AARS HOT TOPICS MEMBER NEWSLETTER

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TABLE OF CONTENTS

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Industry News

LEO Pharma to expand its lead in medical dermatology with acquisition of Bayer's prescription dermatology unit. BusinessWire. July 31, 2018. https://www.businesswire.com/news/home/20180731005552/en/

Significant step to bolster LEO Pharma's role as a leading global dermatology company with its goal of helping 125 million patients by 2025. LEO Pharma and Bayer announced today, that LEO Pharma has entered into a definitive agreement to buy Bayer's global prescription dermatology unit. The portfolio to be acquired includes branded topical prescription treatments for acne, fungal skin infections and rosacea, and a range of topical steroids with an annual turnover in 2017 of more than 280 million euros. It will enable LEO Pharma to expand significantly in key markets worldwide and broaden its therapeutic areas. Bayer's global medical dermatology portfolio, which includes prescription treatment solutions for acne (Skinoren®), fungal skin infections (Travogen® and Travocort®) and rosacea (Finacea®), and a range of topical steroids (Advantan®, Nerisona®, and Desonate®), will add complementary treatment areas and strengthen the existing business of LEO Pharma worldwide, allowing the company to more than double sales in some markets. The transaction does not include Bayer's over-the-counter dermatology portfolio of brands such as Bepanthen® and Canesten® amongst others. "We are very excited about this agreement. With the strong prescription dermatology brands and the new colleagues from Bayer, LEO Pharma advances significantly towards our goal of helping 125 million patients by 2025. We will broaden our treatment range and considerably enhance our size in key markets around the world – underlining our ambition to be a preferred partner in medical dermatology," said Gitte P. Aabo, President and CEO of LEO Pharma. "We are very pleased to have found a good partner in LEO Pharma, who has a long history as a leader in scientific advancement and a culture that values discovery and innovation," said Heiko Schipper, member of Bayer's Board of Management and President of Consumer Health. "With the dedicated support of many employees to whom we are grateful, our prescription dermatology business has grown well since becoming part of Bayer in 2006. Moving forward, we believe that LEO Pharma is the right owner to grow and further develop the prescription dermatology business while enabling us to focus on building our core over-the counter brands". LEO Pharma will acquire the global product rights, except for Afghanistan and Pakistan, and take over the sales and marketing organizations in 14 countries, as well as a factory in Segrate, Italy. In total, around 450 people will join LEO Pharma as part of this transaction. The combination of the local sales and marketing organizations will make LEO Pharma more efficient. The acquisition is expected to close in two steps: During 2018 for the United States, and during the second half of 2019 for all other markets, subject to the satisfaction of customary closing conditions, including approval by the competition authorities. Financial details of the transaction were not disclosed.

Link between diet and skin disease takes center stage at summer AAD. Practical Dermatology, DermWire. Thursday, July 26, 2018. http://practicaldermatology.com/dermwire/2018/07/26/link-between-diet-and-skin-disease-takes-center-stage-at-summer-aad/?c=111&t=

Dermatologists must help patients determine if there are any foods that may cause their skin condition to flare and provide evidence-based recommendations about next steps. "People looking to improve their skin health may think that changing their diet is the answer, but a dermatologist will tell you that's not necessarily the case," says board-certified dermatologist Rajani Katta, MD, FAAD, a clinical professor of dermatology at McGovern Medical School at the University of Texas Health Science Center at Houston. "While diet can impact your skin in certain conditions, a lot of the information that's out there on the web is not based on sound scientific research." Dr. Katta discussed diet

and skin disease at the American Academy of Dermatology's annual summer meeting in Chicago. Since anyone can post anything they want on the Internet, the public should be wary of the information they find there, Dr. Katta says. Many websites are sponsored by companies trying to sell products, she says, so any recommendations they make should be taken with a grain of salt. While individuals may post on blogs or social media about dietary changes that they believe made a difference for their skin, many other factors could have played a role in their situations, she says, and other people may not experience the same effects. "You should not be making changes to your diet based on anecdotal evidence," Dr. Katta says. "One success story is not enough to prove something will work for everyone." Among the biggest misconceptions related to diet and dermatology is an overemphasis on the role of food allergies in skin conditions, Dr. Katta says. While some food allergies can affect the skin, she says, they play a limited role in skin disease overall. "Food allergies are not the cause of every skin condition," she says. "People tend to blame them a lot more than they should." Gluten, in particular, may be mistakenly identified as a source of skin inflammation, Dr. Katta says. Those with inflammatory skin disease like psoriasis and eczema may cut gluten from their diet in an attempt to improve their condition, she says, but such a change would only make a real difference for those with a diagnosed gluten allergy or hypersensitivity. "Gluten is not inherently inflammatory," she says. "The vast majority of people can eat gluten without any problems." Dr. Katta warns against elimination diets in general because they could cause people to miss out on important nutrients or eat too much of other foods to compensate for what they're cutting out. On the other side of the coin, she says, individuals should exercise caution in adding supplements to their diets. Because these substances are not regulated the way medications are, the claims on a bottle may not be verified by scientific evidence, she says, and the public should not just take those claims at face value. "You can't just pick a supplement up off the shelf and say, 'This is going to work for me,'" Dr. Katta says. "In order for a supplement to be helpful, it needs to be the right supplement taken at the right dose for the right person. A board-certified dermatologist can help you determine whether a supplement would help your skin and explain how to take it correctly." A board-certified dermatologist also can help patients with skin diseases like acne and rosacea determine if there are any foods that may cause their condition to flare, Dr. Katta says, and if that's the case, the doctor can recommend dietary changes that might be helpful. She recommends that those considering such dietary changes speak to their doctor first. In addition to providing an accurate diagnosis for patients' skin conditions, she says, a dermatologist can explain what existing scientific research says — and doesn't say — about how diet can affect the skin. And while more research in this area is necessary, Dr. Katta says, the existing evidence does indicate that a diet supporting overall health also supports good skin health. "Nutrient-rich whole foods like fruits and vegetables, whole grains, and healthy fats are good for your whole body, and that includes your skin," Dr. Katta says. "If you're considering changing your diet for the sake of your skin, however, talk to a board-certified dermatologist first."

BioPharmX: FDA grants CARC waiver; Post-hoc analysis for BPX-01 complete. Practical Dermatology, DermWire. Friday, July 20, 2018. http://practicaldermatology.com/dermwire/2018/07/20/biopharmx-fda-grants-carc-waiver-post-hoc-analysis-for-bpx-01-complete

The FDA has waived its requirement for a dermal carcinogenicity study for BPX-01 from BioPharmX Corporation, eliminating several years of non-clinical research normally required for FDA review. BPX-01, a novel topical gel formulation of minocycline for the treatment of inflammatory acne, received the waiver based on the results of a 39-week dermal minipig toxicity study conducted by BioPharmX and the extensive safety history of minocycline products, including the clinical safety data from the BPX-01 Phase 2 acne studies. The 39-week minipig study with BPX-01 found no pre-neoplastic or hyperplastic changes that might be indicative of carcinogenic potential and the clinical studies were also negative in terms of cutaneous toxicity. Based on these data, FDA agreed that no new useful information was likely to be gained by additional non-clinical animal studies. "The FDA waiver is important because

it shaves years off of our non-clinical research, accelerating our regulatory schedule and eliminating concerns about the added time and costs of our non-clinical development," said AnnaMarie Daniels, BioPharmX executive vice president of clinical and regulatory affairs. "Our minipig study confirmed years of prior research showing that our BPX-01 topical minocycline poses no new carcinogenic threat to humans." BioPharmX also has released a post hoc analysis of phase 2b data assessing the impact of BPX-01 on the treatment of acne vulgaris in women. It found that female subjects outperformed the overall study population in the Investigator Global Assessment (IGA) outcomes. The Phase 2b clinical trial (ITT=219) was a 12-week randomized, double-blind, vehicle-controlled, dose-ranging study to assess the safety and efficacy of BPX-01 minocycline topical gel in the treatment of moderate to severe inflammatory acne vulgaris. Relative to the total ITT population, a higher proportion of subjects in the female subgroup (N=149) demonstrated a clinically relevant improvement in acne severity. In female subjects with a baseline IGA score of 3 or 4 (moderate-to-severe), 29.2% achieved a two-grade reduction to clear or almost clear while 25% of the total ITT population achieved this reduction. In female subjects with a baseline IGA score of 3 (moderate only), 31.8% of subjects achieved a two-grade reduction to clear or almost clear. "The results from the female subgroup analysis of BPX-01 in the Phase 2b acne trial is very relevant, and offers promise to a large patient population suffering from acne," said Hilary Baldwin, Medical Director of the Acne Treatment & Research Center in Morristown, NJ, and co-chair of the BioPharmX Medical Advisory Board. "There is a significant need for a product that offers not only efficacy, but just as importantly, cosmetic elegance for women whose treatment options must fit their lifestyles and skin care regimens." The analysis will be presented at the Dermatology Education Foundation's DERM2018 conference in a poster entitled "Subset Analysis of IGA in Female Demographic in BPX-01 Topical Minocycline Gel Phase 2b Trial for the Treatment of Inflammatory Acne Vulgaris," this month in Las Vegas. BPX-01 uses the novel, patented HyantX™ delivery system, which stabilizes and solubilizes hydrophilic molecules in an anhydrous gel environment. This delivery system is capable of carrying a variety of active ingredients—and even combinations of actives—into the skin. Research has shown the delivery system may allow for maximum solubility for multiple actives, which is intended to lead to enhanced skin penetration and increased efficacy and tolerability, has antibacterial properties, and hydrates the skin, making the delivery system a valuable asset in pipeline development and strategic partnering. BioPharmX continues to be in ongoing discussions with a number of potential strategic partners regarding interest in the company's BPX-01 product candidate for the treatment of acne. The company continues to assess several written indications of interest and is evaluating the variety of financial and strategic benefits of the various options. Management remains diligent and deliberate in its thoughtful consideration of options as it works to maintain the best interests of the company and its shareholders.

New Medical News

Target site pharmacokinetics of doxycycline for rosacea in healthy volunteers is independent of food-effect (PI Markus Zeitlinger). Pal A, Matzneller P, Gautam A, et al. Br J Clin Pharmacol. 2018 Jul 22. doi: 10.1111/bcp.13721. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30033542

Aims: DFD-09 (doxycycline) oral capsules 40 mg are approved for the treatment of inflammatory lesions of rosacea. Unlike the food-induced lowering of doxycycline's peak plasma concentration (Cmax), its exposure under fed conditions in skin, the drug's target site for rosacea, is unknown. The present study explored the effect of food on dermal pharmacokinetics of doxycycline. Methods: Pharmacokinetics of doxycycline in dermal interstitial fluid (d-ISF) and plasma of healthy volunteers were assessed in parallel groups under fed (n=6) and fasting (n=6) conditions during a 14-day once-daily treatment course with Doxycycline oral capsules 40 mg (DFD-09). Sampling of d-ISF and

plasma were performed on days 1, 10 (fasting group d-ISF only) and 14. Results: Twelve subjects were randomised, 11 analysed. No causally drug-related adverse events occurred. Dermal doxycycline exposures (Cmax and AUC) under fed state were about 30% lower than fasting state at day 1 but were similar at steady-state. In analogy to skin, plasma exposure showed no between-group difference at steady-state. Accumulation ratios were higher in skin than in plasma. Correcting for plasma protein binding (~90%), dermal doxycycline exposure was approximately 3-fold higher than unbound plasma exposure. Conclusions: At steady state, doxycycline concentrations in skin of fed and fasting healthy volunteers were comparable. Doxycycline's efficacy in rosacea is possibly due to considerable dermal accumulation of unbound doxycycline and is independent of food-effect. EudraCT registration number 2016-001622-34.

Evaluation of long-term efficacy, safety, and effect on life quality of pulsed dye laser in rosacea patients. Bulbul Baskan E, Akin Belli A. J Cosmet Laser Ther. 2018 Jul 24:1-5. doi: 10.1080/14764172.2018.1502453. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30040521

Background: Rosacea is a chronic disease affecting the patients' life quality negatively. Although various laser systems are used in the rosacea treatment, studies reporting efficacy and long-term continuity of benefit of laser therapies are scarce. Objectives: We aimed to evaluate the efficacy, safety, continuity of benefit, and effect on life quality of pulsed dye laser (PDL) in the rosacea patients. Methods: Fourteen rosacea patients treated with PDL were enrolled in the study. The number of treatment sessions were varied from one to four. The efficacy was evaluated by the physicians' clinical assessment (PCA), patients' self-assessment (PSA), and erythema and telengiectasia grading scores. Additionally, the patients were asked about the continuity of the benefit and improvement in their life qualities after the treatment. Results: Both the erythema and telangiectasia scores were significantly improved after the treatment ($p < 0.001$). According to PCA, nine patients had a clinical improvement of >50%. According to PSA, 11 patients had good/excellent improvement. Moderate/significant benefit of treatment continued in 12 patients at the follow-up period (mean 21.64 ± 14.25 months). The life quality scores were significantly improved. No serious side effects were observed. Conclusion: PDL has high and long-term efficacy in the treatment of rosacea with a good safety profile

Topical photodynamic therapy with 5-aminolevulinic acid in Chinese patients with rosacea. Sun Y, Chen L, Zhang Y, et al. J Cosmet Laser Ther. 2018 Jul 24:1-5. doi: 10.1080/14764172.2018.1502455. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30040517

Background: Rosacea is difficult to cure and frequently recurs. Topical photodynamic therapy (PDT) has been tentatively used, with only preliminary results reported. Objective: To evaluate the efficacy and safety of topical PDT in Chinese patients with rosacea. Methods & materials: Seventeen participants with rosacea were treated three times using 5-aminolevulinic acid (ALA)-PDT at intervals of 7-10 days. Papule and pustule numbers, erythema severity, telangiectasia severity, physician's global assessment (PGA) score (1 [best]-6), and patient satisfaction score (0-3 [highest]) were assessed. Rosacea improvement and the total effective rate were calculated. Stratum corneum hydration and sebum levels, and the melanin index (MI) and erythema index (EI) were measured non-invasively. Results: After three treatments with ALA-PDT, the total effective rate (≥50% improvement) was 64.71%, mean PGA score was 2.88 ± 0.93, and mean patient satisfaction score was 1.71 ± 0.69. The EI significantly decreased 1 month after the final treatment (from 468 ± 80.61 to 439 ± 77.78 for the forehead and from 507.65 ± 92.51 to 483.27 ± 78.32 for the nasal ala). Four participants received three additional treatments. They achieved 50-74% improvement after

three treatments and ≥75% improvement after six treatments. Conclusion: ALA-PDT is safe and effective for treating rosacea.

Brimonidine tartrate gel plus topical steroid for the prevention of laser therapy-related postinflammatory hyperpigmentation. Hong JY, Lee HW, Park KY, et al. Dermatol Ther. 2018 Jul 20:e12657. doi: 10.1111/dth.12657. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30028559

Brimonidine gel, originally approved for the treatment of facial rosacea, causes direct vasoconstriction and possesses extensive utilization in dermatologic fields. A Q-switched (QS) neodymium-doped yttrium aluminum garnet (Nd:YAG) laser is generally used to treat solar lentigo (SL), often leaving unwanted postinflammatory hyperpigmentation (PIH), especially in dark-skinned individuals. A 58-year-old man with Fitzpatrick skin type IV presented to remove solar lentigines from his face. Prior to and after laser treatment, topical brimonidine gel and steroid cream were applied. In this study, we investigated whether topical application of the α-adrenergic receptor agonist brimonidine could reduce PIH after QS laser treatment of lentigine in a dark-skinned patient.

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Biofilm production and antibiotic susceptibility of staphylococcus epidermidis strains from hidradenitis suppurativa lesions. Ardon CB, Prens EP, Fuursted K, et al. J Eur Acad Dermatol Venereol. 2018 Jul 19. doi: 10.1111/jdv.15183. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30022542

Background: An aberrant interaction between commensal skin bacteria and the host skin immune system is considered important in the pathogenesis of Hidradenitis Suppurativa (HS). Objective: In this study we investigated the antibiotic susceptibility and biofilm-forming capabilities of S. epidermidis strains isolated from HS patients. Methods: Skin biopsies were taken from active HS lesions such as inflammatory nodules and/or sinuses and non-involved skin from 26 patients and cultured under optimal microbiological conditions for 24 hours. Planktonic growth, biofilm production, antibiotic susceptibility, and biofilm eradication by clindamycin, doxycycline, rifampicin, tetracycline, were tested including a laboratory control strain of S. epidermidis for reference. Results: S. epidermidis was cultured in 16 out of 26 HS patients (62%). In total 27 different S. epidermidis isolates were identified; 16 (59%) from non-involved skin and 11 (41%) from HS lesions. All bacterial strains showed planktonic growth. Twenty-four out of 27 (89%) isolates were strong biofilm producers in vitro. The biofilm-forming capability varied amongst the strains from non-involved skin and lesional skin. Twenty-four strains had an intermediate to resistant antibiotic susceptibility to clindamycin (89%). Rifampicin was the most effective antibiotic at inhibiting planktonic growth and at eradication of biofilm ($p<0.05$). Conclusion: We observed a slight increase in S. epidermidis virulence, characterized by resistance to commonly used antibiotics, increased biofilm production, and resistance to biofilm eradication. Especially the reduced sensitivity to tetracycline and clindamycin, two standard antibiotics in the treatment of HS is alarming. Rifampicin, also important in HS treatment, showed the greatest efficacy at eradicating the biofilm at low MIC concentrations.

Effect of a botanical cleansing lotion on skin sebum and erythema of the face: A randomized controlled blinded half-side comparison. Weber N, Schwabe K, Schempp CM, Wölfle U. Cosmet Dermatol. 2018 Jul 18. doi: 10.1111/jocd.12680. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30022595

Background: Elevated levels of skin sebum are associated with the growth of Propionibacterium acnes. Intensive

degreasing of the skin reduces Propionibacterium acnes but also may cause skin irritation. AIMS: We assessed the degreasing effect and skin tolerability of a botanical face cleanser with hops and willow bark extract and disodium cocoyl glutamate as mild cleansing agent compared to a standard face cleanser with sodium laureth sulfate (SLES). Materials and methods: A total of 21 healthy volunteers with normal to oily skin were enrolled in this study. Both cleansers were applied twice a day on the left or right side of the forehead for 15 days in a standardized manner. Bioengineering measurements were performed on day 8 and 15 and on day 17 after an application break of 48 hours. The sebum level was determined using a Sebumeter®, and skin redness was measured using a Mexameter®. Results: The botanical face cleanser significantly reduced the sebum level ($P < .01$) in the test area on day 17. The SLES containing cleanser showed a statistically relevant degreasing effect already on day 15, but after the application break the sebum level increased again on day 17. None of the cleansers caused skin irritation as determined by skin redness measurements. Conclusions: In contrast to the SLES containing cleanser, the botanical skin cleanser with hops and willow bark extract had a continuous degreasing effect without reactive seborrhoe after the treatment break. Skin cleansing without SLES might be advantageous for sensitive skin.

Oral isotretinoin for the treatment of Aripiprazol-induced acneiform rash. Navarro-Triviño FJ, de Jaime Ruiz P, Porras Segovia A, Garrido Torres-Puchol V. Dermatol Ther. 2018 Jul 17:e12637. doi: 10.1111/dth.12637. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30019366

Acneiform rash is a commonly reported side effect to certain types of medications, including antipsychotic agents. Its clinical presentation consists mainly of papulopustular lesions. Other types of lesions, such as nodular or cystic, can also be observed. Body distribution of the lesions follows a similar pattern to acne vulgaris. Depending on the severity of the case, drug-induced acne may be treated in different ways. In mild cases, the use of topical antibiotics and retinoids in combination is usually effective. With more severe forms, it may be necessary to add oral antibiotics, such as tetracyclines, but a good response is not always achieved. Identification of the drug responsible for the side-effect is mandatory in refractory eruptions. Herein, we present the case of an Aripiprazole-induced acneiform rash successfully treated with oral Isotretinoin. The treatment was effective and well tolerated and there was no need to discontinue the psychopharmacological medication. This is the first study to report this modality of treatment.

An evaluation of peripapillar choroidal thickness in patients receiving systemic isotretinoin treatment. Yavuz C, Ozcimen M. Cutan Ocul Toxicol. 2018 Jul 22:1-13. doi: 10.1080/15569527.2018.1503289. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30033766

Oral isotretinoin (13-cis retinoic acid, 13-cis RA) was approved for severe acne treatment by the FDA in 1982. It is still one of the most preferred drugs in dermatology practice from that date till now. There are numerous side effects of oral isotretinoin therapy. The ocular side effects associated with oral isotretinoin use are mostly dose-dependent. Numerous ocular pathologies affect peripapillary choroidal layer primarily or indirectly. Evaluation of the peripapillary choroidal layer in the patients receiving oral isotretinoin therapy may aid in explaining the pathophysiology of ocular side effects. In this study, peripapillary choroidal thickness was assessed in the patients receiving oral isotretinoin treatment via optical coherent tomography technique. Significant difference was found in the superotemporal and temporal areas.

Reliability of the hidradenitis suppurativa clinical response in the assessment of patients with hidradenitis suppurativa. Kimball AB, Ganguli A, Fleischer A. J Eur Acad Dermatol Venereol. 2018 Jun 29. doi: 10.1111/jdv.15163. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29959796

Background: Hidradenitis suppurativa clinical response (HiSCR) is a validated clinical end point for measuring response to treatment in patients with hidradenitis suppurativa (HS). Previous studies have reported on the validity, responsiveness and meaningfulness of the HiSCR. Objective: To evaluate the HiSCR for inter- and intrarater reliability characteristics. Methods: A stand-alone, two-site, prospective, non-interventional observational study consisted of 22 patients, with self-reported severity between mild, moderate and severe HS. The Patient Global Impression of Change (PGI-C) scale was completed by patients at Timepoint 2. Descriptive statistics of Hurley Stage, total abscesses, total draining fistulas, total inflammatory nodules and total AN count (sum of inflammatory nodules and lesions) were reported at two timepoints. Inter-rater reliability and intrarater reliability for the HS lesion count tool were evaluated at two timepoints (baseline and Day 7) using the HS lesion count tool. Intraclass correlation (ICC) coefficients of lesion counts were calculated to evaluate inter- and intrarater reliability of lesion counts between pairs of dermatologists. Results: The majority of patients demonstrated either no change or minimally worse PGI-C in HS scores. Descriptive statistics were similar between rater groups and timepoints assessed. Inter-rater ICC coefficients for abscess count at Timepoints 1 and 2 were 0.38 and 0.67. The ICC coefficients for draining fistula and AN count were ≥0.61 at both timepoints. In an exploratory model, ICC coefficients were ≥0.68 for all evaluated lesion counts. The test-retest reliability using ICC coefficients was ≥0.70 for total abscess, draining fistula, inflammatory nodule and AN count. Conclusion: The HS lesion count tool had an acceptable inter- and intrarater reliability, indicating that HiSCR has a strong degree of reproducibility and consistency in the evaluation of patients with HS.

Clinical Reviews

Chemical peels in the treatment of acne: patient selection and perspectives. Castillo DE, Keri JE. Clin Cosmet Investig Dermatol. 2018 Jul 16;11:365-372. doi: 10.2147/CCID.S137788. eCollection 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6053170/

Acne vulgaris is the most common skin disorder in adolescents and young adults. It carries a significant psychological and economic burden to patients and society. A wide range of therapeutic options are available, including topicals and systemic therapies. Chemical peeling is a skin resurfacing procedure intended to regenerate normal skin from the application of exfoliative agents. It has been used for the treatment of acne vulgaris and other skin disorders for decades. There are several chemical agents with variable mechanisms of action, usually classified as superficial, medium, and deep peels. When selecting the patient and the appropriate peel, the dermatologist individualizes therapy, and performs an extensive interview, including past medical history and physical exam. Several host factors can affect the outcome of this procedure, including current psychological state, medications, history of surgery, and immune system, among others. The physician must also be confident that the peel is safe and effective for the target patient. The Fitzpatrick skin type scale is a useful tool to classify patients based on skin color and ability to tan, but also can be used to evaluate preoperative risk of postpeel response and complications. Dark-skinned patients (Fitzpatrick skin type IV-VI), including blacks, Asian, and Hispanic/Latino, are at higher risk of postinflammatory/postpeel hyperpigmentation. When treating these populations, deep chemical peels should be avoided, and preoperative preparation emphasized. There are many studies available in the literature supporting the use of superficial to medium depth peels as adjuvant therapy for acne vulgaris. This review article aims to present the most important factors when selecting a patient for a chemical peel, the evidence behind its safety and efficacy, and special considerations when choosing a specific agent.

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Spironolactone effectively treats acne in adolescent females. July 13, 2018. Brunk D. Dermatology News. https://www.mdedge.com/edermatologynews/article/170220/dermatology/spironolactone-effectively-treats-acne-adolescent?channel=171

Spironolactone is a safe and effective treatment for acne in adolescent females, results from a single-center retrospective study have shown. In an interview at the annual meeting of the Society for Pediatric Dermatology, study author Erin Roberts, MD, said that while spironolactone is widely used in dermatology for treating acne vulgaris in women, it is not approved by the Food and Drug Administration for the treatment of acne, likely because published data are lacking. In addition, she said, less is known about its use, safety, and efficacy in the pediatric population. Dr. Roberts, a resident in the department of dermatology at the Mayo Clinic, Rochester, Minn., and her associates retrospectively reviewed 80 female patients younger than 21 years of age who were treated with spironolactone and topical therapies alone, or with spironolactone plus oral antibiotics and/or contraceptive pills. All patients were seen by clinicians at the Mayo department of dermatology and were followed for a mean of 11.2 months. The mean age of patients was 19 years and 71.3% had acne flares with their menstrual cycles, 67.5% had acne located on the jawline, 58.8% had concomitant use of an estrogen-containing oral contraceptive, and 93.8% were unresponsive to other oral treatments prior to using spironolactone. The median spironolactone daily dose was 100 mg, and ranged between 25 mg and 200 mg. Following acne score assessments, the researchers observed that 64 of the 80 patients (80%) experienced improvement of acne on treatment with spironolactone, while 16 (20%) did not respond and were subsequently escalated to oral isotretinoin therapy. Three patients (3.8%) experienced side effects, most commonly lightheadedness, headache, and fatigue, while five patients stopped taking the medication because of adverse effects, cost, or personal preference. "It was nice to see that spironolactone did improve acne," Dr. Roberts said. "We think of it as something to use for patients in their 20s, but not as much for patients in their teens. I think it could be a good option for them." She also recommended starting patients on a dose of 100 mg daily. "We saw that it does have a dose response," Dr. Roberts said. "It wasn't until patients got to 100 mg daily that we started to see significant improvement."

Antiandrogen therapy with spironolactone for the treatment of hidradenitis suppurativa. Golbari NM, Porter ML, Kimball AB. J Am Acad Dermatol. 2018 Jul 9. pii: S0190-9622(18)32222-9. doi: 10.1016/j.jaad.2018.06.063. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/30003993

Background: Hormonal therapy is a potential treatment for hidradenitis suppurativa (HS). However, little data exists describing the efficacy of spironolactone in HS treatment. Objective: To assess whether spironolactone treatment improves HS disease severity and patient reported pain. Methods: We performed a single center chart review of female HS patients treated with spironolactone between 2000 and 2017. Primary outcome measurements included the HS Physician Global Assessment (HSPGA), Hurley Staging, inflammatory lesion count, fistula count, and a numeric rating scale for pain. Results: Subjects on average were exposed to 75mg of spironolactone daily over a 7.1-month follow-up period. Patients achieved significant disease improvement with regards to pain (Δ-1.5, P=.01), inflammatory lesions (Δ-1.3, P=.02), and HSPGA (Δ-0.6, P<.001). As expected, no change was found for Hurley stage (Δ0, P=.32) or fistulas (Δ0, P=.73). There was no difference in improvement between subjects who received less than 75mg daily (n= 25, average 45mg/day) and those who received greater than 100mg daily (n=21, average 112mg/day). Limitations: Retrospective nature, limited sample size, and variations in severity measures documented were limiting factors. Conclusions: Management of HS with spironolactone reduces lesion count, HSPGA and pain. Lower doses appear to be effective and may be an appropriate option for patients with tolerability concerns.

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Current and future treatment of hidradenitis suppurativa. van Straalen KR, Schneider-Burrus S, Prens EP. Br J Dermatol. 2018 Jul 7. doi: 10.1111/bjd.16768. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29981245

This scholarly review on the current and future treatment of hidradenitis suppurativa (HS) focuses on medical and surgical treatment options, while novel pipeline drugs are also discussed. Treatment goals are to limit the incidence and duration of flares, reducing inflammation and suppuration, achieving local cure after surgery and, most importantly, to improve the quality of life of patients with HS. The type of medication and/or surgery should be chosen based on the stage of the disease and the degree of inflammation. However, the lack of a simple scoring system and the lack of clear surgical outcome definitions hamper the interpretation of treatment efficacy and the comparison between different treatment strategies. The therapeutic pipeline for HS is gradually expanding, and will probably lead to a broader panel of more effective therapeutic options.

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The practice of compounding, associated compounding regulations, and the impact on dermatologists. Quertermous J, Desai S, Harper J, et al. J Drugs Dermatol. 2018 Jul 1;17(7):s17-s22. https://www.ncbi.nlm.nih.gov/pubmed/?term=The+Practice+of+Medical+Compounding%2C+Associated+Regulations%2C+and+the+Impact+on+Dermatologists

Medication compounding gained national attention in the fall of 2012 after contaminated compounded medications produced in the New England Compounding Center infected 800 people with fungal meningitis and led to several fatalities. This prompted Congress to pass regulations on compounding through the Drug Quality and Security Act (DQSA) in 2013. The act increased oversight of patient-specific drug compounding taking place in compounding pharmacies, created 503(b) outsourcing facilities to obtain compounded drugs, and added regulations for obtaining compounded drugs from traditional 503(a) pharmacies. These regulations also had a broader overall impact by triggering federal and state-specific policies, which have ultimately limited a physician's ability to perform low-risk, in-office compounding. This article provides an overview of the different types of compounding restrictions, reviews the current federal and state regulations and/or guidelines, discusses how newly proposed policies may affect the practice of dermatology, and presents an algorithm on how the practicing dermatologist should approach compounding.

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Patient Counseling/Communication

What Health-related Quality of Life Factors Influence the Decision of Patients with Acne to Visit a Dermatologist? Chernyshov PV, Petrenko A, Kopylova V. J Clin Aesthet Dermatol. 2018 Jul;11(7):21-25. Epub 2018 Jul 1. https://www.ncbi.nlm.nih.gov/pubmed/30057661

Background: Acne is a common dermatologic disease that can have a profound negative impact on a patient's health-related quality of life (HRQoL). HRQoL correlates with acne severity in some, but not all, studies. In other words, patients with the same level of acne severity might experience different levels of impact on their HRQoL. Objective: We aimed to determine which HRQoL factors are negatively affected most in patients with acne who seek dermatologic consultation and treatment for their acne. Methods: One hundred patients with acne who sought treatment from a dermatologist ("active" patients) and 159 students with a confirmed diagnosis of acne ("passive" patients) who had not sought treatment from a dermatologist were assessed for HRQoL. To avoid differences in acne

severity and possible sex differences, patients were matched according to acne severity grade (mild, moderate, or severe) and sex. All patients completed the Dermatology Quality of Life Index (DLQI) and Cardiff Acne Disability Index (CADI) questionnaires. Results: After matching, 75 active patients and 75 passive patients were selected (mean age: 22.04±4.26 years and 21.00±1.82 years, respectively; 11 male and 64 female patients in each group). Total DLQI and CADI scores were significantly higher in "active" patients. All CADI items and seven (out of 10) DLQI items were more affected by acne in the active group compared to the passive group. A significantly greater number of passive patients reported no effect on their HRQoL, compared to the active group, and a significantly greater number of active patients reported that acne had a moderate effect on their lives, compared to the passive group. Conclusion: Our study demonstrated that the effect acne has on HRQoL is a strong predictive factor for patients seeking dermatological consultation, independent from disease severity. Embarrassment; self-consciousness; aggression and frustration; difficulties in social and leisure activities; difficulties in significant relationships with others, including partners, close friends, and/or relatives; and self-assessment of the current state of the skin were the most important predictive factors that influenced the decision for patients with acne to seek treatment from a dermatologist.