Health Research, Egypt

Introduction & Objectives:

Striae distensae (SD), often referred to as stretch marks, are common linear lesions seen in individuals of all ages. Many treatment choices are available, not yet satisfactory. Amniotic fluid contains many growth factors which can be helpful in treatment of stretch marks.

This study aimed to assess the efficacy and safety of irradiated amniotic collagen matrix with micro-needling in treatment of stretch marks.

Materials & Methods:

As a prospective, right-left comparative study; 40 patients with striae received 6 micro-needling sessions (session every two weeks), the right side treated with irradiated amniotic collagen matrix, and the left side treated with drug-free micro-needling. Patients were followed up for 3 months post-treatment. Skin biopsies were taken before and after treatments. The histological sections of each biopsy were stained with Masson trichrome and Orcein stains to confirm clinical response.

Results:

Significant improvements were shown after the treatment in both sides, and there was significant difference with better results in the right side than the left side according to the score of improvement degree, percent of improvement and start of response.

Conclusion:

The provided striae-treating procedure in this study is easy to be applied in clinics, safe, and effective for curing with minimal side effects.

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Abstract N°: 543

Measuring whole blood Hydroxychloroquine levels – a pilot study in a UK Dermatology department

Eleanor Clarke*[1], Neena Krishnan[1], Hywel Cooper[1], Alexa Shipman[1]

[1]Portsmouth Hospitals University NHS Trust, Dermatology, Portsmouth, United Kingdom

Introduction & Objectives:

Hydroxychloroquine (HCQ) is widely utilised within Dermatology in managing auto-inflammatory conditions such as cicatricial alopecia and cutaneous lupus. Blood level monitoring of HCQ has been explored to assess for sub-therapeutic dosing, non-compliance, and to minimise risks of adverse side effects. However, HCQ blood level monitoring is not routinely performed in the UK. Our Dermatology department (in collaboration with our Rheumatology colleagues) conducted a pilot study (n=26) alongside our Biochemistry department to measure random HCQ levels in our shared patient population.

Materials & Methods:

Our Biochemistry colleagues developed a technique which utilised liquid chromatography coupled with tandem mass spectrometry to accurately measure HCQ levels in whole blood samples. We collected random blood samples in EDTA tubes to monitor whole blood HCQ levels in 21 Dermatology patients and 5 Rheumatology patients.

Results:

HCQ blood levels ranged from 73.2-2408 ng/mL in our patient population. For those taking 200mg daily the levels ranged from 224-1541 ng/mL and for those on 400mg daily they ranged from 73.2-2408 ng/mL. (Figure 1).

There is no standardised target therapeutic HCQ blood level at present, the range 500-1000 ng/mL is often used in research, with a level of <200ng/mL or below as the cut-off for non-adherence. 1 patient had a level indicative of non-compliance (i.e. <200 ng/mL). Only 6 of the 26 patients had a level considered therapeutic of between 500-1000 ng/mL.

Due to our limited sample size, statistical analysis was limited. We did note a moderately positive correlation between the total daily dose of HCQ/kg and blood HCQ level with a correlation coefficient of 0.63 (although this was only able to be calculated for 24 of the 26 patients due to missing data points). This correlation was not seen between total daily dose of HCQ and blood HCQ level (correlation co-efficient of 0.40).

Conclusion:

Figure 1 This was a small pilot study and so drawing conclusions about the utility of HCQ blood level monitoring is not possible. However, what we have noted is that blood levels of HCQ between patients on the same dose can vary significantly, and this may well have implications for their disease control and risk of toxicity. While in our cohort of patients, there was a suggestion that weight-based dosing may be relevant when attempting to achieve target blood HCQ levels, this hasn't been replicated in larger studies. Additionally, it would be valuable to further assess whether these measured HCQ blood levels are stable across time, as there have been some early reports of intra-patient fluctuations of measured blood HCQ levels over a 24

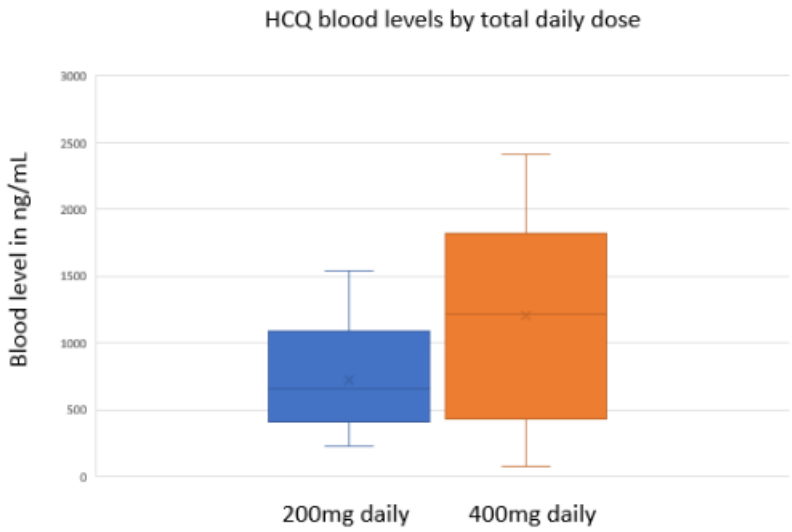

Figure 1

hour period post ingestion.

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Abstract N°: 571

Efficacy and safety of glycopyrronium bromide 1% cream in axillary and extra-axillary primary hyperhidrosis: A real-life two-centre experience on 37 subjects

Anna Campanati[1], Andrea Marani*[1], Helena Gioacchini[1], Federico Diotallevi[1], Sara Lambiase[2], Virginia Maffei[2], Luca Bianchi[2], Elena Campione[2]

[1]Dermatological Clinic, Department of Clinical and Molecular Sciences, Polytechnic Marche University, Ancona, Italy, [2]Dermatological Clinic, University Tor Vergata, Rome, Italy

Introduction & Objectives:

Glycopyrronium bromide (GPB) 1% cream is a recently authorized drug treatment for primary axillary hyperhidrosis (PH). In these patients, GPB has been demonstrated to reduce sweat production by 64% in comparison with baseline with a significant improvement of the Hyperhidrosis Disease Severity Score (HDSS) and Hyperhidrosis Quality of Life Index (HidroQoL) (Abels, 2021). So far, there are no clinical data regarding the efficacy and safety of GPB cream when used in other body areas such as palm, plantar and craniofacial regions (out-of-label use). We report the real-life experience of two tertiary hyperhidrosis dermatology clinics in Italy of the use of GPB for both axillary and extra-axillary localizations in subjects with PH.

Materials & Methods:

We evaluated 37 subjects with HP, 16 women and 19 men; mean age of 40 years. Seventeen subjects (46%) suffered from axillary PH, 5 subjects (13%) with multiple localization PH (axilla, palm and plantar), 7 subjects with palmar-only PH (19%) and 7 subjects with craniofacial PH. Previous treatments were utilized in thirteen subjects (35%). PH was on average present for 23 years. The main efficacy outcomes were the evaluation of HDSS (4-point), HidroQol (36-point) and the 4-item Axillary Sweating Daily Diary (ASDD). Treatment with GPB cream of the affected areas was performed with one application per day for a month (T1) and one application every other day for an additional two months (T2).

Results:

All the subjects but five (13%) completed the three-month treatment period. HDSS score before treatment was 3.3±0.8, HidroQoL 28±8 and ASDD (n=17) 12±3. HDSS was reduced significantly (p=0.0001) to 1.1±1.6 at T1 and to 1.3±1.3 at T2 (-67% and -61% respectively in comparison with baseline). HidroQol was reduced to 8±11 (T1) and 10±10 (T2) (-72% and -65% vs. baseline; p=0.0001). Two subjects with craniofacial PH dropped out due to adverse events (transient blurred vision and urinary hesitancy). Three subjects dropped out due to lack of efficacy. As expected, GPB 1% cream was very effective in subjects with axillary PH where the ASDD score was reduced to 4.5±6 and 3.4±3 at T1 and T2, respectively. Lower efficacy was observed for axillary-palmo-plantar and palmar PH localizations in comparison with axillary PH (reduction of HDSS of -10% and -62% vs. -79%, respectively).

Conclusion:

Our real-life experience with GPB 1% cream confirmed that this treatment is very effective and safe in axillary PH. Moderate-good efficacy was observed also for palmoplantar localizations. The use of GPB cream is not to be recommended in craniofacial PH localization due to the risk of side effects.

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Abstract N°: 633

Actinic cheilitis: Diagnosis and monitoring after treatment with Tirbanibulin using optical coherence tomography

Sarah Hobelsberger[1], Roland Aschoff[1]

[1]University Hospital Carl Gustav Carus Dresden, Klinik und Poliklinik für Dermatologie, Dresden, Germany

Actinic cheilitis: Diagnosis and monitoring after treatment with Tirbanibulin using optical coherence tomography

Actinic cheilitis has a significantly higher risk of developing squamous cell carcinoma than actinic keratoses. Therefore, initiation of treatment is crucial. In daily practice, punch biopsy is used to diagnose actinic cheilitis. Non-invasive imaging devices such as optical coherence tomography use near-infrared light to visualize the lip to a depth of 1-2 mm.

We used OCT to examine a 75-year-old patient with actinic cheilitis who had not yet undergone a biopsy. Signs on OCT were hyperreflective thickened entrance signal, thickened stratum corneum, thickened epidermis with disturbed architecture, hyperkeratosis and ulceration. As the dermoepidermal junction was fully visible, SCC could be excluded. Hyporeflective areas and vessels were seen in the dermis.

As invasive SCC was ruled out by OCT, we decided to start treatment immediately.

Vermilionectomy has shown a good cure rate in previous studies, but patients often suffer from postoperative problem with sensitivity. Non-surgical treatment options have been reported in small cohort studies, including local treatment with diclofenac, photodynamic therapy and imiquimod. There are currently no approved topical treatments for actinic cheilitis.

Tirbanibulin is a Src kinase signaling inhibitor and tubulin polymerisation inhibitor used to treat actinic keratoses of the head and face. As the drug induces apoptosis of tumor cells rather than necrosis, side effects are mild. To date, there have been no systemic reactions following local treatment with Tirbanibulin. Systemic exposure to Tirbanibulin was low in patients treated with topical Tirbanibulin. In addition, studies with much higher doses of oral Tirbanibulin have been conducted in patients with prostate cancer and acute myeloid leukemia with only mild to moderate side effects.

The patient was treated with Tirbanibulin ointment once daily for 5 days.

The patient was seen one week and two weeks later to monitor for possible side effects. There were mild side effects such as minimal lip swelling, erythema, crusts, and scaling.

After two months, the patient was re-evaluated with OCT. The thickness of the epidermis was normal, the dermoepidermal junction was visible and there were no increased vessels in the dermis. The lip was healed clinically and on OCT. Follow-up examinations are planned at three-month intervals for 12 months.

This patient’s actinic cheilitis healed completely after treatment with Tirbanibulin. Optical coherence tomography could be a useful tool for the diagnosis of actinic cheilitis and for monitoring therapy. However, punch biopsy should be performed in unclear cases to exclude squamous cell carcinoma.

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Abstract N°: 673

Arteriosclerosis derived from cutaneous inflammation is ameliorated by the deletion of IL-17A or IL-17F

Takehisa Nakanishi*[1], Shohei Iida[1], Yoshiaki Matsushima[1], Kento Mizutani[1], Yuichi Nakayama[1], Kyoko Sugioka[1], Mai Nishimura[1], Ai Umaoka[1], Makoto Kondo[1], Koji Habe[1], Keiichi Yamanaka[1]

[1]Mie University Graduate School of Medicine, Dermatology, Tsu, Mie, Japan

Introduction & Objectives:

In recent years, organ damage associated with inflammatory skin diseases such as psoriasis and atopic dermatitis has been a heightened focus, and vascular disorders such as arteriosclerosis is one of the serious complications of chronic inflammatory skin diseases. However, the detailed mechanism of arteriosclerosis in dermatitis and the role of cytokines have remained unexplored.

Materials & Methods:

Using a spontaneous dermatitis model of mice overexpressing human caspase-1 in the epidermal keratinocyte (Kcasp1Tg), we investigated the pathophysiology of arteriosclerosis and the treatment options for inflammatory skin conditions.

Results:

Kcasp1Tg showed a reduction in the diameter of the abdominal aorta in comparison to the wild type. mRNA levels for six genes (*Apol11b, Camp, Chil3, S100a8, S100a9, and Spta1*) were increased in the aorta of Kcasp1Tg. A similar upsurge in mRNA levels was observed in the co-cultured vascular endothelial cells, smooth muscle cells, and fibroblast cells with major inflammatory cytokines such as IL-17A/F, IL-1β, and TNF-α. Dermatitis improved, and mRNA levels were partially ameliorated in Kcasp1Tg with IL-17A/F deletion. IL-17A, F, and A/F deleted mice had larger arterial perimeters than the wild type, suggesting that excess IL-17A and F may lead to arterial narrowing. In the abdominal aorta, stenosis was found in the inflammatory model, and its improvement was demonstrated by IL-17 deletion. We speculated that vascular endothelial cells are affected by proinflammatory cytokines in the bloodstream. Although arterial fragility was also evidenced in the inflammatory model, the snap tension in the abdominal aorta revealed the arterial wall elasticity in IL-17A/F-deficient mice.

Conclusion:

Severe dermatitis is closely related to secondary arteriosclerosis caused by the persistent release of inflammatory cytokines. The results proved that the potential therapeutic benefit of targeting IL-17A and F could ameliorate arteriosclerosis.

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Abstract N°: 883

Patients' self-treatment with systemic antifungal drugs

Nadezhda Ershova*[1], Natalya Portnyagina[1], Elena Krylyshkina[2], Irina Sergeeva[1]

[1]Novosibirsk State University, Novosibirsk, Russian Federation, [2]Novosibirsk Regional Clinical Dermatovenerological Dispensary

Introduction & Objectives: There are few systemic antifungal drugs available for the treatment of mycoses. At the same time, a self-medication with systemic antifungal drugs contributes to the growth of resistance to them. The use of antimycotics without the doctor's prescription, increases the situation.

Objective. To analyze the causes and results of patients' self-adminidtration of systemic antifungal drugs.

Materials & Methods: 30 patients (aged from 18 to 88 years) who use systemic antifungal drugs without visiting the doctor. The presence of a fungi was confirmed by direct microscopic examination of skin and nail samples, by microscopy of a native and stained smear from the urogenital tract, cultural study to identify Trichomonas vaginalis, and PCR study to identify N.gonorrhoeae, M.genitalium, M.hominis, U.parvum, U.urealyticum, C.trachomatis.

Results: The most common situation of self-medication with systemic antimycotic drugs was the suspicion of fungal infection of the nail plates in 17 (56.7%) patients and of recurrent vulvovaginal candidiasis in 8 (26.7%) patients. The reasons for self-medication were also suspicions of fungal infection of the skin in 3 (10.0%) patients, of the scalp in 1 (3.3%) patient, and of gastrointestinal tract in 1 (3.3%) patient. Fungal infection was laboratory confirmed only in 13 (43.3%) patients, while in 17 (56.7%) it was excluded. Young patients 16 (53.3%) used self-medication with systemic antimycotic drugs more often. The main source of information about treatment was the Internet - for 11 (36.7%) patients, rarely recommendations of friends and pharmacists - in 5 (16.7%) patients and the previous medical education - in 3 (10%) patients. The treatment prescribed earlier by a doctor and then repeated by the patient was used by 6 (20.0%) patients. 17 (56.7%) patients used fluconazole. Terbinafine was used by 8 (26.7%) patients, itraconazole by 5 (16.7%). Six patients (20%) used a combination of local and systemic antifungal drugs.

Conclusion: The most common reason for self-medication with systemic antifungal drugs was nail changes. The diagnosis of a fungal infection was not confirmed in 56% of cases.

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Abstract N°: 1118

Safety and Efficacy of Oral Gabapentin vs Carvedilol for the Treatment in Patients with Erythematotelangiectatic Rosacea: A Randomized Clinical Trial

Jian Li[1], Wang Zhang[1]

[1]Southwest Hospital, Third Military Medical University, Chongqing, China, Dermatology Department,, ChongQing

Introduction & Objectives: The treatment of facial flushing and erythema in patients with erythematotelangiectatic rosacea (ETR) is challenging owing to commonly accompanying extra facial and extracutaneous manifestations such as sleep disorders, migraine, anxiety, and depression. Gabapentin might be beneficial in patients with ETR, but has not been rigorously evaluated in large randomized clinical trials. We conduct this trail to verify whether gabapentin (300 mg, thrice per day) is noninferior to carvedilol (5 mg, twice per day) in the treatment of patients with ETR.

Materials & Methods: This is a randomized, controlled noninferiority trial in patients with ETR with open-label and concealed allocation. Enrollment began in October 2023 and ended in February 2024. Follow-up ended in March 2024. The principal investigator and outcome assessors were blinded to group allocation, but treatment condition was not blinded for participants or therapists. 315 Patients with ETR accompanied by Clinician's Erythema Assessment (CEA) score (assessing the patient's facial erythema condition, ranking severity on a scale from 0 to 4) of ≥ 2 were randomized selected from the dermatology department of the Southwest Hospital in China. Patients were randomized to receive oral treatment for 12 weeks (either gabapentin or carvedilol) and follow-up for 4 weeks without any treatment. The primary outcome was a masked CEA score after 12 weeks of treatment, The predefined noninferiority margin was 0.5 points on the CEA. Secondary outcomes are composed of the improvement of erythema and facial flushing, sleep disorders, migraine, anxiety, and depression after 12 weeks by clinical measurement tools.

Results: A total of 315 participants (287 females, 28 males; mean [IQR] age, 33.9 [26-42] years) with ETR were randomized: gabapentin (n = 163) or carvedilol (n = 152). At week 12, the mean CEA score was 1.03 points in the gabapentin group vs 0.89 points in the carvedilol group, corresponding to an estimated mean difference was 0.21 points ([1 side 95% CI, 0.04 to 0.38]; P for noninferiority = 0.014). Meanwhile, gabapentin induced faster relief of facial flushing in the early stage (week 4) and dramatically improved the status of sleep disorders and migraine as reflected by a lower PSQI and VAS score compared with carvedilol with no obvious side effects during treatment and follow-up.

Conclusion: Treatment with gabapentin compared with carvedilol resulted in a noninferior difference in improving facial flushing and erythema of rosacea. And gabapentin has unique position to ETR accompanied by sleep disorders or migraine.

TRIAL REGISTRATION: ClinicalTrials.gov Identifier: ChiCTR2300076342

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Abstract N°: 1188

Self-reported disease severity and treatment of Chronic Hand Eczema from the CHECK study - A multinational study in six countries

Sonja Molin*[1], Maria Concetta Fargnoli[2], Marie-Noëlle Crepy[3], Ana Giménez-Arnau[4], Lysel Brignoli[5], Brian Dwyer[5], Michal Krupka[6], Jenny M. Norlin[6], Christian Apfelbacher[7], Anthony Bewley[8]

[1]Queen's University, Division of Dermatology, Kingston, Canada, [2]University of L'Aquila, Department of Biotechnological and Applied Clinical Sciences, L'Aquila, Italy, [3]University Hospital of Centre of Paris , Department of Occupational and Environmental Diseases, Hotel-Dieu Hospital, and Department of Dermatology, Cochin Hospital, AP-HP, Paris, France, [4]Universitat Pompeu Fabra, Department of Dermatology, Hospital del Mar Research Institute, Barcelona, Spain, [5]Oracle Life Sciences, Paris, France, [6]LEO Pharma A/S, Ballerup, [7]Otto-von-Guericke University Magdeburg, Institute of Social Medicine and Health Systems Research, Magdeburg, Germany, [8]Barts Health NHS Trust & QMUL, London, United Kingdom

Introduction & objectives: Chronic Hand Eczema (CHE) ranges from mild, typically managed with emollients and prevention, to moderate-to-severe, requiring potent topical corticosteroids (TCS) or systemic treatment. Few studies have investigated CHE disease severity and treatments in clinical practice. The objective of this study was to investigate self-reported disease severity, symptoms, and treatments in CHE, focusing on participants treated with TCS.

Material & Methods: CHECK (Chronic Hand Eczema epidemiology, Care, and Knowledge of real-life burden) is a population-based study which recruited participants in Canada, Germany, France, Italy, Spain, and the UK aged 18-69 via online panels. A previously published photo-guide was used to assess severity in the past week. Visual Analogue Scales (0-10) were used to assess symptoms in the past 24 hours. Data were descriptively analysed.

Results: Among 60,131 respondents, 1,948 reported physician-diagnosed CHE and completed the full questionnaire. The overall mean (SD) age was 43.2 years (12.6), 64.5% were females. Around half of respondents had moderate-to-severe symptoms (n=994) and reported mild symptoms (n=953).

Current treatments included systemics or phototherapy, with or without topicals, in 10.7% (n=209), TCS, with/without other topicals, in 36.0% (n=702), other topicals only in 21.8% (n=424). 31.1% (n=606) reported no treatment. Six respondents could not recall treatment.

The majority, 76.7% (n=1494) had used TCS at some point, 17.1% (n=333) had never used TCS and 6.2% (n=121) did not know.

Of the respondents using TCS, 60.3% (n=423) assessed their current CHE as moderate-to-severe. Mean (SD) VAS for respondents with moderate-to-severe vs. mild CHE were 5.5 (2.3) vs. 3.6 (2.4) for itch, 4.1 (2.5) vs. 2.2 (2.2) for pain and 3.9 (2.8) vs. 1.9 (2.4) for sleep disturbances, respectively.

Conclusion: Despite the majority being on treatment, half of respondents reported moderate-to-severe symptoms of CHE. Respondents on TCS that had moderate-to-severe symptoms reported problems with itch, pain, and sleep disturbance, indicating a significant unmet need in this population

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Abstract N°: 1333

Heart-Centered Psoriasis Care: Acitretin and Cyclosporine Insights for Cardiovascular Vigilance

Son Mai[1, 2], Thomas Franck[3], Yves Mbama[4], Pauline Gouttefarde[3, 4, 5], Gilles Cizeron[1], Mathieu Oriol[1], François MacCari[6], Beatrice Trombert[5, 7], Jean-Luc Perrot[8, 9], Bienvenu Bongue[1, 10]

[1]Technical Support and Training Center for Health Examination Centers (CETAF), Saint Etienne, France,[2]Science Engineering, Health, Jean Monnet University, Saint Etienne, France, [3]Gérontopôle Auvergne Rhône Alpes (AURA), Saint Etienne, France, [4]PRESAGE, Jean Monnet University, Saint Etienne, France, [5]SAINBIOSE laboratory , Unit INSERM 1059 UMR, Saint Etienne, France, [6]Reso, Saint Etienne, France, [7]CHU of Saint Etienne, Saint Etienne, France, [8]Saint Etienne Dermatology University Hospital, Saint Etienne, France,[9]Laboratory of Tribology of Systems , UMR CNRS 5513, Saint Etienne, France, [10]Elderly Health, Jean Monnet University, Saint Etienne, France

Introduction & Objectives:

Psoriasis affecting 2-3% of the global population with complex clinical manifestations, poses a significant challenge to healthcare system. Among the psoriasis treated medications, cyclosporine has demonstrated efficacy in controlling psoriatic symptoms, while acitretin has a long-standing use as a cornerstone therapy for moderate to severe status. However, concerns regarding these drugs' effect drugs on cardiovascular risk demand particular attention. This scoping review aims to provide insights into cardiovascular risk factors among psoriasis individuals with cyclosporine and acitretin.

Materials & Methods:

Following PRISMA guidelines, PubMed, ScienceDirect, Cochrane Library, and Wiley Online Library were searched for English publications between 2013 and 2023. Screening was conducted based on titles and abstracts, followed by a full-text review.

Results:

The review included 10 publications, comprising 853,984 psoriasis patients. The literature presents conflicting evidence regarding the cardiovascular effects of acitretin. A cohort study in 2013 suggested a potentially favorable cardiovascular profile compared to non-methotrexate/retinoid drugs, while a longitudinal survey in 2015 unveiled an elevated cardiovascular risk compared to alternative therapies. On another hand, results from studies on cyclosporine showed a complex landscape, some indicating a lack of protective effects against cardiac events (CEs), while others highlighted potential elevated risks associated with cyclosporine use in certain subsets of patients, suggesting a need for cautious monitoring.

Conclusion:

The relationship between acitretin and cyclosporine on CEs is complex, emphasizing the importance of careful consideration and individualized treatment approaches based on disease severity and patient characteristics. Further research is warranted to elucidate the nuanced relationship between these medications and CEs, illuminating the intricate interplay.

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Abstract N°: 1388

Therapeutic success of tofacitinib in granuloma annulare: A retrospective case series

Vinay Keshava Murthy*[1], Anubha Dev[1]

[1]Postgraduate Institute of Medical Education and Research, Dermatology Venereology and Leprology, Chandigarh, India

Introduction & Objectives:

Granuloma annulare (GA) is a necrobiotic granulomatous disorder that may sometimes be resistant to treatment, especially the generalized form. Tofacitinib has recently shown promise in the treatment of non-infective granulomatous dermatosis. In this study we aimed to evaluate the response of generalized GA to oral tofacitinib.

Materials & Methods:

This was a retrospective case series in patients of generalized GA who were treated with oral tofacitinib 5 mg twice a day in a tertiary care center in north India. Baseline clinical details and histopathological findings were reviewed. Treatment response was noted in the form of clearance of lesions (complete or partial) along with the time taken to achieve the maximum response.

Results:

A total of 15 patients of generalized GA were included in this study, amongst whom nine patients were resistant to conventional therapies whilst the remaining were treatment naïve. Complete clearance of lesions was noted in eleven patients at a mean treatment duration of 4.4 ± 2.1 months whereas clearance was partial in four, with a mean follow-up duration of 4±1.4 months, with reduction in erythema and infiltration in those lesions. Adverse effects in the form of hyperlipidemia were observed in two patients.

Conclusion:

Tofacitinib, a JAK-STAT inhibitor is beneficial in treating GA especially in those with generalized and recalcitrant disease.

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EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 1571

Real-world evidence of tirbanibulin for actinic keratosis in Germany. Insights into patient-reported outcomes, safety and effectiveness

Markus Heppt[1], Ina Hadshiew[2], Afra Kempf[3], Antje Melzer[3], Carola Berking*[1]

[1]Uniklinikum Erlangen, FAU Erlangen-Nürnberg, CCC Erlangen - EMN, Dermatology, Erlangen,[2]DERMA Köln, Köln, Germany, [3]Almirall Hermal GmbH, Reinbek

Introduction & Objectives:

The synthetic tubulin polymerization inhibitor Tirbanibulin was developed for topical treatment of actinic keratoses (AK). A non-interventional study has been conducted in Germany aiming to evaluate patient-reported outcomes (PROs), effectiveness and safety of tirbanibulin in AK (treatment area of 25 cm2) in dermatology centers (BfArM NIS-No. 7589).

Materials & Methods:

Prospective, open-label, multicenter trial, V1 (day 0), V2 (optional, ~day 8-29), V3 (~day 57), and V4 (optional follow-up, ~day 240). Endpoints: Clearance of AK lesions, safety and tolerability incl. local skin reactions (LSRs), PROs, adherence and treatment satisfaction (physicians, patients).

Results:

543 patients at 58 sites, mean age 73 years (range 40 to 99), 67.8% male. Treatment localizations included face (56%), scalp (25%), and face/scalp simultaneously (19%). 54.9% had received prior treatments, mainly topical therapies, photodynamic therapy, or cryotherapy. The majority of patients adhered to a once daily 5-day application regimen. Compared to baseline, the number of AK lesions was reduced by 4.13 at V3 with statistical significance ($p<0.0001$), with the total number of lesions being reduced by 70%. The average number of AK lesions decreased from 5.9 (baseline) to 1.9 (V3) and to 1.6 (V4), corresponding to 73% lesion count reduction. Patient-related clearance rates at V3 were 37.4% (CR) and 55.0% (partial clearance ≥75%), and 45.8% (CR) and 64.3%** (partial clearance ≥75%) in the subgroup of patients with V3** between day 47 and 67** (adapted to SmPC, day57±10). At V3, 83.2% of physicians were very satisfied or satisfied with therapy outcome. 21.9% (34/155) of patients with 100% clearance at V3 showed lesion recurrence at V4. LSR (total values over all visits) included predominantly erythema (97.6%) and scaling (90.0%). Crusting (63.6%), swelling (20.8%), erosions/ulcerations (17.1%) and blistering (8.9%) were less frequent. LSRs were mostly mild to moderate. PROs have been analyzed as observed cases. A total of 91.5% patients rated the treatment results as completely improved (healed), significantly, moderately and slightly improved. 89% assessed the cosmetic outcome as much improved (60%) or somewhat improved (29%). Almost all patients (99%) would consider tirbanibulin again for an AK treatment (45% definitely, 28% certainly, 15% probably, 11% maybe).

Conclusion:

These real-world data confirmed the results of tirbanibulin pivotal trials. No new adverse reactions were observed. The 5-day short-term application showed a high level of acceptance. Most patients reported a convincing treatment result demonstrated by PGII assessment and improvement of cosmetic appearance in the treated areas. Nearly all patients would consider tirbanibulin again for an AK treatment. These PRO data highlight the benefits from a patient perspective.

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Abstract N°: 1611

Benefits of a low mineralized thermal spring water on sensitive skin: from a fine regulation of skin biomechanics to an overall clinical efficacy

Celine Mias[1], Theunis Jennifer[1], Noharet Julie[1], Sophie Baradat[1], Satge Camille[1], Delphine Vuillermoz[1], Julien Chlasta[2], Aline Stennevin[3], Gautier Doat[3], Sandrine Bessou-Touya[1], Helene Duplan[1]

[1]Pierre Fabre Dermo-cosmetique and Personal Care, R&D, Toulouse, France, [2]Biomeca, Lyon, France, [3]Direction médicale AVENE, Lavaur, France

Introduction & Objectives: The beneficial effects of a low mineral content thermal spring water (LM-TSW) on skin diseases have been recognized for more than two centuries. While the mechanisms of action by which LM-TSW exerts its therapeutic soothing effect are not fully understood, it has been shown to act on cell membrane fluidity, keratinocyte differentiation and to have antioxidative and anti-inflammatory properties. More recently, the influence of LM-TSW on skin biomechanics has been described in physiological conditions in vitro, by preserving skin biomechanics and integrity. The objective of this new study was to ascertain the influence of LM-TSW on sensitive skin, a common condition characterized by the occurrence of unpleasant sensations like tightness, pruritus, or tingling. Clinical evaluations and user perception parameters were combined with biomechanical analysis to evaluate the overall efficacy of LM-TSW on sensitive skin, compared to a competing mineral-rich TSW (MR-TSW).

Materials & Methods: The crossover clinical study was conducted on 24 subjects with sensitive skin, randomized into 2 groups: one receiving 6 daily sprays of LM-TSW on the entire face for 8 days, the other one receiving the MR-TSW with the same application frequency and time. All analysis were performed at day 0 and day 8 and consisted in evaluations of clinical score (skin sensitivity determined by sensitive scale), biometrological tests (hydration, elasticity, micro-relief), skin biomechanics (evaluated by atomic force microscopy), intercorneocyte cohesion imaging and user perceptions.

Results: After 8 days of repeated applications, LM-TSW induced an improvement of the sensitive scale and clinical parameters: cutaneous irritability, redness, tightness, general discomfort and sensation of heat. The skin microrelief was also positively modified after LM-TSW applications and characterized by a significant reduction in mean roughness, indicating a smoothing effect. In addition, this clinical benefit was correlated to significant modification of the skin's nanomechanical profile. A significant reduction in elastic modulus at the surface and depth of the stratum corneum, but also at the cellular level was observed, indicative of a better skin elasticity, compared to comparative group treated with MR-TSW. This biomechanical effect was associated with a better corneocyte cohesion in favor of a barrier strengthening of sensitive skin. Finally, LM-TSW promoted an improvement in use perceptions, described by a significant improvement in skin condition on all proposed items and a significantly softer, more comfortable perceived skin, compared to the competing MR-TSW group.

Conclusion: This global approach demonstrates, for the first time, the clinical efficacy of a low mineral content thermal spring water on sensitive skin through a fine regulation of the skin biomechanics, which lead to a considerable improvement in cutaneous symptoms of people suffering from sensitive skin.

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Abstract N°: 2023

Cimetidine as an Alternative Therapy for Pediatric Warts: A Comprehensive Review and Analysis

Reina Ibrahim[1], Myriam Boueri[2], Leah Nasr[2], Marie Line Chedid[3], Pia Amanzo[4], Nancy Emmanuel*[5]

[1]Faculty of Medicine, University of Balamand,, Koura, Lebanon,[2]Gilbert and Rose-Marie Chagoury School of Medicine, Lebanese American University, Byblos, Lebanon, Byblos, Lebanon, [3]Medical University of Lodz, Poland, Poland, [4]Facultad de Medicina, Universidad Peruana Cayetano Heredia, Lima, Peru,[5]Department of Dermatology, Hospital Das Clínicas of the Faculty of Medicine of the University of São Paulo, São Paulo, Brazil

Introduction & Objectives: This study investigates the prevalence and impact of pediatric warts, examines the challenging nature of their management, explores current therapeutic options, and delves into potential promising treatments. Cimetidine, an H2 receptor antagonist, is presumed to enhance the body's immunological response and promote T-cell function, potentially leading to wart clearance without the discomfort associated with conventional therapies. The study focuses particularly on evaluating cimetidine as a potential therapy, considering its immunomodulatory properties and existing evidence, aiming to provide valuable insights for informed decision-making in pediatric wart treatment.

Materials & Methods: A systematic literature search was conducted between September and November 2023 utilizing various databases. Five authors independently conducted searches, screened articles, and reviewed selected papers to ensure thorough data extraction and establish a robust foundation for analyzing cimetidine's efficacy in pediatric wart treatment.

Results: The results show the effectiveness of cimetidine in treating pediatric warts, with a success rate of approximately 74%, suggesting its potential for complete eradication. Notably, cimetidine significantly shortens the time to resolution, averaging around 12.3 weeks, which is crucial for timely intervention in pediatric care. While recurrence rates are relatively low at approximately 8.5%, ongoing follow-up remains essential. Furthermore, cimetidine's immunomodulatory mechanism, particularly at higher doses, enhances cell-mediated immunity, presenting promising avenues for further exploration in pediatric dermatology and emphasizing its potential as a valuable therapeutic option. However, it is important to note that cimetidine use has rarely been associated with impaired absorption of vitamin B12, potentially leading to symptoms of B12 deficiency, such as neurological issues, gastrointestinal symptoms, irritability, and behavioral problems. It may often lead to laboratory changes which call for close monitoring of laboratory tests, such as liver and kidney function tests.

Conclusion: In conclusion, cimetidine emerges as a promising therapeutic option for pediatric warts, showcasing encouraging outcomes with a significant resolution rate and relatively low recurrence. However, careful consideration of its pharmacokinetics, adverse effects, and interactions is essential before widespread adoption, suggesting the need for larger controlled trials and long-term studies to validate its efficacy and optimize dosages.

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Abstract N°: 2053

Daylight-PDT tolerance could be improved with a prebiotic and panthenol-containing dermocosmetic: Results of a randomized controlled trial in patients with Actinic Keratosis

Gabriella Fredman*[1], Kevin Jacobsen[1], Stine Regin Wiegell[1, 2], Merete Haedersdal[1, 2]

[1]Bispebjerg Hospital, Department of Dermatology, København, Denmark, [2]The University of Copenhagen, Faculty of Health and Medical Sciences, København, Denmark

Introduction & Objectives:

Treatment with daylight photodynamic therapy (dPDT) of actinic keratosis (AK) is associated with local skin reactions (LSR) including erythema, edema, and crusting. This down time may alter patients' quality of life and treatment acceptability. This study explores the potential of a prebiotic and panthenol-containing multipurpose healing dermocosmetic cream (DC) to enhance tolerance and mitigate post-dPDT-induced LSR in the treatment of AKs. ### **Materials & Methods:** In a randomized, intraindividual, controlled trial, 20 patients with ≥10 AKs on their face or décolleté underwent a single treatment session with dPDT on two symmetrical areas. Following dPDT, treatment areas were randomized to i) DC twice daily for 14 days and ii) No-DC. Primary outcome was clinical signs of LSR, graded from 0=none to 3=severe, calculated as a composite score, and assessed on Days 2, 7, 14, and 30 post-treatment. Objective non-invasive assessments included quantification of erythema, measured in arbitrary units (AU) (L*a*b* color space) using Cortex Colorimeter before dPDT as well as at each follow-up visit. ### **Results:** Topical application of DC following dPDT significantly improved post-treatment tolerance up to one week after treatment. By Day 2, significantly milder LSR developed in DC-treated skin (median composite score 3.0, interquartile range (IQR) 2.0-4.8) compared to skin areas with No-DC (median composite score 4.0, IQR 3.0-5.0; p=0.011). While *moderate or severe* erythema was seen in 55% (11/20) of DC-treated skin, it appeared in 100% (20/20) of areas with No-DC.

Objective measurements supported these observations, with milder erythema in DC-treated areas (median AU 21.98, IQR 18.0-28.47) than in areas with No-DC application (median AU 25.81, IQR 22.59-27.82, p=0.045). By Day 7, this significant trend continued with less intense LSR in DC-treated skin (median composite score 3.0, IQR 2.0-3.8) versus the No-DC control side (median composite score 4.5, IQR 3.0-5.8; p<0.001), which was reaffirmed by objectively measured lower intensity of erythema in skin undergoing treatment (median AU 22.77 vs. 26.69; p=0.005).

Additionally, crusting had resolved in a significantly greater proportion of DC-treated areas by Day 7, compared to No-DC control skin (75% vs. 40%; p=0.039).** On Days 14 and 30, the intensity of LSRs had resolved, and no differences were found between DC- and No-DC-treated skin. ### **Conclusion:** Application of a prebiotic and panthenol-containing multipurpose dermocosmetic cream significantly enhances tolerance from dPDT and accelerates healing time during first week after treatment.

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Abstract N°: 2057

Comparative study between topical tofacitinib 2 % ointment and methotrexate 1% gel in the treatment of localized alopecia areata.

Manisha Chandela*[1], Pretty Singla[1], Aarushi Solanki[1], Ashok Saxena[1], Sandip Mohanty[1]

[1]North DMC medical college and Hindu Rao Hospital, Dermatology, Venereology and Leprosy, New Delhi, India

Introduction & Objectives:

Alopecia areata is an autoimmune disease involving the hair follicle with a chronic, relapsing course. Treatment in the form of intralesional steroids is a painful and invasive procedure that requires repeated injections, which can affect patient compliance. We aimed to evaluate the efficacy of Tofacitinib 2% ointment versus Methotrexate 1% gel in the treatment of localized alopecia areata.

Aims and Objectives:

- To compare the efficacy of topical methotrexate 1% gel and tofacitinib 2% ointment in inducing hair regrowth in patients with localized alopecia areata.
- To analyze any differences in treatment response based on factors such as age, gender, and duration of alopecia areata.
- To assess the safety profile of both treatments in terms of side effects and tolerability.
- To determine the cost-effectiveness of both treatment modalities.

Materials & Methods:

- Patients were randomly divided into two groups: Group 1 received Tofacitinib 2% ointment, while Group 2 received methotrexate 1% gel. Both treatments were applied twice daily.
- No supplements were given to the patients
- Pictures were taken before initiation of treatment, 6 weeks, and 12 weeks after treatment.

Inclusion criteria

- 2 years of age or older
- localized patches of alopecia areata
- Stable or worsening disease for 6 months or longer
- No treatment taken
- No evidence of spontaneous hair regrowth

Exclusion Criteria:

- Received treatment known to affect alopecia areata
- History of malignancy, HIV, hepatitis B, or hepatitis C positivity, tuberculosis
- History of leukopenia or anemia
- History of renal or hepatic impairment

- Currently taking immunosuppressive medications
- Women who are pregnant or nursing
- Patients lost for followup.

Results:

Thirty patients were randomly assigned to each group, with 20 males and 10 females in both. In the tofacitinib group, after 6 weeks, 5 patients (18%) exhibited hair growth out of the total 30 patients. Among these, 4 were males and 1 was female. Conversely, in the methotrexate group, after 6 weeks, 4 patients (13%) showed regrowth, all of whom were males, with no females displaying regrowth.

After 12 weeks, both tofacitinib and methotrexate exhibited significant improvement, with rates of 52% and 47%, respectively. Methotrexate showed higher incidence of side effects such as erythema and itching compared to tofacitinib. The efficacy of both topical methotrexate 1% gel and topical tofacitinib 2% ointment in treating localized alopecia areata was high, with no significant differences observed between them based on clinical examination.

Conclusion:

- Topical tofacitinib shows an earlier response compared to methotrexate.
- It’s worth noting that the difference between the two groups is more pronounced at 12 weeks than at 6 weeks.
- The results suggest that Tofacitinib has a higher rate of improvement compared to Methotrexate at both 6 weeks and 12 weeks.
- However, it’s important to note that the difference between the two groups is relatively small.

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Abstract N°: 2219

Enhancement of sun-damaged skin qualities with tirbanibulin (SunDamage Study)

Daisy Kopera*[1]

[1]Medical University Graz, Graz, Austria

Introduction & Objectives: Actinic keratosis (AK) is caused by photo damage, distinctly by ultraviolet (UV) radiation. Subclinical stages of AK are present in epidermal layers before becoming clinically visible. The objectives were to assess efficacy and safety of the treatment with tirbanibulin, and the quality of sun-damaged skin before, immediately after and 2 months after the treatment by standardized VISIA® photography.

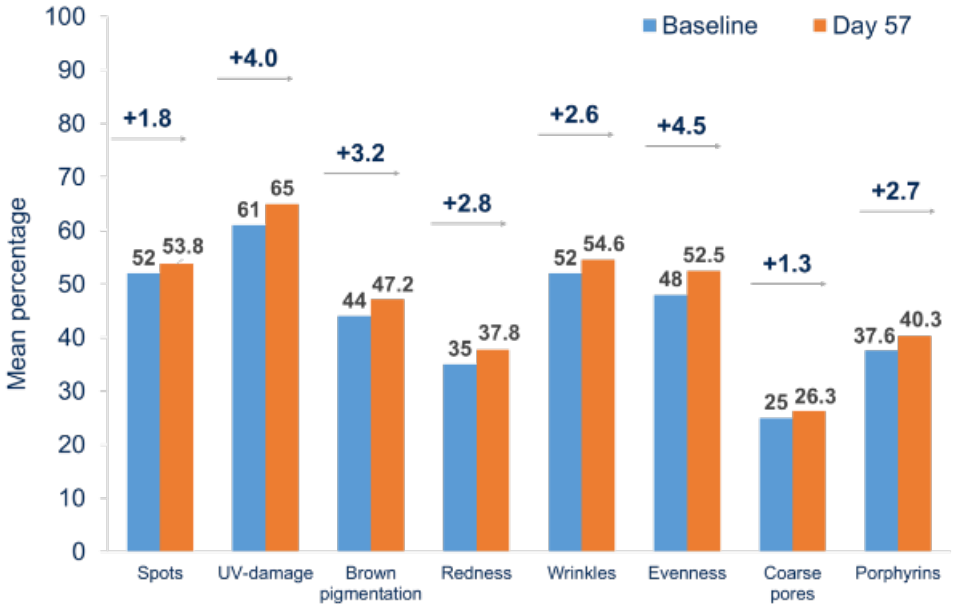
Materials & Methods: "SunDamage" is an interventional, monocentric, national, single-arm, uncontrolled, open, prospective phase IV study. Adult patients diagnosed with sun-damaged skin on the face applied tirbanibulin every night for 5 consecutive days. Disease specific skin parameters (AK lesions, subclinical lesions, sun damage, local skin reactions [LSRs] and other changes of the skin, including those not clinically relevant) were assessed both according to clinical routine and by VISIA® UV imaging1 at baseline, Day 8 (±2) and Day 57 (±7). Safety was analyzed by means of adverse events. LSRs were recorded and graded separately.

Results: A total of 26 patients completed the study (average age: 68 years; female: 58%). All patients presented sun-damaged skin, but no visible AKs. At Day 7, VISIA® measurements of the erythematous skin revealed higher values of redness by 8% points and roughness of the skin of 7% points. Thus, representing the mild LSR to tirbanibulin unmasking very early stages of subclinical AK as a symptom of sun damage. At Day 57, VISIA® measurements revealed improvement in all qualities of the skin in measured percentage points: spots: + 1.8, UV-damage +4.0, brown pigmentation +3.2, redness +2.8, wrinkles +2.6, evenness +4.5, coarse pores +1.3, porphyrins +2.7, revealing enhancement of sun-damaged-skin qualities (Figure 1). All patients developed mild erythema after application of tirbanibulin being visible on Day 7. At Day 57 there was no visible erythema. No safety concerns were observed.

Conclusion: These results confirm tirbanibulin to be effective, safe, and well tolerated in adult patients with facial sun damage. Moreover, tirbanibulin showed enhancement of 8 skin qualities measured by the VISIA system: spots, UV-damage, brown pigmentation, redness, wrinkles, evenness, coarse pores, and porphyrins. VISIA® can contribute to the characterization of sun damage severity and the monitoring of tirbanibulin treatment.

1Canfield Scientifc. VISIA: Redefining the Vision of Skin Care 2022. Available at: https://www.canfieldsci.com/imaging-systems/visia-complexion-analysis/ Accessed January, 2024.

Figure 1 Skin quality at baseline and at Day 57


Baseline
Day 57
Mean percentage
100
90
80
70
60
50
40
30
20
10
0
+1.8
+4.0
+3.2
+2.8
+2.6
+4.5
+1.3
+2.7
52
53.8
61
65
44
47.2
35
37.8
52
54.6
48
52.5
25
26.3
37.6
40.3
Spots
UV-damage
Brown pigmentation
Redness
Wrinkles
Evenness
Coarse pores
Porphyrins

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Abstract N°: 2259

Annular elastolytic giant cell granuloma: Lesions in non-sun exposed areas, treated with topical dapson, alongside topical steroids

Oguzhan Kilicaslan[1], Duru Onan[1], Merih Tepeoğlu[2]

[1]Başkent University Ankara Hospital, Dermatology, Ankara, Türkiye,[2]Başkent University Ankara Hospital, Ankara, Türkiye

Introduction & Objectives:

Annular elastolytic giant cell granuloma (AEGCG) is an idiopathic, chronic, inflammatory, granulomatous skin disease classically seen in sun-exposed areas of adults. The pathogenesis and etiology is unknown.1 Here we present an AEGCG case with lesions seen in non-sun-exposed areas, treated with topical therapy alone.

Materials & Methods: (Case description)

A 90 years old patient presented with erythematous lesions on the back. The lesions were annular and polycyclic, with raised borders and central pallor. The patient had atrial fibrilation and monoclonal gammopathy of unknown significance (MGUS). The patient's medication history revealed metoprolol, doxazosin, lercanidipine and apixaban. We performed two punch biopsies accordingly, with the preliminary diagnoses of urticaria, urticarial vasculitis, erythema annulare centrifugum, granuloma annulare and in the letter biopsy only, annular elastolytic giant cell granuloma. The first biopsy showed urticarial reaction but the patient did not respond to bilastine 20mg/day. In the second, histopathology showed vacuolar degeneration, perivascular mononuclear cell infiltration, multinuclear giant cells among collagen fibers. Elastic tissue histochemistry showed elastolysis. The diagnosis of AEGCG was made. We consequently started the treatment with beclamethasone dipropionate lotion %0.025, 2x1, on weekdays, in combination with topical dapson %7.5, 1x1, only on weekends (first cycle of therapy). Lesions improved slowly, with recurrence after 3 months. Afterwards, we changed the therapy to topical clobetasol propionate lotion %0.05, 2x1 on weekdays and topical dapson %7.5, 1x1, every day, and achieved nearly %90 remission in 4 months (second cycle of therapy). The patient then discontinued follow-up appointments.

Results: (Discussion)

There are limited case reports of AEGCG in non-sun-exposed areas, making it an uncommon initial diagnosis for lesions in sun-sparing areas.2,3,4,5 Treatment options are not well-established, but some success has been seen with oral dapsone. We found three cases successfully treated with oral dapsone, but none treated with topical dapsone.5,6,7 Due to the patient's age and vulnerability, we opted for topical treatment only, using a combination of topical steroid and topical dapsone, which significantly improved the lesions. In the first treatment cycle, topical dapsone was applied once daily on weekends, and in the second cycle, twice daily every day. The increased frequency in the second cycle suggests the main effect is attributed to topical dapsone, although the use of a different topical corticosteroid in the second cycle complicates interpretation

Conclusion:

To conclude, AECGC may be seen in non-sun-exposed areas, and if the suspicion of AEGCG is not indicated to the pathologist in advance, the diagnosis may be overlooked. And topical dapson therapy may be an option in the treatment of the disease, but further research is needed.

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Abstract N°: 2270

A case of cutaneous and osteosarcoidosis successfully treated with Tofacitinib

Sarah Craig*[1], Philip Laws[1]

[1]Leeds Teaching Hospitals, Dermatology, Yorkshire, United Kingdom

Introduction & Objectives:

Sarcoidosis is granulomatous disease that commonly infiltrates the skin, eyes, lungs, liver and bones. It is typically treated with prednisolone, and steroid sparing agents such as methotrexate or hydroxychloroquine. However, it is not uncommon for resistant cases to require alternative systemic agents, anti-TNF inhibitors, or in this case, Janus Kinase Inhibitors (JAKi).

Materials & Methods:

We present the case of a 65-year-old female with sickle cell trait, hypothyroidism and progressive cutaneous and osteosarcoidosis, whom in early 2023, suffered cutaneous lesions on the scalp, face, fingers, toes and buttocks. The lesions were scaly and inflamed leading to pigmentary and anatomical change of the nose and fingers. Confluent distal fingertip involvement caused dystrophic nails, nail loss and functional impairment. Plain films demonstrated multiple lucent areas in the phalanges of the fingers and toes. Although hilar lymphadenopathy was stable, she suffered shortness of breath and pulmonary function tests showed a reducing trend in FVC and FEV1 (without obstructive defect). Serum Angiotensin converting enzyme (ACE) was 21.6U/L *(20.0-70.0)* with stable renal and liver function. Her physicians global assessment (PGA) score was 4 (severe).

Since diagnosis in 2001 via skin biopsy; treatment had been unsuccessful, provided short lived benefit or was poorly tolerated (due to recurrent infections) with Certolizumab, Adalimumab, Infliximab, Hydroxychloroquine, Leflunomide, Methotrexate, Mycophenolate mofetil, Minocycline, Azathioprine, Fumaderm, Thalidomide, Phototherapy (PUVA) and Pentoxifylline.

Results:

After 12 weeks of Tofacitinib 5mg allongside Prednisolone 5mg once daily, her cutaneous disease had significantly improved with no treatment side effects reported. Function was regained in her fingers with a settling of inflammation and improved nail growth. PGA score at this point was 1 (mild) with ongoing improvement to date.

Conclusion:

Tofacitinib is a JAKi approved for the treatment of inflammatory arthropathies and ulcerative colitis. JAK proteins are associated with cell surface cytokine receptors, and so are early mediators of cell response to inflammation whereby STAT driven transcription is initiated. In sarcoidosis, it is predominantly Type 1 inflammatory cytokines and interferon gamma that bind to JAK associated cytokine receptors1. A trial of Tofactinib in 10 patients with systemic sarcoidosis in 2022 demonstrated reduced cutaneous, pulmonary and myocardial granulomas1. However, more research is needed to fully describe the efficacy, durability of response and safety profile of Tofacitinib use in patients with sarcoidosis.

Our case illustrates the potential role of Tofacitinib in cases of cutaneous and systemic sarcoidosis in the not-uncommon cases that are resistant to hydroxychloroquine and methotrexate.

References:

1. Damsky, W., Wang, A., Kim, D.J. *et al.* Inhibition of type 1 immunity with tofacitinib is associated with marked improvement in longstanding sarcoidosis. *Nat Commun* **13**, 3140 (2022). https://doi.org/10.1038/s41467-022-30615-x

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Abstract N°: 2310

The efficacy of the combination of topical minoxidil and oral spironolactone compared with the combination of topical minoxidil and oral finasteride in women with androgenic alopecia, female and male hair loss patterns: A blinded randomized clinical trial

Roya Zeinali*[1], Afsaneh Sadeghzadeh Bazargan[1], Azadeh Goodarzi[1], Zeynab Tavana[1], Abbas Dehghani[1], Alireza Jafarzadeh[1]

[1]Rasoul Akram Hospital, Tehran, Iran

Introduction & Objectives:

Androgenic alopecia (AGA) is the most common cause of hair loss in women, affecting their quality of life. The present study was conducted with the aim of comparing the combined effect of topical minoxidil and oral spironolactone with the combined effect of topical minoxidil and oral finasteride in women with AGA, female and male hair loss patterns.

Materials & Methods:

This clinical study was performed on 60 women suffering from AGA. The patients were divided into two groups receiving spironolactone 100 mg/day and finasteride 5 mg/day. In addition, a 2% minoxidil solution was used in all patients in addition to treatment with finasteride or spironolactone. At 2 months after initiation and at the end of treatment, patients were evaluated using the Ludwig/Norwood–Hamilton scale and the degree of physician and patient satisfaction.

Results:

After 2 months, hair density, hair thickness, and hair loss had improved in both groups; however, statistically, there was no significant difference between the two groups with respect to these parameters ($p > 0.05$). After 4 months, a significant difference was found between the two groups in terms of treatment response (physician satisfaction), hair density, and hair loss severity. So that, the drugs used were ineffective in 6.7% of cases in the minoxidil-spironolactone group and in 16.7% of cases in the minoxidil-finasteride group. In addition, 43.3% of cases in the minoxidil- spironolactone group and 53% in the minoxidil-finasteride group responded well to treatment. The treatment effect was excellent in 56.7% and 0% of the mentioned groups, respectively, and the mentioned difference was statistically significant (p: 0.01). The response to treatment in female pattern hair loss (FPHL) was not statistically significant (p: 0.52), but there was a significant difference in the response to both treatments in male pattern hair loss (MPHL; p: 0.007). In terms of patient satisfaction, minoxidil-spironolactone treatment was significantly better than minoxidil-finasteride regarding hair density and severity of hair loss (p: 0.01). Finally, in terms of treatment complications, the patients in two groups did not have any serious adverse effects.

Conclusion:

The combination of minoxidil and spironolactone could be considered a more effective treatment than the combination of minoxidil and finasteride in women with AGA, FPHL, and MPHL.

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Abstract N°: 2329

Clinical efficacy of chlormethine gel in five patients with mycosis fungoides

Paolo Antonetti*[1], Marianna Breda[2], Giampiero Mazzocchetti[2], Maria Concetta Fargnoli[1]

[1]University of L'Aquila, Department of Biotechnological and Applied Clinical Sciences, University of L'Aquila, L'Aquila, Italy, L'Aquila, Italy, [2]"Santo Spirito" Hospital, Department of Medicine, Pescara, Italy

Introduction & Objectives: Mycosis fungoides (MF) is the most common form of cutaneous T-cell lymphoma, accounting for about 55% of cases. MF typically affects older individuals and is characterized, in most cases, by an indolent clinical course and slow progression. Currently available treatment options for this disease are divided into "skin-directed therapies" (SDT), including, among others, corticosteroids, topical chlormethine (or mechlorethamine) and phototherapy, and systemic therapies. Patients with early-stage disease should be primarily treated with SDT, while systemic therapies should be reserved for patients in advanced stages. Chlormethine gel, an alkylating agent in topical formulation, is recommended by principal guidelines as a first-line treatment for early-stage MF (IA-IIA). We report the experience of two Italian centers including patients with histologically confirmed diagnosis of MF, treated with chlormethine gel.

Materials & Methods: Data on sex, age, previous treatment, treatment duration, treatment response, adverse events, and follow-up duration were collected for each patient. Treatment response was defined as complete in case of total remission of skin lesions, and partial in case of a reduction in their size between 50 and 99%.

Results: Five patients (2 males and 3 females) were included, with a mean age of 64 years (30-77 years). All patients considered had received previous treatment for MF. Specifically, 4/5 (80%) had been treated with UVB-nb phototherapy, 4/5 (80%) had applied topical corticosteroids, and 5/5 (100%) topical emollients. The average duration of treatment with chlormethine gel was 4.2 months. During the follow-up period, with a mean duration of 6.4 months, 3/5 (60%) patients achieved a complete response, and 2/5 (40%) a partial response to treatment with chlormethine gel. All patients developed irritative contact dermatitis during therapy, the management of which required temporary suspension of treatment for 1 week only in one case, and the use of topical corticosteroids in another; in the remaining cases, application of topical emollients was sufficient.

Conclusion: The reported experience confirms the efficacy of chlormethine gel in the treatment of early-stage MF in a real-life setting, describing an individualized approach in the management of the most common adverse effect related to it.

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Abstract N°: 2966

Evaluation of the Efficacy, Tolerance, and Satisfaction of a Bi-Phase Topical Skincare Serum for Intimate Skin Areas

Ana Du[1], Isabela Miulescu[2], Debbie Orak[3]

[1]L'Oreal Research and Innovation, Skincare Scientific Valorization, Clark, United States,[2]L'Oreal Research and Innovation, Evaluation Intelligence, Clark, United States, [3]L'Oreal Research and Innovation, Product Safety, Clark, United States

Introduction & Objectives:

The intimate skin areas, such as the bikini area and underarms, generally can exhibit heightened sensitivity compared to other regions of the body. This sensitivity is attributed to various factors, including frequent exposure to friction and moisture. Moreover, the hair follicles in these areas tend to be coarser and densely packed, making them more prone to pseudofolliculitis, irritation and inflammation caused by shaving practices. Consequently, individuals often experience discomfort, and uneven tone in these delicate regions, which can negatively impact self-confidence when baring these delicate intimate areas. Recognizing the unique needs of these areas, it is crucial to develop skincare topical products that address the dermatological concerns.

The objectives of this present study were to evaluate the effectiveness, safety, and user satisfaction of a bi-phase topical skincare serum specifically formulated for daily external usage. The serum, formulated at a pH of 4, contains a carefully balanced combination of alpha-hydroxy acids and is enriched with antioxidant and skin barrier respecting ingredients, such as astaxanthin, jojoba oil, ashwagandha, and cranberry extracts.

Materials & Methods:

This single center, 4-week, blinded, dermatological controlled clinical study was conducted on 108 men and women aged 18-45, who were regular shavers of armpits and bikini line area. Subjects presented with mild to moderate severity of pseudofolliculitis, uneven skin tone, post-inflammatory hyperpigmentation and erythema (PIH and PIE). Efficacy evaluations included expert clinical evaluations by dermatologist (10-point grading scale), transepidermal water loss (TEWL) using Tewameter® (Courage-Khazaka), hydration using Corneometer® (Courage-Khazaka), pH using pHmeter® (Courage-Khazaka), and clinical images. Safety evaluation included objective and subjective tolerance evaluations by dermatologist and gynecologist and monitoring of adverse events. Additionally, we aimed to assess the formula's impact on individuals' self-confidence following improvements in their intimate skin areas.

Results:

Significant statistical improvements in the intensity and severity of ingrown hairs, skin tone evenness, PIH, PIE were observed through expert grading from the first application of the topical serum. These improvements continued throughout the 4-week test period compared to baseline.

Furthermore, measurements of cutaneous hydration, TEWL, and pH demonstrated that the topical serum effectively maintained the skin's moisture levels, did not cause dryness, and did not disrupt the skin's natural barrier and subjects' usual pH. There were no irritation or product-related adverse events reported. Self-assessment questionnaires revealed over 94% of the panel reported feeling more confidence in baring their skin.

Conclusion:

Our study demonstrated the effectiveness and gentleness of the bi-phase topical skincare serum and holds promise as a solution for addressing unique dermatological concerns in these delicate regions, ultimately contributing to improved well-being and self-confidence for individuals.

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Abstract N°: 3164

Laser-Assisted Drug Delivery for Red Ink Hypersensitivity Reaction Treatment

Patrycja Rogowska[1], Aneta Szczerkowska-Dobosz[1]

[1]Medical University of Gdańsk, Department of Dermatology, Venereology and Allergology, Gdańsk

Laser-Assisted Drug Delivery for Red Ink Hypersensitivity Reaction Treatment

Introduction & Objectives:

Red ink hypersensitivity reactions are one of the cutaneous complications of tattoos, triggered by unknown allergen likely formed during the haptenization process of ink particles in the skin. These reactions may manifest weeks, months, or even years following tattooing and often present with chronic pruritus or pain. Clinically, three types of reactions can be observed, with plaque-like lesions being among the presentations. Effective treatment options for red ink hypersensitivity reactions remain elusive. This case study aims to explore the efficacy of laser-assisted drug delivery (LADD) in managing red ink hypersensitivity reactions, specifically in enhancing the clinical efficacy of topical drugs.

Materials & Methods:

Two female patients, aged 25 and 43, presented with pruritic lesions on red tattoos located on the thigh and hand, respectively. Papules and nodules were observed at the tattoo sites, indicative of a plaque-like clinical type. Biopsies in both cases revealed lymphocytic and eosinophilic infiltrations, suggesting a hypersensitivity reaction to red ink. Previous treatments, including topical clobetasol ointment and triamcinolone injections, yielded unsatisfactory results. Both patients declined tattoo removal.

After topical anesthesia with lidocaine cream, we administered treatment using a carbon dioxide ablative fractional laser (28 mJ, 30W, 100 Hz), followed by the application of triamcinolone 40 mg/ml solution under occlusion with cellophane dressing left in place for 24 hours.

Results:

Following LADD treatment, both patients experienced significant flattening of lesions and reduction in pruritus, indicating a favorable response to therapy.

Conclusion:

Laser-Assisted Drug Delivery (LADD) represents a promising approach in managing tattoo-ink related hypersensitivity reactions. By leveraging fractional ablative laser technology to enhance cutaneous drug uptake, this technique offers a potential avenue for improving the potency of topical treatment regimens. Additionally, LADD is less painful than triamcinolone injections and enables the treatment of the entire area of the tattoo in a single session, optimizing convenience and maximizing patient comfort.

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Abstract N°: 3348

Finding the culprit: rosacea mimickers in the context of corticosteroid-induced rebound

Maria Alexandra Gruia*[1], Ioana Alexandra Badircea[1], Adina Alexandru[1, 2]

[1]Colentina Hospital, București, Romania, [2]Carol Davila University of Medicine and Pharmacy, București, Romania

Introduction & Objectives:

Rosacea represents a chronic inflammatory disease with possible flare-ups induced by topical corticoids. A different, but similar entity is corticosteroid-induced rosacea-like dermatitis, a variant of periorificial dermatitis, which appears after long-term use of topical potent corticoids. Periorificial dermatitis is another chronic inflammatory disease with initial partial relief due to topical corticoids, but later rebound after treatment discontinuation. Herein, we report the case of a 43 year old woman, with a history of rosacea signs, which treated herself for a long period of time with potent topical corticoids, that presented to our Dermatology department with a severe central-facial rash, after stopping the treatment.

Materials & Methods:

A 43 year old woman, with rosacea signs history, without a prior diagnostic, treated herself intermittently for 2 years with topical dipropionate clobetasol and dipropionate bethametasone. One week before her presentation, she was diagnosed in another service with periorificial dermatitis and topical metronidazole, erythromycin and corticoid discontinuation were prescribed. 2 days later, a papulo-pustular rash, with moderate itching, appeared and the treatment changed to topical fusidic acid, oral azithromycin and later oral ciprofloxacin, but without relief. She presented to our department with a severe rash formed by both isolated papules and plaques, measuring a maximum of 4/3 cm (localized in the perioral, mental and supraorbital areas) and isolated pustules on the dorsal nasal surface, infraorbital and malar regions. Our work-up involved blood tests, urine analysis, and bacteriological swab examination from the lesions, all of them in normal rage or negative, exception being an elevated seric level of Immunoglobulin G, ESR and antinuclear antibodies, but with negative anti dsDNA antibodies. During hospitalization it was started treatment with doxycycline 200 mg/day, a short course of methylprednisolone with dose-tapering, bilastine , NSAID on demand, topical 1% metronidazole gel, colorant solution and emollients with slow remission of the rash. At home the patient continued for 2 weeks the same treatment and after that switched to topical ivermectin, oral doxycycline 100 mg/day and emollients, with favorable evolution.

Results:

Collaborating the data, the diagnostic was a corticosteroid-induced rebounded facial dermatitis, with a great probability rosacea considering the good response to topical ivermectin, but without being able to exclude corticosteroid-induced rosacea-like dermatitis, rebounded periorificial dermatitis, or a combination of the above.

Conclusion:

To conclude, rosacea has multiple mimickers that can also exacerbate under long term topical corticoids with suddenly discontinuation. The particularity of the case is the difficult differential diagnosis of the initial rash. As periorificial dermatitis is a well known mimicker of rosacea, with similar treatment regimen, is difficult to establish the original rash, mainly in the context of topical corticoid long term use, which can produce for both rebounds, and also corticosteroid-induced rosacea-like dermatitis. Independently from the diagnostic, the general measures and treatment are the same: discontinuing step by step the topical corticoid and introducing: oral tetracyclines, topical metronidazole, ivermectin, emollients or in severe cases oral low-dose isotretinoin.

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Abstract N°: 3433

Intralesional heparin sodium in the treatment of xanthelasmas, a new therapeutic alternative

Ana Gil Villalba[1], Juan Pablo Velasco-Amador[1], María Dolores Pegalajar García[1], Carlos Llamas-Segura[1], Jose Maria Llamas-Molina[1], Ricardo Ruiz-Villaverde[1]

[1]Hospital Universitario San Cecilio, Dermatology, Granada, Spain

Introduction & Objectives:

Xanthelasmas are the most common variety of cutaneous xanthomas and patients usually require treatment for cosmetic reasons. The most commonly used treatment is surgical resection or CO2 laser depending on the degree of involvement. Recently, case series have been published on the efficacy of treatment with intralesional injection of sodium heparin into the lesions, with cosmetically acceptable results and no adverse effects.

Materials & Methods:

Patients who had consulted for xanthelasmas in the last year were invited to participate in the study. Seven** patients were recruited and signed informed consent for off-label use. A weekly infiltration of heparin** sodium 5000 units in 5 ml (5%) was performed until resolution or maximum 10 sessions without response.** A topical anaesthetic layer was applied and then the heparin was injected until a wheal of approximately 1** mm was created. The dose used did not exceed 0.5 ml between both eyelids, with very low risk of systemic** absorption.**

Each patient's sex and age, family history, skin phototype, degree of involvement, time of evolution and** course (stable or progressing), or if they had received previous treatment were recorded. A baseline lipid** profile was obtained and it was indicated if they took treatment for dyslipidaemia. At each session,** iconography of the lesions was taken and possible adverse effects were registered. After treatment,** patients completed questionnaires on tolerance and satisfaction.

Results:

Of the 7 patients, 6/7 were women, the mean age was 55 years (σ=7). Seventy-one percent (5/7) had** lesions with more than 2 years of evolution and progressive worsening. All patients had hypercholesterolaemia with a mean of 222 mmol/litre (σ=14) and LDL 151 (σ=14). Twenty-eight per cent** (2/7) had received previous treatment. All patients were partial or total responders receiving 10 sessions.

Conclusion:

Intralesional injection of heparin sodium is proposed as an effective and inexpensive therapeutic alternative to reduce the size of xanthelasmas, ideal for patients who do not want to undergo more invasive procedures with the risk of subsequent scarring.

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Abstract N°: 3631

Study on The Effect of Pneumatic Injector on Intradermal Injection with Different Parameters

Xi Huang[1], Jia Deng*[1, 1], Mengjiao Wang[1]

[1]Affiliated Hospital of Guilin Medical University, Guilin, China

Introduction & Objectives:

To observe the effect to the depth of skin injection and the change of skin tissue structure when pneumatic injector by adjusting the parameters of the injection flow (Flow, mL/min) and injection time (Time,s),. To provide the experimental basis for equipment improvement and precise clinical application of the pneumatic injector.

Materials & Methods:

1. Measure the skin thickness and skin elasticity of the shoulder, back, lateral abdomen, and abdominal skin of Bama miniature pigs through the non-invasive skin testing method.According to the measurements, select the injection site and injection region.
2. Use the pneumatic injector to give a needle-free injection of 0.1% methylene blue staining solution (0.1% MB) into the skin of Bama miniature pigs. Combine the following two parameters in pairs: injection flow F, mL/min): 1, 3, 5, 7; injection time (T, s): 1, 2, 4, 8; then conduct the needle-free jet injection experiment according to the parameters respectively. The experimental group was divided into16 subgroups. Parameters F and T of each injection cell were adjusted according to the experimental group, and 0.1% MB staining solution was injected.Control group: local application of 0.1% MB staining solution.
3. Observe the penetration of 0.1% MB staining solution through the skin under different parameters through frozen sections.
4. Measure the injection depth, and statistically analyze the relation between the parameters (F, T) of the pneumatic injector and the injection depths.
5. Select the parameters of layered injection into the epidermis and dermis. According to H&E(Hematoxylin-eosin) staining and PAS(Periodic Acid-Schiff stain) staining, observe the effects of corresponding parameters of needle-free jet injection on the skin tissue structure. Use the electron microscope to observe the effects of needle-free jet injection on the skin ultrastructure.

Results:

1. Based on the results of non-invasive skin measurement, the experimental area for needle-free jet injection was selected as the skin on the lateral abdomen attached to the bone structure of Bama miniature pigs.
2. With different injection parameters, 0.1% MB staining solution can be deposited on different skin layers such as the stratum corneum, epidermis, dermis, and hair follicles. Under the same flow, the injection depth increases with time, with a statistically significant difference ($P<0.05$); At the same injection time, the injection depth increased with the increase of flow rate, with a statistically significant difference ($P<0.05$);
3. Needle-free jet injection can cause a certain degree of damage to the structure of the cuticle, desmosomes between epidermal cells, and desmosomes in the DEJ(Dermal-epidermal junction) region when it is injected into the epidermis and dermis.

Conclusion:

1. Under different parameters of F and T, needle-free injection can cause different degrees of damage to the

skin epidermis, the basement membrane and the superficial dermis. The degree of damage can be controlled by adjusting the parameter settings.

2. The drug delivery into the skin through needle-free injection is achieved by destructing the barrier of skin epidermis and barrier of epidermis and dermis.
3. By adjusting the injection parameters of F and T, the precise layered injection into the epidermis and dermis under the condition of slight reversible damage can be achieved, which provides the experimental basis for equipment improvement.

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Abstract N°: 3652

Developing expert consensus on suitability of systemic therapy in plaque psoriasis patients with limited skin involvement in Japan

Akimichi Morita*[1], Yukari Okubo[2], Shinichi Imafuku[3], Yayoi Tada[4], Masatoshi Abe[5], Mamitaro Ohtsuki[6]

[1]Nagoya City University Graduate School of Medical Sciences, Department of Geriatric and Environmental Dermatology, Aichi, Japan, [2]Tokyo Medical University, Department of Dermatology, Tokyo, Japan,[3]Fukuoka University, Department of Dermatology, Fukuoka, Japan, [4]Teikyo University, Department of Dermatology, Tokyo, Japan, [5]Kojinkai Sapporo Skin Clinic, Sapporp, Japan,[6]Jichi Medical University, Department of Dermatology, Shimotsuke, Japan

Introduction & Objectives:

The study aimed to determine a consensus on which patients with plaque psoriasis with limited skin disease (<10% BSA) would be suitable for systemic treatment, and to present a definition of topical therapy failure.

Materials & Methods:

A Delphi method was used via an online survey to present and administer questions to 45 psoriasis experts in Japan. Two rounds of online survey featured 13 statements each, developed with insights from two steering committees.

Results:

We produced total of 13 statements in 5 domains: general statement, special areas, topical therapy failure, impact on quality of life, and systemic inflammation. Consensus suggests patients with limited skin involvement (<10% BSA) would be suitable for systemic treatment if there is the involvement of special or difficult to treat areas, a patient is suffering from psoriasis-induced psychological distress, there are uncontrolled signs affecting the social life of the patient, or psoriatic arthritis is present. Consensus further suggests that a definition of failure of topical therapy in plaque psoriasis patients in Japan should include: if symptoms and plaques persist, if patients experience poor treatment satisfaction, if they need to increase the quantity of medication or the time for application, or if affected skin corresponds to a PASI >3 or PGA ≥2.

Conclusion:

Our findings identify conditions when systemic treatment is recommended for plaque psoriasis patients with limited skin involvement.

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Abstract N°: 3880

BoNT-A is an effective and safe treatment for PPH: A retrospective case series of 129 patients

Aikaterini Tsiogka[1], Erasmia Adamou*[1], Efthymia Agiasofitou[1], Antonios Tsimpidakis[1], George Kontochristopoulos[1], Alexander Stratigos[1], Stamatis Gregoriou[1]

[1]Andreas Syngros Hospital of Venereal & Dermatological Diseases, Athina, Greece

Introduction & Objectives: This study investigates Botulinum toxin type A (BoNT-A) efficacy in primary plantar hyperhidrosis (PPH). BoNT-A, approved for axillary hyperhidrosis, shows promise for PPH treatment, though comprehensive guidelines are lacking. Scientific data on BoNT-A's efficacy for PPH mainly stem from small studies.** Herein, we evaluate BoNT-A's effectiveness and safety for PPH across a significant patient cohort, addressing this gap in knowledge.

Materials & Methods: A retrospective case series evaluated the efficacy and safety of onabotulinumtoxin-A or abobotulinumtoxin-A in PPH using Minor's iodine–starch test, Hyperhidrosis Disease Severity Scale (HDSS) and patient satisfaction. Medical records of patients who were referred to the outpatient department for hyperhidrosis of a tentiary care hospital from March 2003 until December 2022 were reviewed. Data extracted from medical records included demographics, disease severity, treatment details, adverse events and satisfaction. Statistical analysis utilized SPSS.

Results: The study comprised 129 patients (12 males, 117 females) with a median age of 32 years (range: 16–72), after excluding 24 with insufficient follow-up data. Predominantly, 115 patients (89.1%) received onabotulinumtoxin-A, nine (7.0%) abobotulinumtoxin-A, and five (3.9%) both in successive sessions. On average, patients underwent 2.02 sessions (SD: 2.29), with a mean response duration of 6.16 months (SD: 4.01). Minor's test indicated response rates of 71.67%, 63.44%, 47.78%, and 34.13% after 1, 3, 6, and 9 months, respectively. Patient satisfaction was high, with 21.7% satisfied and 58.9% very satisfied. No serious adverse effects were reported throughout the treatment duration.

Conclusion: Various studies have investigated the impact of BoNT-A treatment on the quality of life (QoL) of patients with primary hyperhidrosis. A significant reduction in Dermatology Life Quality Index (DLQI) was found in patients treated with BoNT-A. Therapeutic modalities for PPH include topical agents, iontophoresis, and BoNT-A injections. Recent trials have also explored oxybutynin gel for PPH. Studies on BoNT-A efficacy in PPH indicate sustained improvement in symptoms and QoL. Despite high patient satisfaction, treatment discontinuation often occurs due to pain and cost issues. Various pain reduction techniques for injections include topical anesthetics, vibration anesthesia, cryoanalgesia, sedation, and nerve blocks. According to our experience, cooling spray right before injection is the optimal method due to its simplicity and lack of adverse effects. The results of this retrospective study indicate that BoNT-A is an effective, safe treatment for PPH . Further randomized controlled trials are necessary to confirm these findings and optimize treatment strategies for PPH.

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Abstract N°: 3913

De-risk and accelerate topical drug product development using Open Flow Microperfusion (OFM) technology

Wen-Kai Hsiao*[1], Manfred Bodenlenz[1], Thomas Birngruber[1]

[1]JOANNEUM RESEARCH HEALTH, Institute for Biomedical Research and Technologies, Graz, Austria

Introduction & Objectives:

The traditional drug development paradigm can allow too many dermal drug candidates to fail costly at late clinical phases, often due to a lack of sufficient pharmacokinetics (PK) data to support effective decision-making. The key deficiencies are (i) PK data not obtained in the relevant animal models or target tissues and (ii) the unbound concentrations according to the free drug theory are not considered. We propose a translational approach based on Open Flow Microperfusion (OFM) technology to address this knowledge gap.

Method & Approach

OFM provides time-resolved, unbound PK data from the interstitial fluid (ISF) space in animal and human tissues [1]. Utilizing a membrane-free open probe structure, OFM can determine unbound concentrations of small- (e.g., JAK inhibitors) and large-molecule (e.g., mAbs) compounds, as well as cytokines and immune cells in the dermal tissues (Fig. 1).

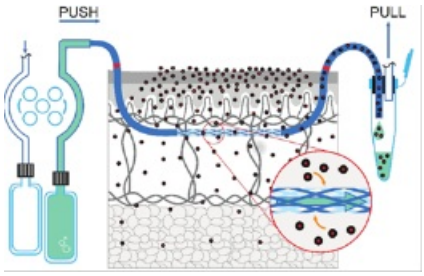

Figure 1. The working principle of OFM in the dermal tissue

A translational approach (Table 1) consists of ex-vivo, in-vivo and clinical OFM studies and has a proven track record in supporting better decision-making in drug development.

Table 1. Translational OFM approach

Study	Species	Rationale/Aim
Ex-vivo (single dosing, without clearance)	Animal	PK to rank/select based on delivery and tissue diffusivity
	Human	PK + drug metabolism
In-vivo (multiple dosing, with clearance)	Animal	PK to rank/select based on free drug concentration vs. EC50
	Human	Fast PoC + tissue PK in healthy subjects/patients + tissue PD in patients

Results:

Case Study 1 – Predicting Clinical Efficacy

ISF PK data from freshly excised human skins collected via OFM (Fig. 2) was shown to be effective in predicting the clinical outcomes of soft topical PDE4 inhibitor candidates rather than biopsy PK data [2].

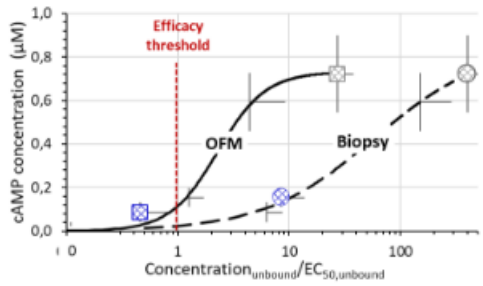

Figure 2. OFM data correctly differentiated clinically efficacious (grey) and inefficacious (blue) soft drug candidate whereas biopsy data erroneously indicated both as efficacious.

Case Study 2 – Performance Benchmarking

OFM PK data of three investigative topical JAK inhibitors (JAKi) and the reference product developed in an in-vivo porcine study (Fig. 3) clearly demonstrates that the time-resolved ISF PK data can be effective in benchmarking permeation performance and support formulation/dosing decisions [3].

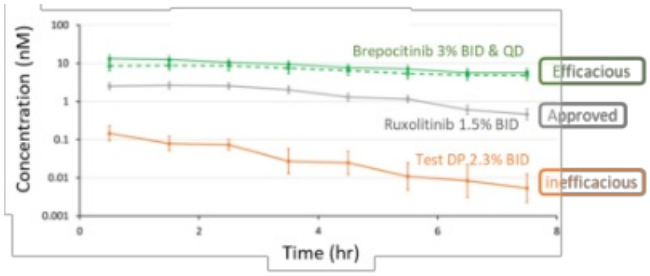

Figure 3. Permeation benchmarking and formulation optimization

Conclusion:

Dermal drug development could be effectively de-risked when clinical studies are informed by the tissue-level drug availability data provided by cutaneous PK sampling methods such as OFM. Selected case studies are presented to demonstrate how this innovative technique could enable a new paradigms of better decision-making and efficient drug product development.

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Abstract N°: 4143

Simple Interventions To Improve Documentation Of Cryotherapy In One Large Dermatology Center

Emily Orr*[1], Muireann Roche[1]

[1]Beaumont Hospital, Dublin, Ireland

Introduction & Objectives:

Cryotherapy is commonly utilised in the dermatology department to treat both benign, and premalignant & malignant conditions. Although frequently employed, complications from cryotherapy can also be a source of patient complaints and litigation1. For this reason it is important that there is suitable documentation in the patient's chart, detailing informed consent. There are no formal guidelines which advise on what should be recorded in the patient's chart when performing cryotherapy. For the purposes of this article audit points were adapted from the British association of Dermatologists (BAD) guidelines for documentation in cryotherapy for cutaneous warts.

Aims:

The documentation relating to cryotherapy in a large dermatology unit in Dublin was Audited. The following documentation was recorded:

\1) Site treated

\2) Dose of liquid nitrogen used - Duration and number of cycles

\3) Written or verbal consent

\4) Provision of a Patient Information Leaflet (PIL)

Materials & Methods:

We selected patients' charts who had received cryotherapy treatment for any condition. Patients were identified by selecting charts that were listed to attend the cryotherapy clinic. The most recent treatment with liquid nitrogen was reviewed. Documentation was assessed to identify if the above standards were met. The outcomes were documented in an excel spreadsheet. Subsequently a cryotherapy proforma sticker was designed for use in the patient notes. The sticker included tick boxes to prompt clinicians to document the site treated, dose of liquid nitrogen used, discussion of risks and whether consent was gained.

Results:

Our data demonstrated that documentation often recorded the site of cryotherapy treatment (96%). However, the dose, duration and number of cycles was infrequently documented (13%). Only 17% of patients received PILs. Documentation of whether consent was given was poor, with only 22% charts recording this. Further to this, only 9% charts recorded a discussion of risks prior to proceeding with cryotherapy.

Cryotherapy documentation was re-audited following implementation of the sticker. Documentation of site improved from 96% to 100%. Documentation of the dose of cryotherapy used increased to 86%. The use of PILs also increased to 71%. All charts which were re-audited following the introduction of the sticker documented a discussion of risk and patient consent.

Conclusion:

This quality improvement project demonstrates how simple initiatives may be effective in improving standards. The introduction of the cryotherapy sticker improved documentation in each standard. Although use of PILs improved with the sticker, uptake is still low. This may be accounted for by many patients receiving multiple treatments with cryotherapy and therefore not requiring the leaflet again.

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Abstract N°: 4149

Treatment Response and Prognostication Factors in Patients with Pemphigus Foliaceus and Vulgaris treated with Rituximab

Vishvan R Naidu*[1], Ali Yalcinkaya[1], John B Mee[2], Richard W Groves[2], Thomas J Tull[2]

[1]King's College London, GKT School of Medical Education, Faculty of Life Sciences & Medicine, London, United Kingdom, [2]St. John's Institute of Dermatology, Guy's and St. Thomas' NHS Foundation Trust, London, United Kingdom

Introduction & Objectives:

Pemphigus is an autoimmune mucocutaneous blistering disorder characterised by antibodies against desmoglein (dsg) proteins. Pemphigus vulgaris (PV) and pemphigus foliaceus (PF) are major subtypes. PF is characterised by anti-Dsg1 antibodies resulting in superficial cutaneous erosions. PV is characterised by anti-Dsg3 antibodies resulting in mucosal erosions, with cutaneous erosions if anti-Dsg1 antibodies are also present. Rituximab is a monoclonal antibody against CD20 licensed for the treatment of PV. Evidence for the efficacy of rituximab to treat PF is less robust and limited to case series and reports. This study compares the efficacy of rituximab in the treatment of PV and PF and identifies prognosticators for response.

Materials & Methods:

Patients with PV and PF treated with rituximab between August 2007 and November 2021 were identified by a systematic search of electronic health records from a single UK tertiary dermatology centre. Patients were administered rituximab according to the Rheumatoid Arthritis protocol and followed up for a minimum of 24 months. Peak rituximab response was categorised as complete remission (CR), partial remission (PR) or no response (NR), according to internationally recognised definitions. Clinic records were used to identify the duration of rituximab response. Quantification of B cell count, T cell subsets, NK cells and anti-Dsg antibody levels were recorded at each clinic visit.

Results:

The dataset comprised of 105 pemphigus patients (89 PV and 16 PF) treated with rituximab. As expected, rituximab administration resulted in decreases of anti-Dsg1, anti-Dsg3 and B-cells 6-12 months post treatment ($p<0.0001$). PF patients were found to respond less well to rituximab overall than PV patients, with lower CR rates (50% versus 67%) and higher NR rates (19% versus 11%) **(Figure 1A)**. PF patients had higher baseline anti-Dsg1 levels than PV patients with cutaneous disease ($p<0.01$), and lower percentage drops in anti-Dsg1 levels at 6-12 months post rituximab ($p<0.01$**) (Figure 1B)**. The median age at disease onset in those relapsing before 24 months post treatment was 46, compared to 52 in those relapsing after 24 months ($p<0.05$) **(Figure 1C)**. The median age at disease onset in patients achieving CR was 51, compared to 44 for PR and 41.5 for NR ($P<0.01$**) (Figure 1D)**. Greater falls from baseline in anti-Dsg1 and anti-Dsg3 antibody levels to 6-12 month follow up predicted greater duration of response ($p<0.01$) **(Figure 1E, 1F)** and peak rituximab response ($p<0.01$). 4 subjects (3.8%) suffered from transfusion related reactions. The most common reported side effect of rituximab was fatigue (15 subjects, 14.2%).

Conclusion:

This study demonstrates both higher rates of CR and anti-Dsg1 antibody level drops in patients with PV versus PF post rituximab treatment, suggesting better treatment response in these patients. Younger age at disease onset

and rituximab treatment were both associated with shorter remission durations and worse peak rituximab response. Greater anti-Dsg 1 and 3 antibody level falls at 6-12 months post rituximab predicted better treatment response and longer disease remission.

Figures

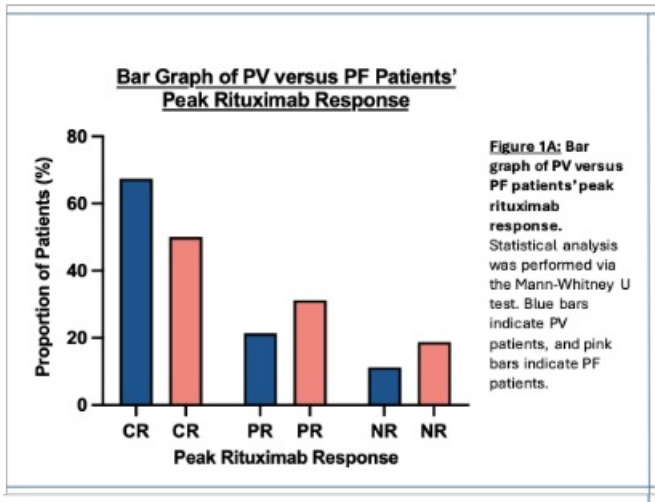

Figure 1A: Bar graph of PV versus PF patients' peak rituximab response. Statistical analysis was performed via the Mann-Whitney U test. Blue bars indicate PV patients, and pink bars indicate PF patients.

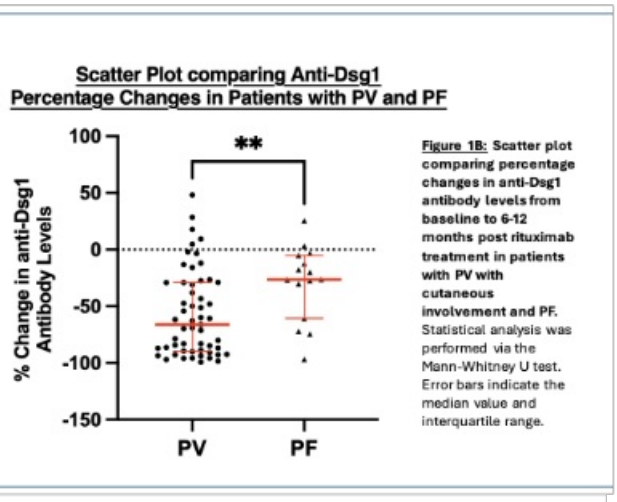

Figure 1B: Scatter plot comparing percentage changes in anti-Dsg1 antibody levels from baseline to 6-12 months post rituximab treatment in patients with PV with cutaneous involvement and PF. Statistical analysis was performed via the Mann-Whitney U test. Error bars indicate the median value and interquartile range.

Figure 1C: Scatter plot depicting age of disease onset in patients relapsing before and after 24 months of rituximab treatment. Statistical analysis was performed via the Mann-Whitney U test. Error bars indicate the median value and interquartile range.

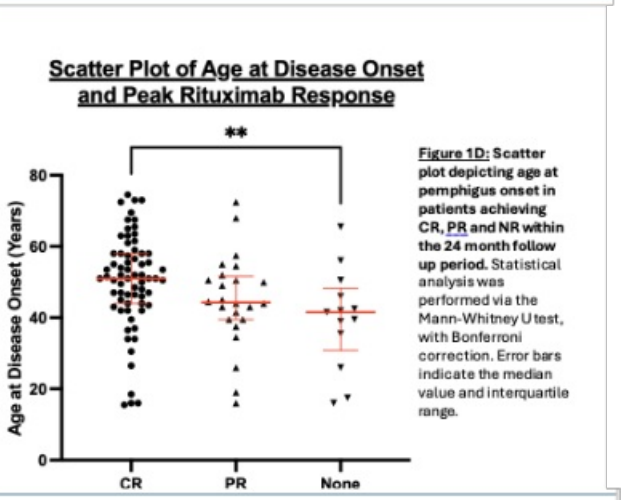

Figure 1D: Scatter plot depicting age at pemphigus onset in patients achieving CR, PR and NR within the 24 month follow up period. Statistical analysis was performed via the Mann-Whitney U test, with Bonferroni correction. Error bars indicate the median value and interquartile range.

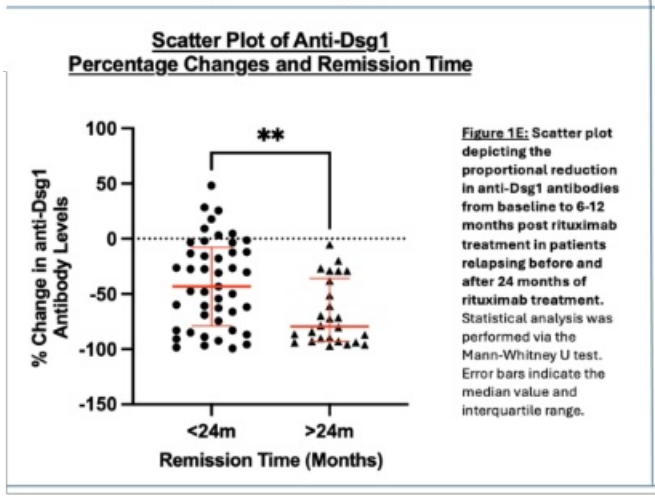

Figure 1E: Scatter plot depicting the proportional reduction in anti-Dsg1 antibodies from baseline to 6-12 months post rituximab treatment in patients relapsing before and after 24 months of rituximab treatment. Statistical analysis was performed via the Mann-Whitney U test. Error bars indicate the median value and interquartile range.

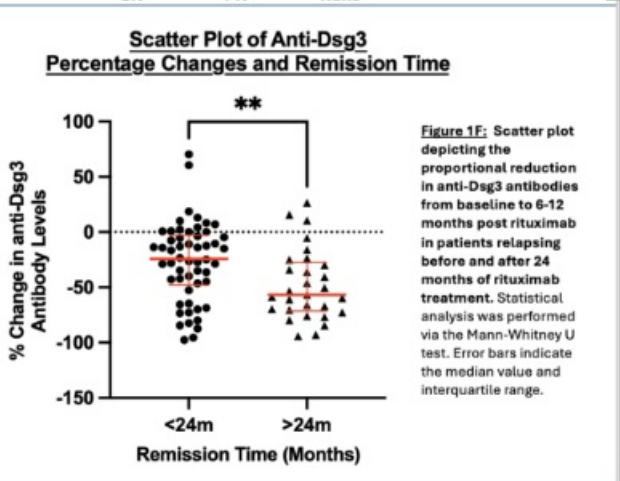

Figure 1F: Scatter plot depicting the proportional reduction in anti-Dsg3 antibodies from baseline to 6-12 months post rituximab in patients relapsing before and after 24 months of rituximab treatment. Statistical analysis was performed via the Mann-Whitney U test. Error bars indicate the median value and interquartile range.

Significance

* P ≤ 0.05
** P ≤ 0.01

EADV CONGRESS
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Abstract N°: 4425

Oral isotretinoin versus acitretin in the treatment of plantar warts in adults

Ahmed Abdelshafy*[1], Ahmad Nofal[1], Samar Najah[1]

[1]Faculty of medicine, Zagazig University, Dermatology, Venereology & Andrology Department, Zagazig, Egypt

Introduction & Objectives: Plantar warts are benign epithelial tumors that are forced inward due to pressure on the toes or sole of the foot and may become very painful if not treated. Many treatment options are available including topical treatments, lasers, and immunotherapy. However, data about systemic therapies are lacking. This study aimed to compare the efficacy and safety of acitretin versus oral isotretinoin in the treatment of multiple plantar warts.

Materials & Methods: This randomized comparative double-blinded study included 80 adult patients with multiple plantar warts. The cases were divided into two groups: acitretin group (40 cases with a dose of 0.5 mg/kg/day) and isotretinoin group (40 cases with a dose of 0.5 mg/kg/day). The reduction in wart size and photographic comparisons at the beginning and every 2 weeks for 3 months were used to assess the treatment efficacy in the two groups. After therapy ended, a follow-up was conducted every month for 6 months to observe any recurrence.

Results: Complete response was observed in 30%, partial response in 55%, and no response in 15% of patients of acitretin group while complete response was achieved in 15%, partial response in 45%, and no response in 40% of patients of isotretinoin group with statistically significant difference in favor of acitretin (P=0.03). Compared with acitretin, oral isotretinoin was associated with a shorter duration to a complete response (83.3% of cases achieved complete response in <2 months compared with only 16.7% in acitretin group) (P=0.006).

Conclusion: Acitretin is superior to oral isotretinoin as a therapeutic option for plantar warts, but both are effective and safe. Since they are resistant to other traditional therapy techniques, they can be seen as valuable therapeutic choices for multiple plantar warts.

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Abstract N°: 4548

Treatment of Nickel Induced Allergic Contact Dermatitis using Roflumilast Cream 0.3%: A Case Series.

Walter Liszewski[1]

[1]Northwestern University, Chicago, Chicago, United States

Introduction & Objectives:

Allergic contact dermatitis (ACD) is an inflammatory response in the skin resulting from cytotoxic T-cells infiltrating the epidermis following allergen exposure. This type IV hypersensitivity reaction is best treated by allergen avoidance, although topical steroids are commonly used to treat flares of ACD. Nickel metal is the most common contact allergen detected by patch-testing. Given the prevalence of nickel allergies, topical ACD therapy that is safer for long-term use and with less side effects than topical steroids would benefit patients. Roflumilast cream 0.3% is a potent topical phosphodiesterase 4 (PDE4) inhibitor approved in 2022 for the treatment of psoriasis, including intertriginous disease. Here we report a case series of nickel-induced ACD treated with roflumilast cream 0.3% once daily for 8 days.

Materials & Methods:

Patients with a 1+ reaction to nickel on routine patch testing were identified and randomized 1:1 to receive roflumilast 0.3% cream (n=4) or roflumilast vehicle (n=4). Patients were instructed to apply the cream once daily. Assessments were daily pruritus numerical rating scale (NRS) and photography of the reactions that were obtained at days 0, 4, 6, and 8. A dermatologist performed a blinded assessment of the photographs to evaluate the signs of ACD resolution, including improvement in erythema and edema.

Results:

Complete resolution of erythema and swelling occurred by day 8 in 4 of 4 (100%) roflumilast treated patients with 1 participant resolved by day 4, 2 by day 6, and the 4th patient by day 8. No participants (0 of 4) treated with vehicle demonstrated resolution of the ACD related erythema and swelling by day 8. Mean baseline pruritus NRS for scores were 1.5 and 0.75 for roflumilast and vehicle, respectively, on day 8 the mean pruritus NRS scores were 0.25 for both groups.

Conclusion:

We report a case series of four patients demonstrating complete resolution of nickel allergy ACD related erythema and edema in patients treated with once daily roflumilast 0.3% cream. None of the vehicle treated patients had resolution of their ACD. Changes in pruritus NRS were parallel between drug and vehicle cohorts. However, at baseline, many patients in both groups had NRS scores of 0 and the mean NRS score for roflumilast treated patients was twice that of vehicle. Given that patients underwent full patch testing were enrolled, it may have been difficult for patients to localize and precisely quantify pruritus for a single spot on the back. In future studies, nickel reactions can be provoked in isolation, and other patient reported outcome measures can be utilized. This report suggests reduction of inflammation treatment with a potent topical PDE4 could offer a treatment option for patients with ACD and further study is warranted.

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Abstract N°: 4581

Topical statins in dermatology – current perspective with evidence analysis

Anna Tekielak[1, 2], Karina Polak[1, 2], Tomasz Muszyński[3], Mikołaj Łanocha[1], Bartosz Miziołek[1], Beata Bergler-Czop[1]

[1]Chair and Department of Dermatology, Silesia Medical University, Katowice, Poland;,[2]Doctoral School, Silesia Medical University, Katowice, Poland, [3]Jagiellonian University Doctoral School of Medical and Health Sciences; 1st Department of General and Oncological Surgery, Jagiellonian University Medical College; Department of Vascular Surgery, St John Grande's Hospital in Cracow

Introduction & Objectives:

Statins are considered the most widely used drugs in the treatment of hyperlipidemia. Their mechanism of action includes inhibiting HMG-CoA reductase, crucial enzyme in the cholesterol synthesis. Statins are structurally similar to HMG-CoA and act as their competitive inhibitors, binding to the active site of HMG-CoA reductase and preventing it from properly interacting with the substrate. The use of topical statins in dermatology may have potential in the treatment of various skin diseases. Statins, being HMG-CoA reductase inhibitors, may exhibit anti-inflammatory, antiproliferative and antioxidant effects, making them potentially useful in the treatment of certain dermatoses. Our aim was to investigate the current evidence on the use of topically applied statins in dermatologic disorders.

Materials & Methods:

We perfomed a literature review in the Pubmed, EMBASE and Google Scholar databases from inception until April 2024 according to the PRISMA guidelines, including keywords such as "topical statins", „statins", „dermatology", „skin". The search was as broad as possible, and the following inclusion criteria were used: original studies, case reports, case series including using topically applied statins in dermatologic diseases in humans published in English. 5 articles covering disease entities such as disseminated superficial actinic porokeratosis, acne vulgaris, eczema, plaque psoriasis were included in the final analysis.

Results:

The analysis showed efficacy in monotherapy or combination therapy with other drugs with a satisfactory safety profile. The results of the analysis are presented collectively in the form of a table summarizing the clinical trials conducted using topical statins in dermatological diseases.

Conclusion:

Topical application of statins appears to be a promising method for treating various dermatological conditions. It can be effective both as monotherapy and in combination with other treatments. This combination can provide a synergistic effect, leading to better control of disease symptoms, which can improve the skin condition and quality of life for patients.

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Abstract N°: 4740

Patient benefit assessment of topical treatment in psoriasis: Validation of the PBI-TOP questionnaire in a longitudinal study

Christine Blome[1], Lisa Lebherz[1], Irene Farese[1], Lennart K Hülswitt[2], Slatina Christov[1], Hatice Birkner[1], Matthias Augustin*[1]

[1]University Medical Center Hamburg-Eppendorf, [2]Überörtliche Berufsausübungsgemeinschaft (GbR) Dr. med. Michael Reusch / Ursula Reusch / Dr. med. Volker Mielke

Introduction & Objectives: To enhance treatment adherence and patient satisfaction in topical treatment of psoriasis, it is important to consider individual patient preferences. The Patient Benefit Index for Topical Treatment (PBI-TOP) questionnaire has recently been developed using rigorous qualitative methods. It is the first patient-reported outcomes measure to assess needs and benefits in topical treatment that covers both effectiveness and product characteristics. It consists of two parts: the Patient Needs Questionnaire assesses the importance of potential treatment goals; the Patient Benefit Questionnaire assesses goal attainment. Using data from both parts, weighted global scores are calculated. These quantify patient-relevant treatment benefit overall as well as in different dimensions: effectiveness regarding quality of life and symptoms as well as favourable product characteristics. In this study, we aimed to validate the PBI-TOP in a longitudinal design and thereby to confirm and complement the favourable psychometric properties found in a previous cross-sectional pilot validation.

Materials & Methods: This is a longitudinal, non-interventional study including 100 patients diagnosed with psoriasis vulgaris who started a topical treatment without (change in) systemic treatment. Data was collected at four time points: (1) at treatment onset, (2) one week later (to investigate retest reliability of the needs items), (3) 4-12 weeks later, and (4) again one week later (to investigate retest reliability of the benefit items). Patients and clinicians recorded demographic, clinician, and patient-reported data. Validity was analysed using classical test theory.

Results: Preliminary analyses were performed on n=65 patients (age 21-76 years, mean 48; 69.1% female; psoriasis diagnosis 0-57 years ago, mean 18). Factor analysis revealed four factors explaining 65.4% of the variance. Internal consistency of the PBI scores and sub scores was good to excellent (Cronbach's alpha > 0.8). The convergent validity analyses indicated global change ratings on quality of life, overall treatment benefit, and treatment satisfaction consistent with the PBI ratings, but correlations were only partly significant, probably due to the small sample size in this interim analysis.

Conclusion: Results of this interim analysis indicated that the favourable psychometric properties found in the pilot study might be confirmed, including the factor structure (except for two items loading on different factors), internal consistency, and convergent validity. However, these results must be interpreted with caution, as only half of the entire sample could be used. Final results will be presented at the EADV, also including missing values analysis, confirmatory factor analysis, thresholds for the interpretation of the benefit scores, and test-retest reliability.

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Abstract N°: 4846

Overcoming the psychological distress of madarosis : Bimatoprost as a Source of Hope

Nada Tahri[1], Yousef Joudeh[1], Ouissal Hormi[1], Nada Zizi[2], Siham Dikhaye[3]

[1]Department of Dermatology, Venereology, and Allergology, Mohammed VI University Hospital, Oujda, Morocco , dermatology, Oujda, Morocco, [2]1.Department of Dermatology, Venereology, and Allergology, Mohammed VI University Hospital, Oujda 2. Epidemiology, Clinical Research and Public Health Laboratory, Faculty of Medicine and Pharmacy, Mohammed 1 University, Oujda, Morocco, dermatology, Oujda, Morocco, [3]1.Department of Dermatology, Venereology, and Allergology, Mohammed VI University Hospital, Oujda 2. Epidemiology, Clinical Research and Public Health Laboratory, Faculty of Medicine and Pharmacy, Mohammed 1 University, Oujda, Morocco, Dermatology, Oujda, Morocco

Introduction & Objectives:

The ophthalmic solution of bimatoprost 0.03% was approved by the Food and Drug Administration (FDA) in 2008 for the treatment of eyelash hypotrichosis. Few case reports and studies on the topical application of bimatoprost to the eyebrows have indicated improvements in growth and patient satisfaction.

The objective of this study was to evaluate the effectiveness of the ophthalmic solution of bimatoprost 0.03% on eyebrow regrowth, as well as the impact of the results on the patient's psychological profile.

Materials & Methods:

This was a prospective descriptive study of data concerning patients with alopecia presenting with madarosis of the eyebrows. Only patients who were treated with bimatoprost ophthalmic solution 0.03% (daily application) without any other local treatment for the eyebrows or systemic treatment for alopecia were included.

The Global Eyebrow Assessment (GEBA) scale was used to assess the fullness of the eyebrows. This is a validated 4-point scale (1 = very sparse, 2 = sparse, 3 = full, and 4 = very full). The efficacy criterion was defined as an increase of at least one grade in the GEBA grade compared to the start of treatment.

Patient satisfaction with the treatment outcome was measured using item 6 of the Eyebrow Satisfaction Scale (ESS, follow-up version).

Additionally, we used a questionnaire to assess the psychological impact of our patients before and after treatment with bimatoprost through the Skindex score in its emotional dimension. The impact on quality of life is particularly significant as the score increases.

Results:

We collected data from 10 patients, including 6 females and 4 males. The mean age was 28.3 +/- 10.4 years with a range from 16 to 47 years. Three patients had universal alopecia, 3 had scalp alopecia areata, and 4 had alopecia areata in patches. The mean duration of eyebrow madarosis was 4.8 +/- 3.2 years. All our patients reported that their madarosis had hindered their romantic and social life.

The means of camouflage used were eyebrow pencils in 40% of cases and microblading in 10% of cases.

We observed an improvement in eyebrow hair growth in 70% of patients (7 cases), notably 5 females and 2 males, after a mean duration of 40 +/- 15.27 days with a range from 30 to 70 days. Their distribution was as follows:

Three patients had an increase of 2 grades, and 4 patients had an increase of one grade. No improvement was noted in the remaining 3 patients. Furthermore, no adverse effects were noted.

Regarding the assessment of patient satisfaction after treatment (item 6 of the ESS) in these patients, 6 patients reported being ‘rather satisfied’ with the appearance of their eyebrows after treatment, and one patient reported being ‘very satisfied’ with the appearance of her eyebrows.

The mean Skindex score in its emotional dimension after treatment was lower than before treatment (41.5% versus 60.6%), indicating a decrease in the emotional impact of madarosis after treatment.

Conclusion:

Damage to the eyebrows can be particularly concerning for psychological well-being, as it occurs on the face, a highly visible and aesthetically important area.

Current evidence is of low quality due to the small sample size but is promising regarding the effectiveness of bimatoprost ophthalmic solution in promoting eyebrow regrowth.

Furthermore, this effectiveness may help alleviate stress and emotional anxiety, which are exacerbating factors in alopecia.

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Abstract N°: 4992

Management of advanced basal cell carcinoma with hedgehog inhibitors: a real-world prospective comparative study

Federico Venturi*[1, 2], Daniela Massi[3], Sara Gandini[4], Vincenzo De Giorgi[3]

[1]S. Orsola-Malpighi Polyclinic, Dermatology, Bologna, Italy, [2]University of Bologna - Faculty of Medicine, DIMEC, Bologna, Italy, [3]University of Florence, Firenze, Italy, [4]European Institute of Oncology, Italy

Introduction & Objectives: The term advanced Basal cell carcinoma (aBCC) has been introduced to include locally advanced BCC (laBCC). When patients aren't eligible for surgery and radiotherapy, Hedgehog Pathway Inhibitors (HHIs) should be offered to patients as a first line treatment. We aimed to describe our long-term approach to manage aBCC based on 10 years' experience with HHIs.

Materials & Methods: We undertook a prospective, monocentric study in Florence, Italy. Patients that were treated with Sonidegib and/or Vismodegib for aBCC were included from January 2013 to December 2023. The treatment response was evaluated respecting the RECIST v1.1 guidelines. The safety evaluation was performed upon the data of reported AEs according to the CTCAE classification and severity assessment.

Results: The study population consisted of 66 patients: 42 males (63,6%) and 24 females (36,4%). 92,4% were > 50 years old of age. Anatomical site was as follows: head and neck (77.3%), trunk (13.6%), arms (9.1%). We assessed histopathological low-risk subtypes in 40.4% of cases and high-risk subtypes in 59.6%. Given the recently published EADO classification of BCCs, we re-evaluated every single case with the following results: 27.3% stage 2A, 19.6% stage 2B, 15.2% stage 3A, 33.3% stage 3B, 3.1% 3C and 1.5% stage 4. 60.6% were treated with vismodegib, 28.8% with sonidegib, and 10.6% were switched to sonidegib after vismodegib discontinuation (due to AEs or PD). Among 40 evaluable vismodegib-treated patients, the ORR was 65%, with CR in 27.5% of cases. mDOR was 10 months, and vismodegib treatment was initiated as neoadjuvant treatment in 20% of the patients. Among 19 evaluable patients treated with sonidegib, ORR and CR were 89.5% and 36.8%, respectively. mDOR was 9 months and TTR was <5 months in 64.8% of cases. Regarding patients switched from vismodegib to sonidegib, the ORR was 71.4% with CR in 42.9% of cases. mDOR was 13 months. Considering the safety profile, in the vismodegib group, the most common all-grade AEs were muscle spasms (90%), dysgeusia (88%), nausea (51%), weight loss (40%), and alopecia (35%). These were typically grades 1 and 2, with few patients experiencing AEs of grade 3. In the group of patients treated with sonidegib, the most common all-grade AEs were nausea (58%), muscle spasms, dysgeusia and weight loss (47% each). These were typically grades 1, with few patients experiencing AEs of grade 2 and no cases of grade 3. In the group of patients switched from vismodegib to sonidegib, we registered dysgeusia (71%), muscle spasms (57%), nausea, alopecia and weight loss (43% each). These were typically grades 1 and 2.

Conclusion: As far as we know, our monocentric prospective study reflects the largest cohort of patients treated with HHIs from a single institution. Moreover, this is one of the first study that analyze the efficacy and safety profile in the subgroup of patients switched from vismodegib to sonidegib.

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Abstract N°: 4994

Unveiling the Hidden Shield: Methotrexate Emerges as a Cardio-Protector in Psoriasis—Insights from a Scoping Review

Son Mai[1, 2], Yves Mbama[3], Pauline Gouttefarde[3, 4, 5], Thomas Franck[4], Gilles Cizeron[1], Mathieu Oriol[1], François MacCari[6], Beatrice Trombert[5, 7], Bienvenu Bongue[1, 8], Jean-Luc Perrot[9, 10]

[1]Technical Support and Training Center for Health Examination Centers (CETAF), Saint Etienne, France,[2]Science Engineering, Health, Jean Monnet University, Saint Etienne, France, [3]PRESAGE , Jean Monnet University, Saint Etienne, France, [4]Gérontopôle Auvergne Rhône Alpes (AURA), Saint Etienne, France,[5]SAINBIOSE laboratory , Unit INSERM 1059 UMR, Saint Etienne, France, [6]Reso, Saint Etienne, France, [7]CHU of Saint Etienne, Saint Etienne, France, [8]Elderly Health , Jean Monnet University, Saint Etienne, France,[9]Dermatology University Hospital, Saint Etienne, France, [10]Laboratory of Tribology of Systems , UMR CNRS 5513, Saint Etienne, France

Introduction & Objectives:

Psoriasis, a chronic inflammatory skin condition affecting millions worldwide, presents a multifaceted challenge to patients and clinicians. Research has consistently linked psoriasis with an elevated risk of cardiovascular diseases (CVD). Amidst this clinical landscape, methotrexate (MTX), a cornerstone in psoriasis therapy, is gaining attention for its potential cardio-protective effects. This scoping study aims to provide a nuanced understanding of MTX's impact on cardiovascular health within the context of psoriasis management.

Materials & Methods:

Adhering to PRISMA guidelines, English-language articles from October 2013 to September 2023 were reviewed across PubMed, ScienceDirect, the Cochrane Library, and Wiley Online Library, yielding 13 relevant studies included in the analysis.

Results:

Findings across various study designs involving 898,744 enrolled patients have consistently demonstrated a low incidence rate of cardiovascular events (CVEs) and a safe cardiac risk profile among individuals receiving methotrexate over the past decade. Evidence from a prospective cohort revealed methotrexate mitigates the likelihood of cardiac disorder by lowering E-selectin and VCAM-1 levels. Comparative studies indicate a decreased hazard risk for major cardiac events in psoriasis patients treated with methotrexate compared to those using alternative medications, along with reduced cardiovascular and cerebrovascular risks in psoriasis patients without arthritis.

Conclusion:

Methotrexate exhibits noteworthy cardiovascular protective effects in patients with psoriasis. Its dual efficacy addresses both dermatological and cardiovascular aspects, making it a cost-effective choice, particularly in resource-limited settings. Future research should explore the long-term cardiovascular benefits of MTX in psoriasis management, highlighting its potential for optimizing patient care and healthcare resource allocation.

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Abstract N°: 5169

Lack of correlation between number of baseline actinic keratoses and local tolerability signs severity in patients treated with tirbanibulin over a 100 cm2 area: results from a Phase 3 study

Neal Bhatia[1], Edward Lain[2], Abel Jarell[3], Janet Dubois[4], Marie Pierre Malice[5], Laura Padulles[6], Raquel Otero*[5], Andrew Blauvelt[7]

[1]Therapeutics Clinical Research, San Diego, United States, [2]AICR (Austin Institute for Clinical Research) at Pflugerville, Pflugerville, United States, [3]allCUTIS Research, Inc. , Portsmouth, United States, [4]DermResearch, Austin, United States, [5]Almirall, Sant Feliu de Llobregat, Spain, [6]Almirall, Barcelona, Spain, [7]Blauvelt Consulting, LLC, Lake Oswego, United States

Introduction & Objectives: Actinic keratosis (AK) is a pre-cancerous skin disease that may progress to squamous cell carcinoma.1 The objectives of this analysis were to evaluate the tolerability of tirbanibulin ointment 1% applied to a field of 100 cm2 on the face or balding scalp in adults with AK and to analyse local tolerability by subgroup analysis of patients based on the number of AK at baseline.

Materials & Methods: A Phase 3, multicenter, open-label, single-arm study (NCT05279131) was conducted in adults with a treatment field on the face or balding scalp of approximately 100 cm2 containing 4-12 AKs. Patients were treated with tirbanibulin for 5 consecutive days and were followed until Day 57. At each study visit (Day 5, Day 8, Day 15, Day 29, Day 57), local tolerability signs (LTS; erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation, erosion/ulceration) were scored 0-3 (absent-severe) and summed to a composite score (0-18). LTS by subgroup of patients with ≤8 and >8 AKs at baseline were analysed.

Results: A total of 105 patients were included in the safety analysis set (69% males; 65% ≥65 years; 7.7 mean number of AKs). In the subgroup with ≤8 baseline AK lesions (N=65), mean (95% Confidence Interval) total composite LTS was 4.02 (3.40-4.64) at Day 8 (visit with maximum score); in the subgroup with >8 baseline AKs (N=40), it was 3.39 (2.80-3.97), achieving baseline values or below at Day 29 (0.39/0.61, respectively). A higher number of AKs at baseline did not lead to higher scores in LTS composite nor individual LTS metric. Regression analysis on the number of AK lesions for composite score produced a similar result.

Conclusion: There was no correlation between number of baseline AKs and local tolerability of tirbanibulin in adults treated over a 100 cm2 area. The good tolerability profile of tirbanibulin applied over a 100cm2 area is consistent with use over a 25cm2 area. Therefore, area size nor number of AKs in the treatment field affected tolerability with tirbanibulin treatment.

1Siegel JA et al. Br J Dermatol. 2017;177(2):350-358.

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Abstract N°: 5173

Efficacy and safety of tirbanibulin 1% ointment for the treatment of actinic keratosis in conditions close to routine clinical practice in Spain and Italy (TIRBASKIN study)

Yolanda Gilaberte Calzada*[1], Oriol Yelamos[2], Javier Cañueto[3], Carlos Serra-Guillén[4], Andrea Conti[5], Francesca Pajuelo Lorenzo[6], Alberto Lecchi[7], Valentina Cappello[6], Belchin Kostov[8], Marco Romanelli[9]

[1]Hospital Universitario Miguel Servet, Zaragoza, Spain, [2]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, [3]Complejo Asistencial Universitario de Salamanca, Salamanca, Spain, [4]Instituto Valenciano de Oncología, Valencia, Spain, [5]Ospedale Infermi di Rimini, Rimini, Italy,[6]Almirall, Barcelona, Spain, [7]Almirall, Milano, Italy, [8]Almirall, Sant Feliu de Llobregat, Spain, [9]Ospedale Santa Chiara, Pisa, Italy

Introduction & Objectives: Efficacy and safety of tirbanibulin have been evaluated in two Phase III trials in the US1. However, there was no clinical experience with tirbanibulin in Spain and Italy at the time Tirbaskin study started. The objective was to evaluate the efficacy and safety of tirbanibulin administered to patients with actinic keratoses (AKs) in conditions close to routine clinical practices in Spain and Italy.

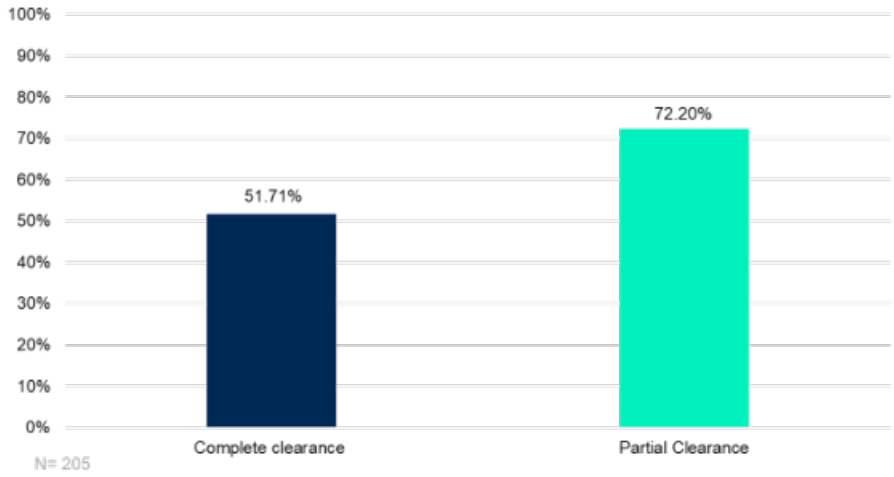
Materials & Methods: TIRBASKIN is a multicenter, single-cohort, phase IV, low-interventional, clinical study conducted among adult patients with 4-8 non-hyperkeratotic non-hypertrophic AK lesions of the face or scalp in an area of up to 25 cm2 not previously treated in the last 6 months on the same area. Patients applied tirbanibulin 1% ointment for 5 consecutive days. Efficacy was assessed by the percentage of patients with complete (100%) clearance (CC) of all lesions within the application area and the percentage of patients with partial clearance (PC), defined as a reduction of at least 75% in the number of lesions within the application area, at Day 57. Safety was assessed by incidence and severity of adverse events (AEs) and local tolerability signs (LTS) (erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation and erosions/ulcerations) on a grading scale ranging from 0=absent to 3=severe.

Results: Interim analysis results are presented. A total of 205 patients (mean age: 75 years; male: 84%; Fitzpatrick skin type II: 59%) with AK on face (46%), scalp (53%) or both (0.5%) completed study assessments at Day 57. At Day 57, there was a change from baseline of -75% in the number of lesions. CC was achieved by 52% of patients, and PC was achieved by 72% of patients (Figure 1), similar to the results obtained in Phase III trials1. At Day 8, 49% of patients provided information on LTS; LTSs were mostly mild or moderate erythema (37%), flaking/scaling (19%) and crusting/scabs (16%), resolved at Day 57. As AEs of special interest, two patients experienced basal cell carcinoma outside the application area. Neither AEs leading to death nor serious AEs occurred.

Conclusion: Tirbanibulin 1% ointment is effective, safe, and well tolerated, consistently with results reported in pivotal trials1. These results in conditions close to clinical practice consolidate tirbanibulin as a valuable choice among AK available treatments.

1Blauvelt A et al. N Engl J Med. 2021;384(6):512–20.

Figure 1 Complete and partial clearance after treatment with tirbanibulin for AKs


100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
51.71%
72.20%
Complete clearance
Partial Clearance
N= 205

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Abstract N°: 5329

Efficacy, safety and tolerability of intralesional vitamin D injections in children warts in Benghazi – Libya

Wafa Elserti[1], Gamal Elduweb*[2]

[1]Benghazi Aljadida Polyclinic, Dermatology Department, Benghazi, Libya,[2]Faculty of Medicine, Benghazi university, Dermatology Department, Benghazi, Libya

Introduction & Objectives: Warts are very common in the general population, especially among children. The prevalence of warts among primary schoolchildren is reported to be 22% to 33%. Aim of the study: To study the demographic features of warts in Libyan children and assess the efficacy and tolerability of intralesional vitamin D in those patients.

Materials & Methods: In this quasi-experimental longitudinal study, a total of 35 patients attending dermatology outpatient clinics at Benghazi Aljadida Polyclinic, Benghazi, Libya, were enrolled in this study. A detailed disease history and a complete dermatological examination were carried out on all patients. The selected warts were injected first with 0.2 ml of lidocaine (20 mg/ml), then, after a few minutes, 0.2 ml of Vitamin D3 (15 mg/ml) was slowly injected into the base of each wart with a 30-gauge insulin syringe. Clinical response assessment was done and documented at 2 weekly intervals for 4 sessions and 6 months after the last injection. Complete clearance was considered if all the warts were both treated and the distant warts resolved completely.

Results: The percentage of warts among dermatological cases attending the clinic is 4.9%, and the percentage of the disease in children below 16 years was 2.7%, of which 55% were female. Among the 35 cutaneous wart patients included in this study, the patients's ages ranged from 3 to 15 years (mean 8.2 years). The number of wart lesions ranged from 1 to 9 (mean: 5 lesions). Verruca vulgaris was seen in 45.6% of patients. A family history of the disease was recorded in 62.9% of cases. The mean duration of the disease was 3.1 months. Most patients (54.2%) received 1-2 injections, followed by 3-4 injections in 40%. Regarding the total response to treatment, it was observed in 94% of the cases, and the clearance of the disease was seen in 82.9% of treated children. The highest response was observed in 8 patients (100%) aged below 5 years, followed by the age group 6–10 years (78.9%), and it's not statistically significant ($p=0.332$). More children with a number of lesions of 5 or less had complete clearance and presented in 86.7% of cases. In relation to the clinical type of wart, clearance was seen in 100% of plantar warts, followed by common warts (85.7%).

Conclusion: Intralesional vitamin D injections were effective, safe, and well tolerated in children and could be a choice in the treatment of plantar and periungual clinical types.

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Abstract N°: 5401

Exploring the Therapeutic Role of Enoxaparin in Erosive Lichen Planus

Alexandra Starica*[1], Daciana Elena Branisteanu[1, 2], Diana Stefania Dirzu[1], Cristina Colac-Botoc[1], Antonia Clivet[1], Ionela Oprescu[1], Mihaela Paula Toader[1, 2]

[1]Hospital CFR, Iași, Romania, [2]Universitatea de Medicină și Farmacie „Grigore T. Popa" din Iași, Iași, Romania

Introduction & Objectives:

Erosive Lichen planus (LP) is a very painful and debilitating condition with a significant impact on the life of the patients. Oral prednisone is often considered one of the most effective treatments for patients requiring systemic medication, albeit associated with side effects. However, in recent decades, low-dose low-molecular-weight heparin (enoxaparin) has emerged as a treatment for different types of LP.

Materials & Methods:

We present the case of a 58-year-old female patient with lesions on the oral and genital mucosa accompanied by discomfort, burning sensation, and pain. Histopathological confirmation in 2016 revealed oral erosive LP, for which she underwent various topical treatments (corticosteroids in orabase and calcineurin inhibitors in orabase), showing unfavorable progression. Subsequently, she underwent systemic treatments (systemic corticosteroids and azathioprine), with fluctuating outcomes. At one stage, due to a broken leg, she received a daily dose of 0.6 mg of subcutaneous enoxaparin for a duration of 6 weeks.

Results:

While receiving enoxaparin for her broken leg, she discontinued all other systemic or topical treatments for erosive LP due to significant improvement of the lesions. The Dermatology Life Quality Index (DLQI) score decreased from 25 to 5, the initial Visual Analog Scale (VAS) score of 7 decreased to 3, while Physician Global Assessment (PGA) improved by 4 points. The improvement in the disease persisted for an additional 1.5 months after discontinuation of the anticoagulant therapy. No side effects were reported during the treatment period.

Conclusion:

Although the exact cause of LP remains unknown, evidence suggests cell-mediated immune responses to altered antigens expressed in keratinocytes as a potential pathogenesis. Following keratinocyte destruction, cytokine release leads to lymphocyte accumulation and epidermal destruction, resulting in a lichenoid reaction. The heparanase enzyme (endoglycosidase), present on CD4 + lymphocytes surfaces, cleaves heparan sulfate side chains in the extracellular matrix, facilitating the penetration of T lymphocytes into the subendothelial basal lamina in the upper dermis. Low-dose, low-molecular-weight heparin – enoxaparin - inhibits heparanase expression and delayed-type hypersensitivity response, preventing T lymphocyte access to target tissue. Enoxaparin's disaccharide structure also inhibits cytokine roles in inflammation, particularly TNF alpha expression. Tumor necrosis factor (TNF) α, a pro-inflammatory cytokine, is implicated in LP pathogenesis and inflammation, with heparin reported to inhibit TNF α production. Studies investigating the treatment of various types of LP with enoxaparin have reported improvements in a range of 61% up to 83% of patients, while other studies have not demonstrated improvement in LP with enoxaparin. At the moment, the European guidelines suggest that low molecular weight heparin (enoxaparin 3 mg/week) could be considered for cutaneous and mucosal LP treatment.

Based on available evidence, enoxaparin may play a crucial role in LP management, warranting exploration

through well-designed clinical trials and experimental studies to identify its anti-inflammatory fragments, elucidate mechanisms of action, and determine appropriate therapeutic doses of these non-anticoagulant fragments.

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Abstract N°: 5434

Exploring The Therapeutic Role of Ivermectin in Seborrheic Dermatitis

Alexandra Starica*[1], Daciana Elena Branisteanu[1, 2], Yassine Chatri[1], Diana Dirzu[1], Roxana Ciobanu[1], Mihaela Paula Toader[1, 2], Andreea Tucaliuc[1], Cristina Muntean[1]

[1]Hospital CFR, Iași, Romania, [2]Universitatea de Medicină și Farmacie „Grigore T. Popa" din Iași, Iași, Romania

Introduction & Objectives:

Topical ivermectin has demonstrated efficacy in treating inflammatory papulopustular rosacea in adults. Given its potential anti-inflammatory properties, it may also be effective in other facial dermatoses, particularly in seborrheic dermatitis (SD), especially due to its significant association with Demodex infestation.

Materials & Methods:

We present a small case series of 3 patients with recalcitrant facial SD. All patients attempted multiple treatments prior, including topical antifungals, dermocosmetic creams for SD, and even topical corticosteroids, with no satisfactory improvement. In all cases, the Wood Lamp examination of the lesional skin revealed white-yellow fluorescence indicative of Malassezia furfur presence, while dermoscopic examination showed yellowish scales and Demodex tails in the follicular openings. We initiated topical treatment with 1% ivermectin cream which was applied once daily on the affected skin for 12 weeks. Clinical follow-up assessments were conducted at four-week intervals for three months. Efficacy was evaluated using a global improvement scoring system ranging from 0 (no improvement), to 4 (complete or almost complete resolution of lesions) and Patient Quality of Life survey. Photography documented clinical response at each visit.

Results:

All patients demonstrated a favorable response to topical ivermectin, with gradual reduction in inflammatory lesions. Complete clearance was achieved in all cases after 12 weeks of treatment. Each patient documented a reduction in symptoms and expressed satisfaction with the treatment. Adverse events were transient and included mild to moderate desquamation, stinging, and burning.

Conclusion:

Multiple studies have shown a significantly higher number of Demodex mites in both lesional and nonlesional areas of patients with SD, suggesting a potential relationship between the condition and Demodex. When other etiological causes are excluded, Demodex mites may play either a direct or indirect role in the pathogeny of SD. Furthermore, SD may create a proper environment for Demodex, as the main food source of these mites is sebum. Additionally, a small study by Barańska-Rybak et al. investigating the possible application of topical ivermectin in SD due to its potential anti-inflammatory activity, reported promising results. Firstly, ivermectin suppresses the production of inflammatory mediators such as NO and prostaglandin E2, and reduces mRNA expression levels of inducible NO synthas and cyclooxygenase-2. Secondly, clinical trials have demonstrated the anti-inflammatory effects of topical ivermectin through decreased counts of inflammatory lesions. Considering the data on the safety and efficacy of topical 1% ivermectin cream, physicians could regard this as a valid treatment option for SD.

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Abstract N°: 5482

Patient and physician-reported outcomes with tirbanibulin 1% ointment for actinic keratosis in conditions close to routine clinical practice in Spain and Italy (TIRBASKIN study)

Yolanda Gilaberte Calzada*[1], Oriol Yelamos[2], Javier Cañueto[3], Carlos Serra-Guillén[4], Andrea Conti[5], Francesca Pajuelo Lorenzo[6], Alberto Lecchi[7], Valentina Cappello[6], Belchin Kostov[8], Marco Romanelli[9]

[1]Hospital Universitario Miguel Servet, Zaragoza, Spain, [2]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, [3]Complejo Asistencial Universitario de Salamanca, Salamanca, Spain, [4]Instituto Valenciano de Oncología, Valencia, Spain, [5]Ospedale Infermi di Rimini, Rimini, Italy,[6]Almirall, Barcelona, Spain, [7]Almirall, Milano, Italy, [8]Almirall, Sant Feliu de Llobregat, Spain, [9]Ospedale Santa Chiara, Pisa, Italy

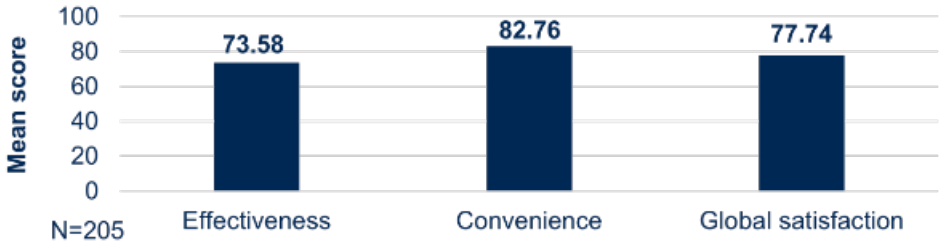
Introduction & Objectives: Patient-reported outcomes such as treatment preference or satisfaction have not been assessed in patients treated with tirbanibulin for actinic keratoses (AKs) in Spain and Italy. The objective was to evaluate patient- and physician-reported outcomes following treatment with tirbanibulin ointment 1% once daily for 5 consecutive days in conditions close to routine clinical practice.

Materials & Methods: TIRBASKIN is a multicenter, single-cohort, phase IV, low-interventional, clinical study conducted among adults with 4-8 non-hyperkeratotic, non-hypertrophic AK lesions of the face or scalp in an area of up to 25 cm2 not treated in the last 6 months on the same area. Patients completed Treatment Satisfaction Questionnaire for Medication Version 9 (TSQM-9) survey at Day 57 comprising 3 domains: treatment effectiveness, convenience of use and global satisfaction with the treatment. Both patients and physicians completed the Expert Panel Questionnaire at Day 57, rating the overall skin appearance, satisfaction with improvement in “how skin looks” and “skin texture”, overall satisfaction, and likelihood to consider to be treated with tirbanibulin again (if needed), on a 5-point adjectival response scale from 0 to 5. Physicians’ version refers to physician’ experience/observation of tirbanibulin effects on their patients.

Results: Interim analysis results are presented. A total of 205 patients with AK lesions on face (46%), scalp (53%) or both (0.5%) completed the study (mean age: 75 years; male: 84%; Fitzpatrick type II: 59%). Of them, 65% received previously at least one AK therapy. At Day 57, patients reported high levels of tirbanibulin satisfaction for all the 3 domains of TSQM-9 (Figure 1). 96% of physicians and 93% of patients rated overall skin appearance after tirbanibulin ointment to be much/somewhat improved and 91% of physicians and 88% of patients were extremely/very satisfied or satisfied with tirbanibulin to improve “how skin looks” and “skin texture”. Moreover, 88% of physicians and 85% of patients reported tirbanibulin to be much/somewhat better compared with the previous topical treatment and both (87%) reported much/somewhat likelihood to consider tirbanibulin again, if needed.

Conclusion: Physicians’ and patients’ overall satisfaction with tirbanibulin for 5-days was high, and both reported great (much/somewhat) likelihood to use tirbanibulin in future, considering tirbanibulin as a valuable option for treating AK lesions.

Figure 1 Tirbanibulin patient satisfaction scores at Day 57, reported through TSQM-9


Mean score
100
80
60
40
20
0
73.58
82.76
77.74
N=205
Effectiveness
Convenience
Global satisfaction

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Abstract N°: 5561

Improvement of Fox-Fordyce disease with botulinum toxin type A

Lanyu Sun[1], Diogo de Sousa[1], Cláudia Brazão[1], João Guilherme Patrocínio[1], Pedro de Vasconcelos[1], Luís Soares-Almeida[1], Joao Silva[1], Paulo Filipe[1]

[1]Hospital de Santa Maria, Dermatology, Portugal

Introduction & Objectives: Fox-Fordyce disease (FFD) is a rare, chronic condition characterized by the appearance of symmetric, often itchy, skin-colored papules centered around hair follicles in areas with apocrine glands, such as the axillary, anogenital, or periareolar skin. While its exact cause remains unclear, evidence suggests a hormonal influence, given its predilection for women aged 15 to 35, with symptoms sometimes resolving after menopause. Managing FFD poses a significant challenge.

Results: A 36-year-old pre-menopausal woman presented with a four-year history of multiple mildly itchy papules in both axillae. She had no significant medical history and denied previous laser hair removal or use of topical products/fragrances. Physical examination revealed multiple firm, non-tender, skin-colored follicular papules grouped in the bilateral axilla. A punch biopsy showed dilated hair follicles filled with lamellated keratin, spongiosis, and a superficial perivascular lymphocytic inflammatory infiltrate with few foamy histiocytes, confirming FFD diagnosis. Treatment with methylprednisolone aceponate 1mg/g ointment and clindamycin 1% gel yielded no improvement after 3 months. Due to concomitant hyperhidrosis, she received one session of intradermal injection of 75 U botulinum toxin type A (BTX-A, Botox®, Allergan, Inc) into each axilla. The injection points were marked 1.5-2.0-cm apart and 2.5 U were injected at each site using a dilution of 5 U/0.1 mL of normal saline. At a 3-month follow-up, the patient reported significant reduction in sweating and complete resolution of pruritus, along with a decrease in the number of lesions from the baseline.

Conclusion: FFD is a chronic, pruritic condition resulting from keratin plugging in the follicular infundibulum at the distal portion of the apocrine sweat duct. This obstruction causes apocrine sweat retention and, over time, rupture of glands with secondary inflammatory dermal alterations. There is no standardized treatment for FFD. First-line treatments include topical corticosteroid. Other modalities with varying success rates include topical calcineurin inhibitors, tretinoin, clindamycin, oral contraceptives, laser therapy, surgical excision, and phototherapy. BTX-A injections have shown promise in refractory cases. The application of BTX-A injections in our patient resulted in the disappearance of pruritus and a partial clinical response after a single treatment. The improvement of pruritus may be explained by sweat reduction which is a known trigger of pruritus in FFD. The exact mechanisms that led to the clinical reduction of skin lesions are unknown. Further research is needed to elucidate its precise mechanisms in FFD management, but BTX-A injections should be considered in patients with recalcitrant FFD.

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Abstract N°: 5562

Sucessful treatment of a rare case of widespread extragenital lichen sclerosus with narrow band UVB phototherapy

Lanyu Sun[1], Diogo de Sousa[1], Sofia Duarte[1], Cláudia Brazão[1], Dora Mancha[1], Pedro de Vasconcelos[1], Luís Soares-Almeida[1], Paulo Filipe[1]

[1]Hospital de Santa Maria, Dermatology, Portugal

Introduction & Objectives: Lichen sclerosus (LS) is a chronic inflammatory skin condition that typically affects the anogenital regions, but the extragenital variants comprise 15% to 20% of all LS cases. Furthermore, only 6% of the LS cases are of extragenital lichen sclerosus (EGLS) alone, without any genital involvement. EGLS can be localized or widespread, but disseminated forms of the disorder are extremely rare.

Results: A 79-year-old woman presented with a six-months history of a disseminated severe pruritic eruption. She had no significant medical history. Physical examination revealed widespread hypochromic, atrophic, and bright plaques, with parchment paper-like atrophy involving mainly the upper trunk, arms, forearms, and tights. No genital involvement was observed. Two punch biopsies of the upper back and left forearm showed hyperkeratosis, hypogranulosis, marked atrophy of the epidermis, hyalinization of the dermis' collagen with sparse perivascular interstitial lymphocytic infiltrate. Based on the clinical and histopathological findings, a diagnosis of EGLS was made. She was treated with clobetasol 0.05% cream twice a day and antihistamines with yielded no improvement after 3 months. We initiated narrowband UV-B (NB-UVB) twice-weekly therapy. The patient underwent 25 sessions, with an irradiation dose that ranged from 100 to 2,000mJ/cm2 per session, with a total dose of 29,100mJ/cm2 and an exposure time of 3 to 10 minutes per session. Four months after discontinuation of phototherapy, the patient reported complete resolution of pruritus, and a significant improvement in the clinical picture was observed, with improved atrophy and cutaneous surface texture.

Conclusion: LS is a chronic inflammatory disease of unknown etiology, although hereditary, endocrine, infectious, and autoimmune factors are suggested to be involved. Standard treatments include ultrapotent topical corticosteroids and calcineurin inhibitors, with variable therapeutic success. Extragenital lesions are less sensitive to conventional therapy. There are reports on the use of colchicine, cyclosporine, methotrexate, mycophenolate mofetil and phototherapy modalities (NB-UVB, UVA-psoralen, UVA-1). NB-UVB radiation has been believed to delay the development of skin sclerosis by decreasing proinflammatory cytokines and increasing matrix metalloproteinases. Our patient's response suggests that NBUV-B therapy can be beneficial in treating LS, producing not just symptomatic relief but modification of the disease course as well.

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Abstract N°: 5667

A newer modality in the treatment of topical steroid damaged face -Pimecrolimus

Dr Sanvi Nigade[1], Yoganand Phulari[1]

[1]D Y Patil Medical College and Hospital , Dermatology , Venereology and Leprosy, Kolhapur, India

Introduction & Objectives:

Topical Steroid Damaged/Dependent face (TSDF) is a phenomenon which has been described. It is characterized by a plethora of symptoms caused by a usually unsupervised misuse/abuse/overuse of topical corticosteroid of any potency on the face over an unspecified and/or prolonged period of time. This misuse and damage have a serious effect on the quality of life of the patients in general and the skin of the face in particular.

This is a case report of TSDF with excellent response to topical 1% pimecrolimus cream.

Materials & Methods: A 38-year-old female (Fitzpatrick type IV-V) presented with persistent erythema of the face with associated itching and burning sensation. On enquiring, she gave history of application of betamethasone dipropionate cream twice daily for past 9 months. She was advised by a local pharmacist to apply betamethasone dipropionate cream for her pigmentation. Since last 2 months, she has been experiencing a burning sensation on face and a persistent erythema. Patient was asked to stop the topical steroid application and was advised strict photoprotection. Topical pimecrolimus was prescribed at nighttime for 8 weeks. In addition, a physical sunscreen was also advised. Burning sensation decreased within 2 weeks. Erythema was assessed using a clinician erythema assessment scale and it showed a 2-grade reduction (baseline grade-4) after 4 weeks.

Treatment was continued till 8 weeks, after which it was stopped and patient was asked to continue using the sunscreen. There was no relapse in the next 4 weeks, after which the patient was lost to follow up.

Results:

Retrospective analysis of the data and digital photographs of this case was carried out and the data analysis revealed a significant therapeutic benefit with excellent result. Improvement was noticed after the first session and in all the clinical parameters. No adverse effects were reported. Psychological counseling as well as physical soothing of the sensitive skin was done.

Conclusion:

Since there are no recommended guidelines and practicing dermatologists use their discretion in managing TSDF patients, the treatment mostly becomes symptomatic. In such a scenario, treatment-related side effects are not uncommon .This case is an initiative to highlight the need to bring treatment option for the management of TSDF patients.

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Abstract N°: 5720

efficacy and safety of oral tranexamic acid versus microneedling with tranexamic acid in the treatment of melasma

Ikram El Modafar[1, 2, 2], Bendaoud Layla[1, 2], Maryem Aboudourib[1, 2], Hocar Ouafa[1, 2], Said Amal[1, 2]

[1]Mohamed the VIth University Hospital, Dermatology department, Marrakech, Morocco,[2]Faculty of Medicine and Pharmacy, Cadi Ayyad University, Biosciences and Health Laboratory, Marrakech, Morocco

Introduction & Objectives:

Melasma is a common disorder of hyperpigmentation that mainly affects the face. It is difficult to treat and is a cause of major cosmetic concern for patients.

This study was conducted to compare the therapeutic effect and safety of oral tranexamic acid (TXA) versus TXA with microneedling for the treatment of melasma.

Materials & Methods:

Twenty-five female patients with bilateral symmetrical melasma were recruited in our study. They were divided into 2 groups. Group A included 10 patients who received TXA with microneedling and group B contained 15 carefully selected patients, who received oral TXA at a dose of 250mgx2 per day during 3 months. Clinical efficacy was assessed using a modified Melasma Area Severity Index (mMASI) at the baseline and every month for 4 months. Global photographs underwent blinded review by 2 dermatologists. Patient self-assessment and satisfaction were recorded.

Results:

Most of the patients had centrofacial pattern of melasma 14 (56%), followed by malar pattern seen in 11 (44%) of patients. The majority of patients had a phototype IV (72%). The baseline mMASI score was 12,7 in group A and 11.13 in group B. The mean mMASI score in Group A at the end of 4, 8, 12 and 18 weeks was 8.75, 7.6, 7, 6,2 while these values were 9.7, 8.2, 5.68, 4.5 for group B. At the end of 24 weeks follow-up

period, good (51%-75% improvement) and very good (>75% improvement) response occurred in 5 (25%) and 3 (70%) patients in group A and 11(55%) and 4 (45%) patients in group B, respectively. The final reduction in mMASI score was 59% with oral TXA vs 51% with microneedling. We

observed that there was no significant difference between the results in the 2 groups. The maximal response of TXA with microneedling was observed after the first session.

Relapse occurred at 24 weeks in 2 patients from group A with a severe melasma. No significant adverse effects were observed in both groups.

There were 2 patients who complained of gastrointestinal discomfort in group B.

	mMasi score before treatment	mMasi score at 4 weeks	mMasi score at 8 weeks	mMasi score at 12 weeks	mMasi score at 18 weeks	Final percentage reduction in mMasi score	Relapse
Group A, n=10 (TXA with microneedling)	12,5	8,75	7,6	7,6	6,2	51%	2 patients
Group B, n=15 (Oral TXA)	11,3	9,7	8,2	5,68	4,5	59%	None

Treatment of melasma is difficult and relapse often occurs. Tranexamic acid (TXA) is a treatment option for this difficult-to-treat condition.

TxA leads to significant reduction in MASI as seen in our study and previous studies. The preferred route of administration of TxA has also been studied. Sharma et al and Konisky and al concluded that TxA is an effective treatment for melasma and the route of administration does not alter the effectivity wich accords with the results of our study . Similar to our study, there were no significant side effects observed in any group.

However, oral TXA must be prescribed with caution due to its mechanism of action as a plasmin inhibitor. Thus, doctors must screen any patients for history of thromboembolic events and active thrombotic disease as well as intracranial bleeding, traumatic events, and color blindness.

Microneedling with TXA could be a great alternative to patients suffering from melasma who are not candidate to oral treatment.

Conclusion:

Both oral TXA and microneedling with TXA could be safe and effective in the treatment of melasma. Route of administration does not determine the clinical efficacy of the drug.

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Abstract N°: 5777

Nail involvement in patients used self-medication with topical antifungal drugs: clinical features and diagnosis

Anna Chasnyk[1], Elena Gubanova[2], Vera Pahomova[2], Natalya Shipilova[2], Irina Sergeeva[1]

[1]Novosibirsk State University, [2]Novosibirsk Regional Clinical Dermatovenerological Dispensary

Introduction & Objectives: Nail diseases (onychomycosis and nail dystrophies) are common in dermatology. Lab tests should be used for diagnosis of fungal infection. The global prevalence of self-medication and self-prescription ranges from 11.2% to 93.7%, depending on the country and target population. Often, people practiced self-medication accept any affected nails as fungal infection and use local treatment with over-the-counter antifungal agents, that can give a false negative lab tests result.

Objective. To evaluate the clinical features and lab tests results among patients who used self-medication with topical antifungal agents for nail changes.

Materials & Methods: 41 patients with nail changes (the mean age 61.3 ± 11.3) which used topical antifungal drugs without visiting the doctor. We performed a clinical examination, direct microscopic examinations and fungal cultures from nail scrapes. When first KOH microscopy results were negative, we repeated it up to three times. Species identification testing was done for Candida isolates using Candida-Screen Microlatest.

Results: Male to female ratio was 1:1.16. Clinical changes of affected nails were discoloration in 100%, brittleness in 80,5%, onycholysis in 75,6%, hyperkeratosis in 70,7%. Every patient had combination of two or more symptoms. Duration of nail disease ranged from 1 year to 6 years; total dystrophic damage of toenails prevailed (68,3%). Most of our patients used self-medication with amorolfine-containing nail lacquer as well as naftifine solution without atraumatic nail removal. Out of 39 patients who had undergone full mycological laboratory testing was diagnosed with onychomycosis in 78,4%. Of these, fungal hyphae were detected during the first light microscopy only in 34.5%; during repeat (second or third) microscopic tests in 51,7%; false-negative rates of KOH but positive culture in 13.8%. Out of culture-positive cases, besides the most common dermatophytes T. rubrum and T. mentagrophytes var. interdigitale, Candida krusei was isolated in 6,9%.

Conclusion: Our study shows an ineffectiveness of local self-medication for onychomycosis and progression of fungal nail infection. The findings clearly indicate that self-medication complicate the pathogen detection.

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Abstract N°: 5817

Treatment patterns in moderate to severe Chronic Hand Eczema - Results from the multinational RWEAL medical chart review

Ana Giménez-Arnau*[1], Anthony Bewley[2], Christian Apfelbacher[3], Maria Concetta Fargnoli[4], Bleuenn Rault[5], Alexanne Morillo[5], Douglas Maslin[6], Jenny M. Norlin[6], Marie -Noëlle Crépy[7], Sonja Molin[8]

[1]Department of Dermatology.Hospital del Mar Research Institute. Universitat Pompeu Fabra. Barcelona. Spain, [2]Barts Health NHS Trust & QMUL, London, United Kingdom,[3]Institute of Social Medicine and Health Systems Research, Otto-von-Guericke University Magdeburg, Magdeburg, , Germany, [4]Department of Biotechnological and Applied Clinical Sciences, University of L'Aquila, L'Aquila, , Italy, [5]Oracle Life Sciences, Paris, France. , Tassin-la-Demi-Lune, France, [6]LEO Pharma - LEO Pharma A/S, Ballerup, Denmark, [7]University Hospital of Centre of Paris Department of Occupational and Environmental Diseases, Hotel-Dieu Hospital, and Department of Dermatology, Cochin Hospital, AP-HP, Paris, , France, [8]Division of Dermatology, Queen's University, Kingston, Canada.

Introduction & objectives: There is limited evidence on the treatments used by patients with moderate-to-severe Chronic Hand Eczema (CHE) in clinical practice. The objective was to investigate treatment patterns in patients with moderate-to-severe CHE over 12 months, focusing on topical corticosteroid (TCS) therapy.

Material & Methods: The RWEAL (Real-World trEatment & mAnagement of chronic hand eczema in cLinical practice) study is a medical chart review involving 292 physicians from Canada, Germany, France, Italy, Spain, and the UK. Patients ≥18 years of age with moderate-to-severe CHE treated with TCS in the past 12 months, or with TCS contraindication, were included. Data on treatments used in the 12 months prior to the last visit was collected and analysed descriptively.

Results: Of the 1939 patients, 53.6% (n=1039) were females. Mean (SD) time since diagnosis was 6.0 (7.2) years. The worst severity, based on physician assessment, over the past 12-months was moderate in 56.8% (n=1101) and severe in 43.2% (n=838) of patients.

As per inclusion criteria, 99.1% (n=1922) of patients reported use of TCS in the past 12 months and 0.9% (n=17) had a contraindication for TCS. Use of low-potency TCS was reported in 7.9% (n=154), medium-potency TCS in 30.5% (n=592), high-potency TCS in 20.5% (n=398), and ultra-high-potency TCS in 42.7% (n=828).

Additionally, use of biologics was reported in 8.0% (n= 155), oral JAK inhibitors in 1.7% (n= 32), other oral treatment in 17.5% (n=340), phototherapy in 3.9% (n=76), and Topical Calcineurin Inhibitors in 6.7% (n=130).

Physicians considered 48.1% (n=925) of patients to have inadequate treatment response to TCS.

Conclusion: More than 90% of moderate-to-severe CHE patients had medium, high or ultra-high potency TCS. Despite being a first-line treatment, almost half of patients were considered inadequately treated with TCS. A considerable proportion of patients progress to systemics, which may be associated with additional monitoring, safety concerns and high costs.

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Abstract N°: 5905

Molecular effects in the skin of atopic dermatitis patients after oral treatment with orismilast

Emma Guttman-Yassky[1], James G. Krueger[2], Marjolein de Bruin-weller[3], Anne Weiss[4], Jakob Felding[4], Morten O. A. Sommer[4, 5], Jonathan I. Silverberg[6]

[1]Icahn School of Medicine at Mount Sinai Medical Center, Department of Dermatology, and Laboratory of Inflammatory Skin Diseases, New York, United States, [2]The Rockefeller University, Laboratory of Investigative Dermatology, New York, [3]UMC Utrecht, Department of Dermatology & Allergology, Utrecht,[4]UNION therapeutics A/S, Hellerup, Denmark, [5]Technical University of Denmark, DTU Biosustain, Kongens Lyngby, Denmark,[6]George Washington University School of Medicine and Health Sciences, Department of Dermatology, Washington

Introduction & Objectives:

Orismilast is a potent phosphodiesterase-4B and -4D inhibitor.1 Efficacy and safety of orismilast modified-release tablets were demonstrated in a 16-week, Phase 2b, double-blinded, placebo-controlled, dose-finding study (20mg, 30mg and 40mg BID) in patients with moderate-to-severe atopic dermatitis (AD)(NCT05469464, ADESOS). Here, we report skin biomarker data based on tape strip samples from patients in the ADESOS study. The primary objective of this biomarker study was to evaluate the effect of orismilast on a broad spectrum of inflammatory markers in AD skin lesions using tape strips as a non-invasive sampling technology combined with the Olink® technology. The biomarker data and conclusions will be presented and discussed.

Materials & Methods:

Tape strips were collected from lesional and nonlesional skin at baseline and lesional skin at week 16 of each patient. The biomarker population is a subpopulation of the ITT population. Protein extracts from patients treated with 20mg orismilast BID (N=30/58), 30mg orismilast BID (N=32/61) and 40mg BID (N=32/59) were analyzed using the Olink® technology. 21 selected proteins were quantified using the Olink® Flex panel.

Results:

The main objective of this analysis was to compare changes in biomarker levels in lesions of patients with AD (baseline vs week 16) after treatment with different oral doses of orismilast (20 mg, 30 mg or 40 mg BID). A broad immunomodulatory effect was observed for patients treated with orismilast as demonstrated by a significant reduction in key proteins related to T-helper 2 (e.g. thymus and activation-regulated chemokine (TARC), log2FCH = -1.76 (20mg); -2.48 (30mg); -1.47 (40mg) adjusted $p < 0.05$ and -0.1 (placebo)) , T-helper 17 (e.g. C-C Motif Chemokine Ligand 20 (CCL20), log2FCH = -2.07 (20mg); -2.37 (30mg); -1.69 (40mg) adjusted $p < 0.05$ and -0.13 (placebo)) and innate immune pathways.

Conclusion:

This biomarker evaluation, based on tape strip skin samples from patients with AD participating in the Phase 2b ADESOS study, demonstrate a reduced level of multiple cytokines and chemokines across several immune pathways. We consider the significant reduction observed for TARC particularly important and supportive of the clinical efficacy observed for orismilast as serum TARC levels has been described as the most reliable disease severity biomarker in AD.2 Finally, the study underlines tape strip sampling of the skin as a powerful, non-invasive technology to obtain data on protein changes when used in combination with the Olink® technology.

\1) Silverberg et al. Pharmacology of orismilast, a potent and selective PDE4 inhibitor. J Eur Acad Dermatol

Venereol. 2023;37(4):721-729. doi: 10.1111/jdv.18818.

\2) Renert-Yuval et al. Biomarkers in atopic dermatitis-a review on behalf of the International Eczema Council. J Allergy Clin Immunol. 2021;147(4):1174-1190.e1.

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Abstract N°: 6006

Beyond Active Ingredients: The Impact of Control Arms in Dermatology

Chawalpat Siripanich*[1, 2], Yan Ching Chow[1, 2], Faisal Ali[3, 4]

[1]University of Central Lancashire, School of Medicine and Dentistry, Preston, United Kingdom,[2]National Centre for Remote and Rural Medicine, Moor Row, United Kingdom, [3]Mid Cheshire NHS Foundation Trust, Crewe, United Kingdom, [4]St John's Institute of Dermatology, London, United Kingdom

Introduction & Objectives:

Understanding the efficacy of dermatological treatments relies not only on active agents but also on the nuanced insights from control arms. The objective of this study is to delve into the often-overlooked significance of control arms in dermatological research and clinical practice, shedding light on their role in shaping treatment paradigms and patient care strategies.

Materials & Methods:

Data from various clinical trials focusing on acne, rosacea, actinic keratoses, and melasma were analysed. Control arms were compared with active treatment arms to evaluate treatment efficacy.

Results:

Acne: Two identical, large-scale, 12-week, double-blinded, randomised, multicentre, and vehicle-controlled phase 3 studies (n = 1,524 and n = 1,293) demonstrated that once-daily application of trifarotene 50 µg/g cream significantly improved both facial and truncal acne, with success rates of up to 42.3% and 42.6%, and reduced mean inflammatory lesions by up to 66.2% and 65.4%, respectively ($p < 0.001$ for all factors). Importantly, the control arm using vehicle cream also showed notable improvements, with success rates of up to 25.7% and 29.9%, and mean inflammatory lesion reduction of up to 51.2% and 51.1% for facial and truncal acne, respectively. The difference in noninflammatory lesion reduction was even more marginal.

Rosacea: Two identical, large-scale, 12-week, double-blinded, randomised, multicentre, and vehicle-controlled phase 3 studies (n = 683 and n = 688) showed effectiveness of once-daily application of ivermectin 1% cream in reducing rosacea symptoms, with success rates reaching 38.4% and median inflammatory lesion reduction reaching 76.0% ($p < 0.001$ for both). The vehicle also had a measurable impact, with success rates reaching 18.8% and median inflammatory lesion reduction reaching 50.0%.

Actinic keratoses: A 6-month, randomised, and vehicle-controlled trial (n = 588) highlighted the preventive benefits of once-daily in the morning and as needed throughout the day application of sunscreen SPF 17 in actinic keratoses, with remission rates of baseline lesions reaching 25% and overall mean remissions reaching 28% ($p <$ 0.05 for both), compared to 18% and 20% with the vehicle, respectively.

Melasma: A 40-week, randomised, and vehicle-controlled trial (n = 30) showed that twice-daily application of isotretinoin 0.05% gel insignificantly reduced melasma severity and melanin pigmentation by 68.2% and 47%, respectively. The vehicle also showed a reduction of 60% and 34%, respectively.

Full discussion of trials will be discussed in main paper where there are fewer space restrictions

Conclusion:

Whilst active treatments consistently outperformed control arms, the latter achieved at least half the effectiveness in most cases, highlighting the inherent value of foundational skincare practices such as moisturising and cleansing. These findings accentuate the importance of integrating good skincare habits into patient care strategies, reinforcing that effective skincare alone may account for a significant portion of the overall treatment efficacy. It is imperative for healthcare providers to emphasise to patients the benefits of consistent and proper skincare practices, which can profoundly complement and enhance the results of specific dermatological treatments.

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Abstract N°: 6023

Topical Administration of a BCL-2 Inhibitor Alleviates Cutaneous Lupus Erythematosus by Targeting Senescent Cells and Age-Associated B Cells

Jiao Jiang[1], Ming Yang[2], Bingyi Yang[2], Haijing Wu[2], Qianjin Lu[1]

[1]Hospital for Skin Diseases, Institute of Dermatology, Chinese Academy of Medical Sciences & Peking Union Medical College, Nanjing, [2]Department of Dermatology, Hunan Key Laboratory of Medical Epigenomics, The Second Xiangya Hospital of Central South University, Chang Sha, China

Introduction & Objectives:

Cutaneous lupus erythematosus (CLE) is an autoimmune disease characterized by recurrent skin inflammation and manifestations. Recent research has highlighted the significant role of cellular senescence in the development of LE, and the efficacy of senolytic B-cell lymphoma 2 (BCL-2) inhibitors in selectively promoting the clearance of senescent cells has been demonstrated across diverse diseases. However, the potential of utilizing senolytic BCL-2 inhibitors for the treatment of CLE remains uncertain.

Materials & Methods:

In this study, we assessed the efficacy of a novel topical application of senolytic ABT-737 gel in a humanized mouse model of CLE. We evaluated the effects of this treatment on various indexes including skin appearance, immune complex deposition of C3 and IgG, as well as the frequencies of p21+ senescent cells and age-associated B cells (ABCs).

Results:

We found the topical application of senolytic ABT-737 gel effectively improved skin lesions, histopathological characteristics, and immune complex deposition in the humanized mouse model of CLE. Mechanistically, the senescent cells and ABCs in skin lesions of CLE mice were reduced through the application of ABT-737 gel.

Conclusion:

These findings establish a strong theoretical basis, indicating that the senolytic ABT-737 gel delayed CLE disease progress through targeting senescent cell populations. Our study provides promising and robust preclinical evidence supporting the therapeutic potential of ABT-737 gel in the treatment of CLE.

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Abstract N°: 6092

Clinician Perspectives on the use of Acitretin as Chemoprophylaxis in Non-Melanoma Skin Cancer

Vidette Wong*[1], Laura Skillen[2]

[1]Royal Victoria Hospital, United Kingdom, [2]Antrim Area Hospital, United Kingdom

Introduction & Objectives:

Cutaneous squamous cell carcinoma (cSCC) is the second most common type of skin cancer in the United Kingdom and Ireland and remains a large burden on dermatology services and patients alike.

There is evidence that retinoids such as acitretin are beneficial as a maintenance or suppression therapy for those who have had recurrent squamous cell carcinomas, especially those immunosuppressed in the transplant population.

Materials & Methods:

This qualitative clinician survey was distributed via the Irish Association of Dermatologists platform and looks at the use of acitretin in patients with recurrent non-melanoma skin cancers (NMSC) amongst dermatologists in Northern Ireland and Republic of Ireland. Results from 55 dermatologists show that majority of clinicians (83.6%) prescribe acitretin for recurrent NMSCs in both the immunosuppressed and immunocompetent cohort as chemoprophylaxis.

Answers were mostly free-text based allowing clinicians to describe their own practice.

Results:

Clinicians were asked what criteria they had for commencing a patient on acitretin for NMSC prophylaxis if they were immunosuppressed. The highest proportion of respondents (51.0%) cited their inclusion criteria as a patient developing 2 or 3 cSCCs prior to commencing on acitretin. A number of dermatologists (18.3%) broadly stated ‘recurrent’ or ‘multiple’ SCCs as their indication without any specific fixed quantity of SCCs. There was mention of decisions dependent on factors such as short time frame during which multiple cSCCs occurred, risk grading of SCC, site, patient choice, and individual surgical burden.

Acitretin was also prescribed for patients who were immunocompetent but who may be considered part of the high-risk population group with recurrent cSCCs. A significant number of respondents (>70%) either had the same criteria or a slightly higher threshold for commencing acitretin compared to immunosuppressed patients. A small proportion of clinicians stated that they did not prescribe acitretin at all for this particular patient cohort.

The majority (55.1%) of dermatologists prescribed a standard 10mg daily dose of acitretin, followed by 20% who suggested 10-20mg daily doses, then varying proportions suggested a 10-25mg, 20-30mg and 0.3mg/kg dose. A small number of clinicians used a reduced frequency of acitretin dosing such as 10 mg three times a week or alternate day initially and then uptitrated.

All dermatologists did baseline bloods prior to starting patients on acitretin with 100% checking and monitoring lipids and liver function tests. Bloods were most commonly checked between 3 to 6 months after starting acitretin.

Other factors that dermatologists considered for acitretin in this patient group included tolerability, co-morbidities, potential rebound effect if stopped, the need for long-term follow up and a patient’s gender or child-

bearing potential.

Conclusion:

To our knowledge, this is the first type of study to assess prescribing practice for acitretin in this particular patient cohort and would infer that the use of long term acitretin is a largely accepted management option for recurrent NMSCs. Criteria for initiation of acitretin, along with dosing was highly variable between clinicians and dependent on multiple factors. It identifies a need for more clinical studies looking at the efficacy of retinoids in the non-immunosuppressed high risk patient group with recurrent NMSCs to guide acitretin prescribing in the future.

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Abstract N°: 6095

efficacy and tolerability of the combination adapalene and benzoyl peroxide 0.1%/2.5%, gel in the management of acne vulgaris

Soukayna Kabbou[1], Ouiame El Jouari[1], Salim Gallouj[1]

[1]University Hospital Tanger, dermatology, tanger, Morocco

Introduction & Objectives:

Acne vulgaris is a common skin condition affecting mainly adolescents. It is characterised by the formation of comedones, papules, pustules and sometimes nodules on the face, back and chest. This condition can have a significant impact on patients' quality of life and self-esteem . Adapalene is a third-generation retinoid which works by normalising the follicular desquamation process, thereby reducing the formation of comedones. It also acts by modulating epidermal cell differentiation and reducing local inflammation . Benzoyl peroxide is an antibacterial agent that works by releasing active oxygen into the pilosebaceous follicles. This action helps to eliminate the bacteria responsible for the infection of blackheads and pustules .The combination of Adapalene and Benzoyl Peroxide has become a popular treatment option for acne vulgaris due to its complementary properties and its potential to reduce inflammation and prevent the formation of new lesions.

Materials & Methods:

This prospective study included patients suffering from acne, divided into two groups according to the severity of their condition .The first group comprised 65 patients with moderate to severe acne. These patients were treated with a combination of oral Tetralysal 300 mg and topical adapalene 0.1%/benzoyl peroxide 2.5% (Gr A).The second group consisted of 62 patients with mild to moderate acne. These patients were treated only with the A-P combination, without any oral treatment (Group B).The duration of treatment for both groups was 12 weeks.Tolerance was assessed through evaluations of local facial tolerance and adverse events. At each visit, the investigator assessed erythema, desquamation, dryness and tingling/burning on a scale ranging from 0 (none) to 3 (severe).

Results:

127 patients did participate in this study , Both groups of participants showed a high level of satisfaction with the efficacy of the treatment at the end of 12 weeks, with 76.3% of patients in group A and 72% in group B saying they were 'very satisfied'. The p-value was less than 0.001, suggesting a statistically significant difference in satisfaction rates between the two groups.A-P treatment was well tolerated by patients in both groups, and treatment-related adverse events were similar in both groups, with 19.35% of patients in group A and 16.12% in group B reporting adverse events. However, this difference was not statistically significant.The most common adverse events were dryness (8.06% grA, 9.68% grB), erythema (6.45% grA, 3.22% grB), flaking (3.22% grA, 1.67% grB) and tingling/burning (1.62% grA, 1.7% grB).

Conclusion:

Combination therapy is commonly used to treat acne because of its proven efficacy in treating this complex, chronic condition. The fixed-dose combination of adapalene 0.1% and benzoyl peroxide (BPO) 2.5% offers a therapeutic approach combining two agents that act in different ways to target the multiple pathophysiological factors responsible for acne . Our results suggest that this combination is globally effective and well tolerated, both as monotherapy and in combination with oral therapy. Additional studies have also confirmed these

observations, including a prospective study of 517 patients, which demonstrated that the fixed-dose combination of adapalene and BPO offered significantly superior efficacy for the treatment of acne vulgaris from the first week compared with monotherapies, while presenting a safety profile similar to that of adapalene alone.

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Abstract N°: 6368

Management Approach for Confluent and Reticulate Papillomatosis

Shashikumar Bm[1]

[1]Mandya Institute of Medical Sciences, Mandya, dermatology, Mandya, India

Introduction & Objectives:

Confluent and reticulate papillomatosis (CRP) is an uncommon benign, acquired keratinization disorder. It usually presents sporadically, with onset typically occurring in young adulthood. It clinically manifests as scaly, dull, brownish, centrally confluent, and peripheral reticulate macules and papules that coalesce to form patches on the upper trunk and neck

Objectives:

1. To study the association of CRP with thyroid disturbances
2. To evaluate the efficacy of minocycline in management of CRP

Materials & Methods:

Thirty patients with a diagnosis of confluent and reticulate papillomatosis were included in the study. Diagnosis was made based on clinical findings, histopathology and dermoscopy. Thyroid profile was done on all the patients. They were treated with minocycline 100 mg OD for 3 weeks, treatment was continued for another 2 weeks in those who had incomplete response

Results:

6 (20%) out of 30 patients had hypothyroidism, and hyperthyroidism was not detected in any of them. 22 (72%) of patients showed complete response to treatment, partial response was seen 3 patients (10%) and no response was seen even after 6 weeks of treatment in 5 patients.

Conclusion:

The male to female ratio was 1:1.5 (12 males and 18 females). Hypothyroididm is a common association among patients with CRP. Oral minocycline is a effective treatment for CRP.

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Abstract N°: 6465

Hair regrowth in a patient with generalized alopecia areata during upadacitinib therapy

Jowita Sroka-Tomaszewska*[1], Aleksandra Herkowiak[1], Magdalena Trzeciak[1], Aleksandra Wilkowska[1], Roman Nowicki[1]

[1]Medical University of Gdańsk, Department of Dermatology, Venereology and Allergology, Gdańsk

Introduction & Objectives:

The patient, diagnosed with atopic dermatitis at the age of 9, initially remained in remission for 10 years after starting a dairy-free diet. Around the age of 20, the disease worsened with frequent exacerbations and lack of full symptom control. The patient remained under care at the Allergic Skin Diseases Clinic since 2017. Generalized alopecia occurred during treatment with cyclosporine (2018). Due to the recurrence of severe atopic dermatitis and the coexistence of alopecia areata, the patient was qualified for upadacitinib treatment. The objective was to evaluate hair regrowth under systemic treatment.

Materials & Methods:

Patient medical records were retrospectively reviewed.

Results:

The patient has been receiving Upadacitinib since the beginning of March 2024, and in the clinical examination, gradual hair regrowth has been observed on the scalp, eyebrows and beard.

Conclusion:

The prognosis for achieving regrowth is less favourable if the last episode of the disease lasts longer than 5 years, but this should not be a decisive factor in waiving treatment or qualifications for patients for treatment. JAK inhibitors should be the first choice in alopecia areata due to the best documented in multicenter clinical trials randomized effectiveness and safety, confirmed by formal registration for this indication.

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Abstract N°: 6523

Tranexamic acid for the treatment of Rosacea

Rasha Moumna*[1], Kenza Khachani[1], Syrine Hamada[1], Nadia Ismaili[1], Laila Benzekri[1], Karima Senoussi[1], Meriam Meziane[1]

[1]Ibn Sina Hospital, Dermatology Department, Rabat, Morocco

Introduction & Objectives:

Rosacea, though very common, presents a therapeutic challenge in our daily practice. Recommended treatments for erythemato-telangiectatic rosacea primarily include light-based therapies and lasers, which, despite their effectiveness, can be costly and come with side effects such as bruising and post-inflammatory hyperpigmentation. Tranexamic Acid (TXA), recognized for its efficacy in managing various dermatological conditions such as hereditary angioedema and melasma, has emerged as a new promising therapeutic option for rosacea, physiopathologically proven to target its vascular network and persistent erythema. However, research on its oral and topical use is very limited.

Our study features the largest patient sample to date and is the first to compare the efficacy of both oral and topical treatment modalities on clinical, dermoscopic, and psychological scales.

Materials & Methods:

We conducted an unblinded study enrolling 32 patients diagnosed with erythemato-telangiectatic rosacea who provided written consent. Exclusion criteria included individuals with chronic diseases, hypercoagulative disorders, pregnancy or breastfeeding, oral contraceptive use, or any recent rosacea treatment within the previous 6 months. Patients were evenly divided into four groups:

- Group 1 received oral TXA (500mg/day)
- Group 2 applied a topical 10% TXA solution (prepared from TXA injectable solution 500mg/5ml) twice daily.
- Group 3 applied a 10% TXA solution-infused wet dressing twice a week.
- Group 4 served as a control and only used sunscreen.

After a 3-month treatment period, we assessed clinical improvement using the Investigator's Global Assessment of Rosacea Severity Score (IGA-RSS), the Rosacea Area and Severity Index (RASI), as well as dermoscopy analysis. Subjective symptoms were evaluated using Visual Analog Scales (VAS), while the psychological impact of rosacea was measured using the Arabic version of the Dermatology Life Quality Index (DLQI).

Results:

Our study included 32 participants, with 8 individuals in each group. Demographic and baseline clinical characteristics of the included patients were roughly similar in the 4 groups, as summarized in Table 1. After a 3-month period, we observed a statistically significant improvement in the treated groups compared to the control group. The highest improvement rates were noted in Group 1, followed by Group 2 and then Group 3, as shown in Figure 1. This improvement was objectively documented by the significant reduction in IGA-RSS, RASI, and DLQI scores among treated patients, as well as the decrease of the scales of subjective symptoms, particularly flushing (Figure 2).Haut du formulaireBas du formulaire Dermoscopy confirmed these findings, revealing decreased erythema and vessel caliber, as well as reduced vessel branching in the treated groups. Secondary benefits included improved skin hydration, reduction of the Melasma Area and Severity Index (MASI) in two patients, and a

decrease in associated post-inflammatory hyperpigmentation observed in 6 patients. Furthermore, no systemic or local adverse effects were reported by any of the participants.

Conclusion:

Our findings suggest that TXA, whether administered orally or topically, represents a safe, affordable and effective treatment option for erythemato-telangiectatic and steroid-induced rosacea, particularly interesting in dark phototypes with associated melasma or post-inflammatory hyperpigmentation.

	Group 1 (n=8)	Group 2 (n=8)	Group 3 (n=8)	Group 4 (n=8)
Sex, n (%) - Men - Women	 0 (0) 8 (100)	 0 (0) 8 (100)	 0 (0) 8 (100)	 1 (12,5) 7 (87,5)
Age, mean	34	46,5	47	38,5
Duration of rosacea (years)	4	9	5	8
Form of rosacea, n (%) - Erythemato-telangiectatic - Steroid-induced	 7 (87,5) 1 (12,5)	 6 (75%) 2 (25%)	 5 (62,5) 3 (37,5)	 7 (87,5) 1 (12,5)
Phototype according to the Fitzpatrick scale, n (%) - IV - III	 6 (75%) 2 (25%)	 4 (50%) 4 (50%)	 4 (50%) 4 (50%)	 2 (25%) 6 (75%)

Table 1: Demographic and baseline clinical characteristics of the included patients.

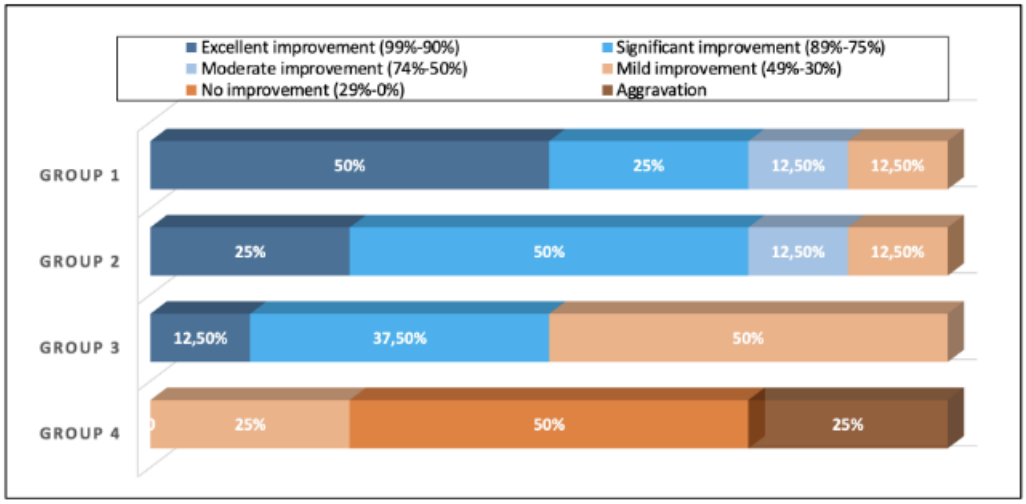

Figure 1: Investigator's global assessment of the clinical improvement after 3 months.

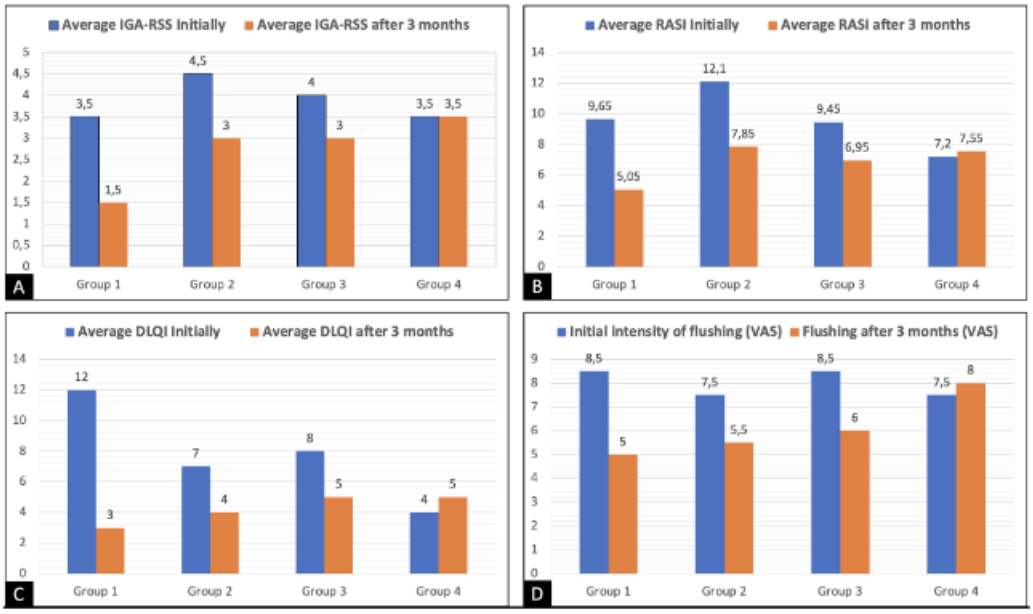

Figure 2: Comparison of the average IGA-RSS **(A)**, RASI **(B)**, DLQI **(C)**, and Flushing **(D)**, initially and after 3 months.

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Abstract N°: 6543

Imiquimod for the Treatment of Lentigo Maligna in Surgical Difficulties: Two Case Reports with One-Year Follow-Up

Ferdi Öztürk[1], Cansu Irmak Ünlü[1], Şaduman Balaban Adım[2], Hayriye Saricaoglu[1]

[1]Bursa Uludag University Faculty of Medicine, Dermatology, Bursa, Türkiye,[2]Bursa Uludag University Faculty of Medicine, Pathology, Bursa, Türkiye

Introduction & Objectives:

Lentigo maligna (LM) is a type of melanoma in situ that occurs in sun-damaged skin and may progress to invasive lentigo maligna melanoma (LMM). Treatment choices for LM are surgery, topical imiquimod, radiotherapy, cryotherapy, curettage, and laser. Topical imiquimod is frequently preferred today due to its different mechanisms of action.

Materials & Methods:

We present two cases treated with 5% topical imiquimod for facial LM.

Case 1 is a 63-year-old female patient with hypertension and kidney disease who was admitted for pigmented lesions on her nose and lips for 6 years. Dermoscopy revealed asymmetric follicular pigmentation. The result of punch biopsies were taken from the lip, right and left mustache regions revealed LM. Since papillary dermis invasion was suspected in the biopsy taken from the tip of the nose, plastic surgery excised it. For other lesions, imiquimod 5% cream was recommended once a day, 5 days a week. The excisional biopsy result was melanoma in situ. The treatment was continued for 6 months. The lesions completely regressed. During the 1-year follow-up, no relapse was observed based on clinical and dermatoscopical examinations.

Case 2 is a 60-year-old female with convulsions and hypertension. She applied for a lesion that had existed in the right malar region for 10 years and had grown for 1 year. On dermoscopy of the lesion, pseudo-network, asymmetrical, and occasionally black-brown follicular pigmentations were present. Punch biopsies taken from two different suspicious areas on dermoscopic examination of the lesion were compatible with LM. Since the lesion was very large and a large scar would remain after excision, imiquimod treatment was planned. Imiquimod 5% cream was recommended for the lesion once a day, five days a week. When she came to the follow-up after 1 month, irritation occurred more than expected in the lesional and perilesional areas, extending to 2 cm in diameter. The cream was interrupted for 1 week, and a wet dressing with saline was recommended. After 1 week, the cream treatment was continued for 4 months. The lesions completely regressed. During the 1-year follow-up, no relapse was observed based on clinical and dermatoscopical examinations.

Results:

The management of LM is controversial. For the treatment of the disease, surgical excision with 5–10 mm margins is generally preferred. Non-surgical treatments are effective but may result in long-term recurrence, scarring, or secondary skin cancer. Therefore, they should be preferred when resection cannot be performed with adequate margins due to lesion size or localization, in the elderly and in those who refuse surgery. Topical imiquimod, a non-surgical treatment, stimulates both innate and acquired immune pathways and stands out with its antitumor, antiangiogenic, and pro-apoptotic properties. These features make it especially preferred in the treatment of subclinical spread. It is accompanied by an increased risk of irritation, flu-like symptoms, hypopigmentation, and the risk of recurrence.

Conclusion:

Information on imiquimod therapy is limited to case series and uncontrolled studies. In light of the findings, satisfactory results can be obtained. On the occasion of these two cases, we aimed to discuss the efficacy of imiquimod treatment in cases of LM where surgical treatment is not possible or difficult.

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Abstract N°: 6673

Topical Treatment of Tyrosine Kinase 2 Inhibitor through Borneol-embedded Hydrogel: Evaluation for Preventive, Therapeutic, and Recurrent Management of Psoriasis

Zhenrui Shi[1], Yuhsien Lai*[1]

[1]Sun Yat-sen Memorial Hospital, Sun Yat-sen University, Department of Dermatology, Guangzhou，Guangdong

Introduction & Objectives:

Psoriasis, an immune-mediated inflammatory skin disorder characterized by a chronically relapsing-remitting course, continues to be primarily managed through topical therapy. While oral administration of tyrosine kinase 2 inhibitors (TYK2i) stands as an effective approach for psoriasis treatment, the potential efficacy of topical application of TYK2i remains unexplored. Herein, we developed a hydrogel system as a new topical carrier of TYK2i and explored the effects on treating psoriasis in vivo and in vitro models.

Materials & Methods:

The carbomer/alginic acid hydrogel is embedded with borneol (BO) as a new topical carrier for TYK2i (TYK2i-BO-gel). The preventative, therapeutic, and relapse models of psoriasiform dermatitis (PsD) in mice were established by topical application of imiquimod (IMQ) or hydrodynamically delivered of IL-23 minicircle plasmid DNA (IL23MC). The efficacy of TYK2i-BO-gel in different models was evaluated by psoriasis severity index (PSI), histology (H&E staining), immunohistochemistry (IHC), and reverse transcription polymerase chain reaction (RT-PCR) . Furthermore, we assessed the anti-inflammatory effect of the TYK2i-BO-gel in vitro culture of lesional skin explant from patients with psoriasis.

Results:

In the preventative, therapeutic, and relapse mouse models, the TYK2i-BO-gel all demonstrated superior efficacy compared to hydrogel embedded with BO (BO-gel) or TYK2i alone (TYK2i-gel), which was evidenced by the improvement of PSI scores, reduction in epidermal thickness and Munro microabscess count, decreased local immune cell infiltration, and suppression of various pro-inflammatory factors (Il17a, Il22, Il1b, Il6, S100a8, S100a9, Cxcl1, Cxcl2) in the skin lesions. Furthermore, TYK2i-BO-gel outperforms topical corticosteroid therapy by significantly preventing psoriatic lesion recurrence. Most importantly, a strengthened anti-inflammatory effect caused by TYK2i-BO-gel is seen in a human skin explant model, highlighting its potential for clinical use. The addition of BO in hydrogel not only increased skin permeability but also inhibited expression of antimicrobial peptides in keratinocytes and facilitated the anti-Th17 response of TYK2i with suppressed activation of STAT3.

Conclusion:

This work represents the accessibility and effectiveness of TYK2i-BO-hydrogel as a new topical formulation for anti-psoriasis management and shows great potential for clinical application.

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Abstract N°: 6899

Risk and timing of isotretinoin-related laboratory disturbances- A population-based study

Shirin Emtenani[1], Mariam Abdelghaffar*[2], Ralf J. Ludwig[1], Enno Schmidt[1], Khalaf Kridin[1]

[1]University of Lübeck, Lűbeck Institute of Experimental Dermatology, Lübeck, Germany,[2]Royal College of Surgeons in Ireland - Bahrain, Al Sayh, Bahrain

Introduction & Objectives:

The optimal labratory monitiring routine for acne patients udnergoing tretnoin treatment is currently uncertain. This review aims to assess the incidence of mild and severe labratory abnromalities in patients treated with isotreatnetb comparde to oral antibiotics. Additionally, we examine the fluctuations in labratory abrnormalities over time to estbalish the most effective frequency for routine testing.

Materials & Methods:

A global population-based retrospective cohort study assigned two groups of patients with acne prescribed isotretinoin (n=79,012) and oral antibiotics (n=79,012). Comprehensive propensity-score matching was conducted to optimize group comparability. Participants in both groups were followed longitudinally to assess the risk of disturbances in the following laboratory parameters: triglycerides, total cholesterol, alanine transaminase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), and creatinine.

Results:

Compared to acne patients treated with oral antibiotics, those managed with isotretinoin demonstrated an increased risk of grade≥3 hypertriglyceridemia (hazard ratio [HR], 7.85; 95% confidence interval [CI], 5.58-11.05; P<0.001) and grade≥3 elevated aspartate transaminase (AST) levels (HR, 1.45; 95% CI, 1.13-1.85; P=0.003) within the initial three months of treatment. The absolute risk of these abnormalities among isotretinoin initiators was 0.4% and 0.2%, respectively. The risk difference of these findings was clinically marginal: in detail, three and one additional case(s) per 1,000 patients starting isotretinoin, respectively. There was no significant risk of grade≥3 impairment in cholesterol, alanine transaminase (ALT), gamma-glutamyl transferase (GGT), or creatinine levels under isotretinoin. In time-stratified analysis, most laboratory abnormalities were documented within the first3 months after drug initiation.

Conclusion:

Our findings indicate that acne patients undergoing insotretinoin treatment face an elevated risk of severe hypertriglyceridemia and AST hypertransaminasemia. The period of highest risk for labratory abnormalities occurs within during the first 3 months after treatment initiation, suggesting this timeframe as optimal for routine blood testing.

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Abstract N°: 7261

Back to the basics: dapsone successfully used in the treatment of generalized morphea -a report of two cases

Daciana Elena Branisteanu[1, 2], Catalina Anca Munteanu[1], Roxana-Paraschiva Ciobanu[1], Andreea-Caterina Rusu[1], Cristina Colac-Botoc[1], Elena Porumb-Andrese[1, 2], Antonia Clivet*[1]

[1]Iași, Railway Clinical Hospital, Iași, Romania, [2]Iași, Dermatology Department, " Gr. T. Popa" University of Medicine and Pharmacy, Iași, Romania

Introduction & Objectives:

Generalized morphea(GM) represents a rare and severe form of morphea, distinguished by multiple plaques appearing in more than two distinct areas. Despite ongoing research, the full pathogenesis of the condition remains incompletely understood, resulting in limited treatment options both in terms of effectiveness and variety. The unique characteristics of patients and the scarcity of therapeutic options compel physicians to explore alternatives, particularly in cases where treatment resistance is encountered. The objective of these case reports is to underscore the potential of dapsone as one of the primary treatment options in resistant cases of GM.

Materials & Methods:

We present two cases of generalized morphea both treated succesfully with oral dapsone.

Results:

Case 1: A 74-year-old Caucasian female was initially admitted to our clinic with a solitary plaque of morphea situated on the left supramammary region, alongside concomitant histopathologically confirmed psoriasis lesions on both elbows and knees. A biopsy was performed confirming the diagnosis of plaque morphea. Both types of lesions were managed with high-potency topical steroids, resulting in complete resolution of the psoriasis lesions and a favorable outcome for the morphea lesion. However, a year later, the patient returned to our clinic with generalized plaque morphea lesions located on the thorax and both legs, confirmed through histopathological examination. Immunological testing was conducted, with all tests returning negative results. Following assessment of the glucose-6-phosphate dehydrogenase(G-6-PD) levels, treatment with a minimal dose of dapsone was initiated. Remarkably, the patient exhibited complete clearance of the lesions after three months of treatment, with no observed side effects during the course of therapy.

Case 2: A 61-year-old Caucasian female presented to our clinic with generalized plaque morphea lesions affecting the anterior abdominal wall and both thighs. The onset of the disease occurred three years prior to her admission to our service, and despite undergoing various treatments, there was minimal improvement in the lesions. The diagnosis was confirmed histopathologically and immunological testing was performed with negative results. After determining the levels of G-6-PD, dapsone treatment was initiated, resulting in complete clearance of the lesions within two months of initiation.

Conclusion:

Morphea is characterized by inflammation and aberrant immune activity in the skin, resulting in the hallmark thickening and hardening of the affected areas. Dapsone’s capacity to diminish inflammation and modulate immune responses may aid in relieving symptoms and fostering healing in morphea lesions. Furthermore, dapsone may possess additional mechanisms of action that bolster its effectiveness in treating GM, though these

mechanisms remain incompletely elucidated.

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Abstract N°: 7272

Glutathione- Skin Lightening Therapy in Cosmetic Dermatology

Ajay Kumar Singh[1, 2]

[1]Devansh skin and laser clinic (DSL CLINIC), COSMETIC DERMATOLOGY , Delhi, India,[2]Jawaharlal Institute of Postgraduate Medical Education and Research, DERMATOLOGY, Puducherry, India

Introduction & Objectives

Many countries in South Asia and South East Asia were colonized by Europeans. Their white race was deemed the superior race and the dark-skinned race were considered lower class, viewed as slaves. This understanding of white supremacy has been deeply etched into our minds, passed down from generation to generation in Asia and manifests itself in the Asian obsession with white skin. So the origin of the belief that white is synonymous with power and that white equals beauty began not with the modern beauty industry, but at the time of colonization in many Asian countries.

Glutathione is a very popular and potential Antioxidant in Asian Dermatology and cosmetic usage as**Skin Whitening Agent**

It's using by these routes in our body - Orally, Topically, Sublingual, I/VAND I/M

1. Direct chemical neutralization of singlet oxygen, hydroxyl radicals, and superoxide radicals
2. Cofactor for several antioxidant enzymes
3. Regeneration of vitamins C and E
4. Neutralization of free radicals produced by Phase I liver metabolism of chemical toxins
5. Transportation of mercury out of cells and the brain
6. Regulation of cellular proliferation and apoptosis

Glutathione is involved in the detoxification of both xenobiotic and endogenous compounds.

It facilitates excretion from cells (Hg), facilitates excretion from body (POPs, Hg) and directly neutralizes (POPs, many oxidative chemicals).

It Inhibits the tyrosinase (enzyme for melanogenesis): Direct inhibition: Thiol group binding with the copper-containing active site of the enzyme

Indirect inactivation: Exerted via the antioxidant effect of glutathione that leads to quenching of free radicals and peroxides

Switching production of eumelanin to phaeomelanin

Direct inactivation of tyrosinase (the key enzyme of melanogenesis) by binding with the copper-containing active site of he enzyme .

Indications of Glutathione in Aesthetic Dermatology –

Hyperpigmentation, Melasma, PIH,Past Acne Hyperpigmentation,PDL

Dose: 20-40 mg/kg body weight per day (i.e. 1-2 grams GSH per day) divided into two doses, for skin lightening effects.

Maintenance dose: After attaining the 'desired' skin colour, a maintenance dose of 500mg/day for an indefinite duration has been suggested.

Materials & Methods:

Scavenging of free radicals, most importantly hydrogen peroxide

Translocation of amino acids across cell membranes

Detoxification of xenobiotics

Participation as a coenzyme in certain important processes of cellular metabolism

Glutathione is a substance made from the amino acids glycine, cysteine, and glutamic acid. It is produced naturally by the liver and involved in many processes in the body, including tissue building and repair, making chemicals and proteins needed in the body, and for the immune system.

Glutathione is a tripeptide (cysteine, glycine, and glutamic acid) found in surprisingly high levels—5 millimolar—concentrations in most cells this is the same concentration in cells as glucose, potassium, and cholestero Considering the high level of metabolic activity required to produce glutathione.

Results:

Glutathione can induce skin whitening among people with type iv skin type.

Conclusion:

Glutathione directly scavenges diverse oxidants: superoxide anion, hydroxyl radical, nitric oxide, and carbon radicals. Glutathione catalytically detoxifies: hydroperoxides, peroxynitrites, and lipid peroxides.

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Abstract N°: 7328

Evaluation of the Efficacy, Safety, and Satisfaction Rate of Topical Latanoprost in Patients with Hypopigmented Burn Scars Treated with Fractional CO2 Laser: A Double-Blind Randomized Controlled Clinical Trial

Alireza Jafarzadeh*[1], Najmolsadat Atefi[1], Afsaneh Sadeghzadeh Bazargan[1], Azadeh Goodarzi[1]

[1]Department of Dermatology, Rasool Akram Medical Complex Clinical Research Development Center (RCRDC), School of Medicine, Iran University of Medical Sciences, Tehran, Iran , Dermatology, Tehran, Iran

Introduction & Objectives:

Burn scars present psychological and social challenges for patients, classified into atrophic and hypertrophic types. Treatments like corticosteroid injections, laser therapy, and platelet-rich plasma (PRP) injections are commonly recommended for hypertrophic scars, while regenerative medicine and fractional CO2 lasers are linked to some degree of improvement for atrophic scars. Hypopigmented and depigmented burn scars pose ongoing challenges for healthcare providers and patients, with therapies such as intense pulsed light and fractional CO2 laser showing variable effects in treating these conditions. This study evaluates the effectiveness of latanoprost, a prostaglandin analog, in combination with fractional CO2 laser for repigmentation of hypopigmented burn scar lesions.

Materials & Methods:

During the study, patients were treated with 0.005% latanoprost eye drop or normal saline twice a day for 6 months and underwent six monthly fractional CO2 laser sessions. Treatment instructions were provided by the physician, and patients were instructed to report any complications and avoid using other medications in the treatment area. Assessments included photography at the start of the study and in three follow-up sessions at three-month intervals. Improvement was assessed using the Subject Global Aesthetic Improvement Scale (SGAIS) by both the physician and patients. Patient satisfaction was evaluated using a Grade scale, and side effects were monitored in all follow-up sessions.

Result:

In the third follow-up session, physicians assessing the Subject Global Aesthetic Improvement Scale (SGAIS) observed that a higher proportion (85.7%) of cases in the fractional CO2 laser with latanoprost group achieved a grade of 4 (50-74% improvement). In the placebo group, 0% of patients achieved grade 4, and 71.4% were classified as grade 2 (0-24% improvement), indicating a significant difference (P-value: 0.0001). Patient satisfaction, measured by the “Grade scale to evaluate patient satisfaction” index, revealed a notable contrast between the two groups, with average satisfaction scores of 8.50±0.65 and 4.64±1.00 for the fractional CO2 laser with latanoprost and placebo groups, respectively, indicating a statistically significant difference (P=0.0001). Furthermore, throughout the study, no severe side effects were reported by any of the patients.

Conclusion:

Using topical latanoprost is a successful method for promoting repigmentation in hypopigmented and depigmented burn scar lesions. When this topical medication is combined with fractional CO2 laser treatment, it improves the laser’s efficacy and overall effectiveness in treating the lesions.

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Abstract N°: 7401

High-dose topical melatonin unfolds major anti-aging effects in mature human skin ex vivo

Tatiana Gomez Gomez[1], Kinga Linowiecka[1, 2], Mara Hartoyo[1], Daniela Buchbinder[1], Francesca Dostillio[1], Tara Samra[1], Ramtin Kassir[3], Jérémy Chéret*[1, 4], Ralf Paus[1, 4]

[1]University of Miami Leonard M. Miller School of Medicine, Dermatology, Miami, United States,[2]Nicolaus Copernicus University, Department of Human Biology, Toruń, Poland, [3]Kassir Plastic Surgery, New York, United States, [4]CUTANEON - Skin & Hair Innovations, Hamburg & Berlin, Germany

Introduction & Objectives:

Since skin is constantly exposed to aging-promoting stressors, effective, well-tolerated anti-aging actives are much-needed. We have shown that high-dose melatonin (MT) exerts potent anti-aging effects in organ-cultured human eyelid skin when added to the medium, i.e. after 'systemic' treatment. Yet, MT's rapid liver metabolism encourages a topical mode of application. Hence, we have asked if high-dose topical MT improves key skin aging biomarkers.

Materials & Methods:

4 mm scalp full-thickness skin punches were collected from healthy aged donors (40+ years) and high-dose MT (100 µM and 1 mM) in a vehicle that contained only FDA-approved ingredients was topically applied for 6 days *ex vivo*. 7µm of tissue cryosections were performed and processed for quantitative (immuno)-histomorphometry analyses.

Results:

Quantitative immunohistomorphometry revealed that topical MT significantly increased SIRT1, Lamin B1, and mitochondrial function parameters (VDAC, PGC1α) in the epidermis, and increased collagen I and fibrilin-1 expression in the dermis. Mimicking the effects of rapamycin, 100µM MT significantly reduced epidermal activity of the aging-promoting mTORC1 pathway ex vivo as shown by reduced S6 phosphorylation. When we silenced TSC2, the key endogenous inhibitor of mTORC1 activity, in the presence of MT ex vivo, MT not only prevented the expected up-regulation of p-S6 after TSC2 silencing, but also rescued the siRNA-induced downregulation of TSC2 itself.

Conclusion:

In summary, MT exerts prominent, differential anti-aging effects on human skin even when applied topically. Moreover, this study introduces MT as a novel stimulator of TSC2, the key physiological negative control of mTORC1 activity, thus further expanding our understanding of MT's multifaceted functions.

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Abstract N°: 7575

An Analysis of Topical Corticosteroid Availability in Irish Community Pharmacies

Nicole Fagan*[1], Aoife Lally[1], Aisling Ryan[1]

[1]St. Vincent's University Hospital, Charles Centre of Dermatology, Dublin, Ireland

Introduction & Objectives:

To assess the real-world availability of topical corticosteroid (TCS) preparations in Irish community pharmacies. A secondary aim was to understand the factors limiting availability, if applicable, and collect perspectives on suggested improvements.

Materials & Methods:

A 27-item survey online survey was distributed to pharmacists via a database of 3935 email addresses supplied by the Pharmaceutical Society of Ireland. The response rate was 9% and 359 completed responses were included in analysis. Data was analysed using descriptive statistics and qualitative responses using Braun and Clarke methodology.

Results:

Most frequently respondents were independent pharmacy employees (34%), with over 20 years' experience (45%) and had a role in managing stock in the pharmacy (93%). Over half had difficulty filling TCS prescriptions daily (57%). The top three factors that influenced TCS stocking were supplier availability (87%), patient demand (75%) and prescribing patterns of prescribers (66%). The majority of respondents reported issues with the pricing and reimbursement of unlicensed medications (ULM) by the Primary Care Reimbursement Service (PCRS) (64%). On the shelf TCS availability by formulation ranged from 4% to 94% across pharmacies. In stock availability did not match shortages listed by the Health Products Regulatory Authority (HPRA) which were analysed weekly over a 4-week period. Thematic analysis of open ended questions identified areas for improvement including prescribing of alternatives by prescribers and challenges such as reimbursement of ULM by the PCRS.

Conclusion:

Ireland has ongoing shortages of TCS. Shortages listed by the HPRA may not accurately reflect real world, in stock availability of TCS.

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Abstract N°: 7986

DELTA FORCE trial: A 24-week head-to-head phase 3 trial comparing the efficacy and safety of topical delgocitinib cream with oral alitretinoin capsules in adults with severe chronic hand eczema

Ana Giménez-Arnau*[1], Andreas Pinter[2], Wiebke Sondermann[3], Ziad Reguiai[4], Richard Woolf[5], Charles Lynde[6], Franz Legat[7], Antonio Costanzo[8], Juan F. Silvestre Salvador[9], Berith Fredsted Hagen[10], Natja Mellerup[10], Ursula Plohberger[11], Lasse Ryttig[12], Andrea Bauer[13]

[1]Hospital Del Mar Research Institute, Universitat Pompeu Fabra, Spain,[2]Department of Dermatology, Venereology, and Allergology, Goethe-Universität Frankfurt am Main, Germany, [3]Department of Dermatology, Venereology and Allergology, University Hospital Essen, Germany, [4]Department of Dermatology, Polyclinique Courlancy, France, [5]St John's Institute of Dermatology, Guy's and St Thomas' NHS Foundation Trust, United Kingdom, [6]Lynde Institute for Dermatology and Lynderm Research, Markham, Ontario, Canada, and Department of Medicine, University of Toronto. Canada, [7]Department of Dermatology, Medical University of Graz Austria, [8]Department of Biomedical Sciences, Humanitas University, Milan Italy,[9]Department of Dermatology, Hospital General Universitario Dr Balmis, ISABIAL. Alicante, Spain, [10]LEO Pharma A/S, Ballerup. Denmark, [11]LEO Pharma A/S, Ballerup Denmark, [12]LEO Pharma A/S, Ballerup , Denmark, [13]Department of Dermatology, University Allergy Center, University Hospital Carl Gustav Carus, Technical University Dresden. Germany

Introduction & Objectives: In patients with moderate to severe Chronic Hand Eczema (CHE), delgocitinib cream, a topical pan-Janus kinase inhibitor, demonstrated significant improvement in all key efficacy endpoints and was well tolerated vs cream vehicle in phase 3 DELTA 1 (NCT04871711) and DELTA 2 (NCT04872101) as well as when used long-term as needed in open label DELTA 3 (NCT04949841). The aim of this head-to-head Phase 3 DELTA FORCE trial (NCT05259722) was to compare the efficacy, effect on quality of life (QoL), and safety of twice-daily topical delgocitinib cream (20 mg/g) with once-daily oral alitretinoin, currently the only approved drug for severe CHE.

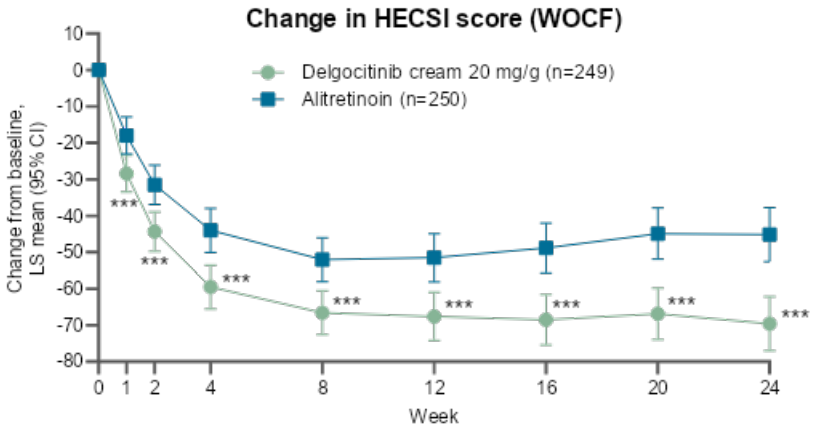
Materials & Methods: DELTA FORCE was a randomised, assessor-blind, active-controlled, multi-site trial. Adults (aged ≥18 years) with severe CHE were randomised 1:1 to delgocitinib cream (n=254) or alitretinoin (n=259) for 24 weeks. The primary endpoint was change in Hand Eczema Severity Index score (HECSI) from baseline to Week (W)12. Key secondary endpoints were ≥90% improvement in HECSI (HECSI-90) at W12, Investigator's Global Assessment for CHE treatment success (IGA-CHE TS) at W12, defined as IGA-CHE score of 0/1 (clear/almost clear), changes in Hand Eczema Symptom eDiary (HESD) itch and pain scores from baseline to W12, as well as area under the curve (AUC) for HECSI-90 and change in Dermatology Life Quality Index score (DLQI), and change in HECSI from baseline to W24. Safety endpoints included numbers of adverse events (AEs), serious AEs (SAEs), and AEs leading to trial drug discontinuation.

Results: A significantly greater least squares (LS) mean decrease in HECSI from baseline to W12 was observed with delgocitinib cream (67.6) vs alitretinoin (51.5; $P<0.001$; **Figure**). At W12, a greater proportion of patients treated with delgocitinib cream vs alitretinoin achieved HECSI-90 (38.6% vs 26.0%; $P=0.003$) and IGA-CHE TS (27.2% vs 16.6%; $P=0.004$). A greater LS mean decrease from baseline was observed with delgocitinib cream vs alitretinoin in HESD itch/pain at W12 (3.0/2.9 vs 2.4/2.3; $P\leq0.018$) and HECSI at W24 (69.6 vs 45.1; $P<0.001$); LS mean AUC for HECSI-90 (49.2 vs 34.9; $P<0.001$) and AUC for the change in DLQI (1124.7 vs 790.7;$P<0.001$) were higher with delgocitinib cream vs alitretinoin. Fewer patients in the delgocitinib cream group than in the alitretinoin group reported AEs (number of events [E]=280 in 125 [49.4%] patients vs E=620 in 188 [76.1%] patients), SAEs (E=5 in 5 [2.0%] patients vs E=12 in 12 [4.9%] patients), and AEs leading to trial drug

discontinuation (E=4 in 3 [1.2%] patients vs E=44 in 25 [10.1%] patients).

Conclusion: In a head-to-head comparison with the only approved oral systemic therapy, topical delgocitinib cream 20 mg/g demonstrated superior treatment effects, QoL improvements and a more favourable safety profile vs oral alitretinoin over 24 weeks. These data highlight the benefit of delgocitinib cream over alitretinoin in the treatment of patients with severe CHE.

Figure. Greater reduction from baseline in HECSI score was observed with delgocitinib cream versus alitretinoin over 24 weeks.



Endpoint	Delgocitinib 20 mg/g (n=249), LS mean	Alitretinoin (n=250), LS mean	Difference (95% CI)	*P*-value
Week 12 Primary	-67.6	-51.5	-16.1 (-23.3 to -8.9)	<0.001
Week 24 Key secondary	-69.6	-45.1	-24.5 (-32.6 to -16.4)	<0.001

***$P \leq 0.001$ vs alitretinoin.

LS mean change from baseline with 95% confidence interval are shown. An ANCOVA model was used: Change in score from baseline = treatment + hyperkeratotic/non-hyperkeratotic subtype + baseline score. Missing data were imputed with WOCF, including baseline value.

Data collected after initiation of rescue treatments or permanent discontinuation of trial drug were treated as missing.

ANCOVA, analysis of covariance; CI, confidence interval; HECSI, Hand Eczema Severity Index; LS mean, Least Squares mean; WOCF, worst observation carried forward.