VOLUME 13 • NUMBER 4 • WINTER 2019 • www.jdpa.org

JDPA

Journal of Dermatology for Physician Assistants

Official Journal of the Society of Dermatology Physician Assistants

ONYCHOMYCOSIS*

Your patient's dirty secret?

TIME TO CLEAN IT UP

AT THE SITE OF INFECTION[1]

JUBLIA®
(efinaconazole)
Topical Solution 10%

*For the treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

JUBLIA allows some patients to have clearer toenails grow back.[1] Individual results may vary.

№1
PRESCRIBED BRAND FOR TOENAIL FUNGUS[2]

INDICATION

JUBLIA (efinaconazole) topical solution, 10% is indicated for the topical treatment of onychomycosis (tinea unguium) of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes.*

IMPORTANT SAFETY INFORMATION

- JUBLIA is for topical use only and is not for oral, ophthalmic, or intravaginal use.
- Patients should be instructed to contact their health care professional if a reaction suggesting sensitivity or severe irritation occurs.
- The most common adverse reactions (incidence >1%) were (vs vehicle): ingrown toenail (2.3% vs 0.7%), application-site dermatitis (2.2% vs 0.2%), application-site vesicles (1.6% vs 0%), and application-site pain (1.1% vs 0.2%).
- JUBLIA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and should be used with caution in nursing women. The safety and effectiveness in pediatric patients have not been established.

To report SUSPECTED ADVERSE REACTIONS contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Brief Summary of full Prescribing Information on the adjacent page.

Find out more by visiting **www.JubliaRx.com**.

References: 1. JUBLIA [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. **2.** Toenail fungus market summary – TRx: February 2018. IQVIA.

Ortho | Dermatologics

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This Brief Summary does not include all the information needed to use JUBLIA safely and effectively. See full prescribing information for JUBLIA.

JUBLIA® (efinaconazole) topical solution, 10%

For topical use
Initial U.S. Approval: 2014

INDICATIONS AND USAGE

JUBLIA (efinaconazole) topical solution, 10% is an azole antifungal indicated for the topical treatment of onychomycosis of the toenail(s) due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*.

DOSAGE AND ADMINISTRATION

Apply JUBLIA to affected toenails once daily for 48 weeks, using the integrated flow-through brush applicator. When applying JUBLIA, ensure the toenail, the toenail folds, toenail bed, hyponychium, and the undersurface of the toenail plate, are completely covered.

JUBLIA is for topical use only and not for oral, ophthalmic, or intravaginal use.

CONTRAINDICATIONS

None.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two clinical trials, 1227 subjects were treated with JUBLIA, 1161 for at least 24 weeks and 780 for 48 weeks. Adverse reactions reported within 48 weeks of treatment and in at least 1% of subjects treated with JUBLIA and those reported in subjects treated with the vehicle are presented in Table 1.

Table 1: Adverse Reactions Reported by at Least 1% of Subjects Treated for up to 48 Weeks

Adverse Event, n (%)	JUBLIA N = 1227	Vehicle N = 413
Ingrown toenail	28 (2.3%)	3 (0.7%)
Application site dermatitis	27 (2.2%)	1 (0.2%)
Application site vesicles	20 (1.6%)	0 (0.0%)
Application site pain	13 (1.1%)	1 (0.2%)

DRUG INTERACTIONS

In vitro studies have shown that JUBLIA, at therapeutic concentrations, neither inhibits nor induces cytochrome P450 (CYP450) enzymes.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies with JUBLIA in pregnant women. JUBLIA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Systemic embryofetal development studies were conducted in rats and rabbits. Subcutaneous doses of 2, 10 and 50 mg/kg/day efinaconazole were administered during the period of organogenesis (gestational days 6-16) to pregnant female rats. In the presence of maternal toxicity, embryofetal toxicity (increased embryofetal deaths, decreased number of live fetuses, and placental effects) was noted at 50 mg/kg/day [559 times the Maximum Recommended Human Dose (MRHD) based on Area Under the Curve (AUC) comparisons]. No embryofetal toxicity was noted at 10 mg/kg/day (112 times the MRHD based on AUC comparisons). No malformations were observed at 50 mg/kg/day (559 times the MRHD based on AUC comparisons).

Subcutaneous doses of 1, 5, and 10 mg/kg/day efinaconazole were administered during the period of organogenesis (gestational days 6-19) to pregnant female rabbits. In the presence of maternal toxicity, there was no embryofetal toxicity or malformations at 10 mg/kg/day (154 times the MRHD based on AUC comparisons).

In a pre- and post-natal development study in rats, subcutaneous doses of 1, 5 and 25 mg/kg/day efinaconazole were administered from the beginning of organogenesis (gestation day 6) through the end of lactation (lactation day 20). In the presence of maternal toxicity, embryofetal toxicity (increased prenatal pup mortality, reduced live litter sizes and increased postnatal pup mortality) was noted at 25 mg/kg/day. No embryofetal toxicity was noted at 5 mg/kg/day (17 times the MRHD based on AUC comparisons). No effects on postnatal development were noted at 25 mg/kg/day (89 times the MRHD based on AUC comparisons).

Nursing Mothers

It is not known whether efinaconazole is excreted in human milk. After repeated subcutaneous administration, efinaconazole was detected in milk of nursing rats. Because many drugs are excreted in human milk, caution should be exercised when JUBLIA is administered to nursing women.

Pediatric Use

Safety and effectiveness of JUBLIA in pediatric subjects have not been established.

Geriatric Use

Of the total number of subjects in clinical trials of JUBLIA, 11.3% were 65 and over, while none were 75 and over. No overall differences in safety and effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and the younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year dermal carcinogenicity study in mice was conducted with daily topical administration of 3%, 10% and 30% efinaconazole solution. Severe irritation was noted at the treatment site in all dose groups, which was attributed to the vehicle and confounded the interpretation of skin effects by efinaconazole. The high dose group was terminated at week 34 due to severe skin reactions. No drug-related neoplasms were noted at doses up to 10% efinaconazole solution (248 times the MRHD based on AUC comparisons).

Efinaconazole revealed no evidence of mutagenic or clastogenic potential based on the results of two in vitro genotoxicity tests (Ames assay and Chinese hamster lung cell chromosome aberration assay) and one in vivo genotoxicity test (mouse peripheral reticulocyte micronucleus assay).

No effects on fertility were observed in male and female rats that were administered subcutaneous doses up to 25 mg/kg/day efinaconazole (279 times the MRHD based on AUC comparisons) prior to and during early pregnancy. Efinaconazole delayed the estrous cycle in females at 25 mg/kg/day but not at 5 mg/kg/day (56 times MRHD based on AUC comparisons).

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information).

Manufactured for:
Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA

Manufactured by:
Valeant Pharmaceuticals International, Inc., Laval, Quebec H7L 4A8, Canada

U.S. Patents 8,039,494; 7,214,506

Based on 9462903 JUB.0045.USA.18 Rev 02/2018

JDPA Journal of Dermatology for Physician Assistants

EDITORIAL MISSION: The JDPA is the official clinical journal of the Society of Dermatology Physician Assistants. The mission of the JDPA is to improve dermatological patient care by publishing the most innovative, timely, practice-proven educational information available for the physician assistant profession.

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KEEP CURRENT WITH THE SDPA:

JDPA/Journal of Dermatology for Physician Assistants (ISSN 1938-9574) is published quarterly (4 issues per volume, one volume per year) by the Society of Dermatology Physician Assistants (SDPA), 300 N. Washington Street, Suite 407, Alexandria, VA 22314. Volume 13, Number 4, Winter 2019. One year subscription rates: $40 in the United States and Possessions. Single copies (prepaid only): $10 in the United States (Include $6.50 per order plus $2 per additional copy for US postage and handling). Periodicals postage rate paid at New York, NY 10001 and additional mailing offices.

POSTMASTER: Send address changes to Society of Dermatology Physician Assistants, Inc., 300 N. Washington Street, Suite 407, Alexandria, VA 22314 844-DERM-PAS, email SDPA@dermpa.org, www.dermpa.org

Blessings

It is with great gratitude and appreciation that I write my final editor's message. Reflecting back on these past thirteen years working with the JDPA, I have been filled with the reoccurring thought of just how blessed we are.

We are blessed to have PA leadership who believed enough in the vision of the JDPA to allow us to get started and, through the years, have continued to support it.

We are blessed to have such wonderful partnerships with our industry supporters; patient advocacy groups, pharmaceutical companies, state affiliate chapters, and all of the many others who have helped to support the JDPA and our profession through the years.

We are blessed to have fellow dermatology PAs and other clinicians willing to take time out of their busy lives, to write and submit many quality articles over the years. These articles have in turn helped to make impactful change upon our audience and in our patients' lives.

We are blessed to have a team of amazing and talented individuals, our production family, who are dedicated to pouring tremendous amounts of energy and talent into each and every issue. Their efforts have helped to provide our Society with a quality product that has become respected amongst PA specialty organizations.

We are blessed to have all of you as well, our audience. You have consistently shared your thoughts and feedback to help us to improve the JDPA. We are grateful for your continued support.

As we move forward from here, we look forward to the next chapter of the JDPA. We thank each and every person who has leant a hand in this labor of love and want you to know how very grateful we are for you and all that you have done throughout these past thirteen years.

In the end it has always been about our patients. I truly feel that our mission has been fulfilled, "Improving dermatological patient care from print to practice." I am blessed to say that personally, the JDPA has definitely helped me to become a better clinician for my patients. Thank you for being part of this meaningful journey with us and we now look forward to seeing what the future holds for the JDPA.

Travis Hayden, MPAS, PA-C
JDPA Editor in Chief
editor@jdpa.org

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DEPARTMENTS

CALENDAR OF EVENTS

2020

MARCH
AAD Annual Meeting
March 20-24, 2020
Denver, CO

APRIL
AAPA Annual Meeting
April 15-18, 2020
Los Angeles, CA

MAY
SDPA Annual Summer Dermatology Conference
May 13 - 17, 2020
Hyatt Regency Denver at Colorado Convention Center
Denver, CO

AUGUST
AAD Summer Meeting
August 13-16, 2020
Seattle, Washington

OCTOBER
SDPA Annual Fall Dermatology Conference
October 29 – November 1, 2020
InterContinental Miami
Miami, Florida

Empower. Educate. Advance.
The Future of Dermatology

FROM THE SDPA
NEWS & CURRENT AFFAIRS

Dear Colleagues:

January of 2020 marks the halfway point of my presidency. These past 6 months have impacted my understanding of how we are all "Connected" in one way, shape, or form. I recently observed this at the 17th Annual SDPA Fall Conference in Arizona when I was surrounded by over 700 dermatology PAs and colleagues who all aspire to gain knowledge, build relationships, and grow our profession. Obviously, we are all connected because we are dermatology PAs, but we are also connected on many other levels through shared personal and professional experiences. In life, we build our relationships on the "connections" we make with individuals and I am proud of the environment the SDPA fosters to build those connections with its members and partners. These connections will continue to build our organization and membership.

I am incredibly appreciative and amazed by the personal connections I have been able to build with SDPA members and dermatology colleagues through these semi-annual meetings. Some connections have come from shared interests outside of the dermatology world. For example, I was able to connect with a speaker on a mere mutual interest in prosecco and another over sharing our parenting stories with each other. Of course, there is always the chance meeting with someone you have lost contact with over the years. I recently was able to reconnect with a former college sorority sister who just so happens to be a dermatology PA.

I am not alone in experiencing these chance opportunities to build strong and lifelong relationships. Recently, I witnessed a passionate dermatology PA preaching about the greatness of our culture and collaboration to an internal medicine PA who was on the fence over accepting a dermatology position. Needless to say, he accepted the dermatology position and is now part of our team.

Stories like these from others as well as my own are the reason I get excited about every new day being a part of the SDPA family. My biggest pleasure comes from seeing connections between the current and past SDPA leaders and members who wanted to give back to their profession and become involved within the SDPA. The Nominations Committee and Leadership reception was well attended with over twenty members ready and wanting to serve. The most endearing moment and connection I witnessed was when a former President of the SDPA was able to share her gratitude towards her mentor and award him a Life Time Achievement Award.

As with any family, there are times in which we will have differences and not agree on certain topics, treatment plans, or policies. But, with the love and respect we have for our fellow members, we will always work together and collaborate to make the future the best it can be. In the end, we are all connected, and we intend to keep the family strong and connected.

Best Regards,

Gina Mangin, MPAS, PA-C
President SDPA
Diplomate SDPA

Dermatology Market Watch

La Roche-Posay Changes The Face Of Acne With Latest FDA Approved Acne Ingredient And Premieres Artificial Intelligence-Based Skin Analysis

La Roche-Posay recently announced the launch of Effaclar Adapalene Gel 0.1% Acne Treatment, containing adapalene, a prescription-strength retinoid acne treatment, now available over-the-counter. La Roche-Posay is also launching My Skin Track PoreScan, their first skin analysis powered by artificial intelligence. La Roche-Posay is providing consumers new and innovative tools developed with dermatologists to address their skin concerns.

La Roche-Posay now offers a topical prescription-strength retinoid (adapalene) acne treatment in addition to its award-winning Effaclar Duo micronized benzoyl peroxide acne treatment. The American Academy of Dermatology (AAD) describes topical retinoids and benzoyl peroxide as first line treatments for mild to severe acne.

Along with skincare, La Roche-Posay believes better-looking skin starts with a personalized skin analysis and skincare regimen. Recognizing that many consumers are confused about which products are right for their skin type and concern, La Roche-Posay is launching My Skin Track PoreScan. This tool uses artificial intelligence to make personalized skincare recommendations for those concerned with clogged pores, raised imperfections, and residual marks. To create this innovative tool, La Roche-Posay partnered with dermatologists from around the world to analyze more than 6,000 images of men and women of multiple ethnicities, ages, and skin types. My Skin Track PoreScan was presented at the Worldwide Congress of Dermatology in June of 2019.

An Overview of the Economic Benefit and Cost-Effectiveness of Siliq (Brodalumab) in the Treatment of Moderate-to-Severe Psoriasis in the United States

By Robert Casquejo, PA-C, Joseph Langshaw, PA-C, and Jason Cheyney, PA-C

Psoriasis is a potentially debilitating disease associated with considerable physical and psychiatric consequences.[1] The overall economic burden of psoriasis is also substantial, with annual cost in the Unites States exceeding $110 billion. Both the direct (e.g., drug costs) and indirect (e.g., loss of productivity) costs are considerable.[1] Biologics are recommended for the treatment of patients with moderate-to-severe psoriasis, and there are multiple biologics available that have demonstrated high levels of efficacy.[2] The development of targeted biologics has revolutionized the treatment of moderate-to-severe psoriasis; however, these treatments can be costly. The economic burden can be lessened by choosing therapies that are associated with high levels of skin clearance, which reduce indirect costs.[3]

Siliq (brodalumab) is a monoclonal antibody that reduces the effects of inflammatory cytokines involved in psoriasis and has demonstrated high levels of efficacy, with >80% of patients achieving 75% improvement from baseline in psoriasis area severity index (PASI 75) after 12 weeks in clinical trials.[4] In the randomized AMAGINE-2/-3 trials, brodalumab was shown to have superior efficacy to ustekinumab.[5] A meta-analysis showed that brodalumab results in similar or higher rates of PASI 75, PASI 90, and PASI 100 response as with other biologics.[6] Additionally, the direct costs of purchasing brodalumab are relatively lower than costs of other biologics, suggesting that brodalumab may have economic benefits in the treatment of moderate-to-severe psoriasis.[7]

Two recent studies have modeled the extent of the economic benefit and cost-effectiveness of brodalumab relative to other biologics in patients with moderate-to-severe psoriasis.[7,8] Wu and colleagues developed economic models that compared the total annual costs and cost-effectiveness of brodalumab with those of other biologics

including adalimumab, ixekizumab, secukinumab, and ustekinumab.[7] This model accounted for drug discounts, copays, and adverse event monitoring. In addition to having lower direct drug costs than other biologics, brodalumab was associated with relatively low additional costs due to poor skin clearance (e.g., additional office visits, subsequent drugs) because of its high level of efficacy (i.e., PASI ≥75). Considering all of these factors, the total annual cost to a health plan per patient with brodalumab ($38,538) was substantially lower than that with adalimumab ($51,246), ixekizumab ($65,484), secukinumab ($57,510), and ustekinumab ($57,013; *see Figure 1A).* Additionally, brodalumab was considerably more cost-effective than any of the other biologics investigated, as determined by the estimated average cost of obtaining one PASI 75, PASI 90, or PASI 100 response *(see Figure 1B).*

Figure 1

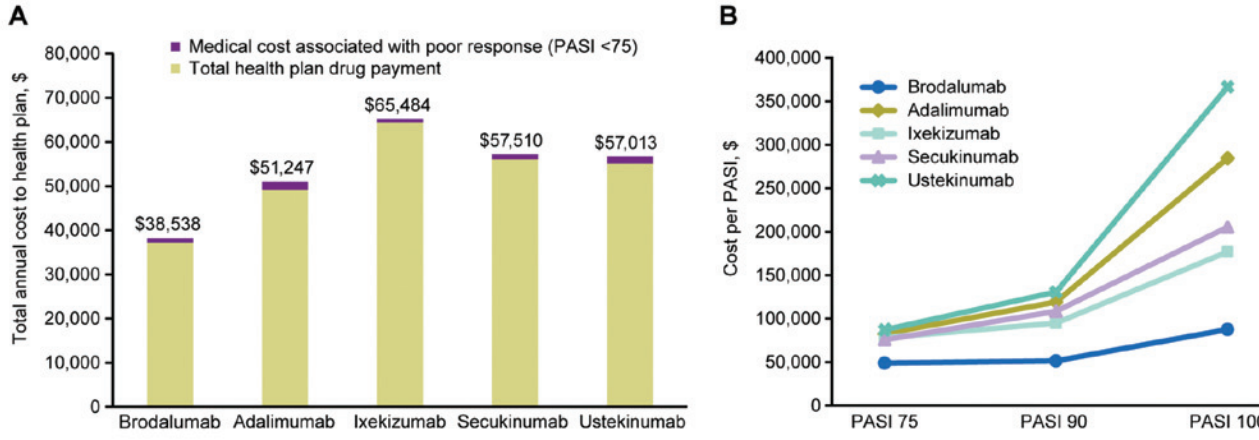

Figure 1. *Total costs and cost-effectiveness of various biologics in the treatment of moderate-to-severe psoriasis.[7]* ***A,*** *total annual health plan cost per patient. Values also include a $278-per-patient cost for adverse event monitoring for all biologics.* ***B,*** *cost-effectiveness as determined by the cost for achieving PASI 75, PASI 90, or PASI 100 response. PASI 75, 90, and 100, psoriasis area severity index 75%, 90%, and 100% improvement.*

Feldman and colleagues compared the economic burden and cost-effectiveness of brodalumab versus those with ustekinumab in biologic-naive and biologic-experienced patients.[8] It has been suggested that the use of prior biologics could affect the efficacy of subsequent biologics,[9] thereby also influencing the cost-effectiveness of succeeding treatments. An integrated analysis of the AMAGINE-2/-3 trials showed that brodalumab had higher rates of skin clearance versus ustekinumab in both biologic-naive (PASI 75, 87.1% vs 72.2%) and biologic-experienced (PASI 75, 81.7% vs 62.3%) patients.[9] Accordingly, the total annual cost to a health plan per patient treated with brodalumab was estimated at ~$38,000 for both biologic-naive and biologic-experienced patients.[8] This was lower than the total annual cost with ustekinumab, which exceeded $54,000 in both groups. Therefore, brodalumab had greater cost-effectiveness than ustekinumab in biologic-naive and biologic-experienced patients. Additionally, the reduced costs and greater cost-effectiveness with brodalumab versus those with ustekinumab were also observed in patients who experienced treatment failure with prior biologics.

While the development of targeted biologics has greatly improved the lives of patients with moderate-to-severe psoriasis, these benefits have come with increased drug prices. However, these analyses suggest that increased efficacy may not necessarily be associated with an increase in total cost. Brodalumab has better efficacy than most other biologics at a lower overall cost.

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Acknowledgements:
This study was supported by Ortho Dermatologics. Editorial assistance was provided under the direction of the authors by Scott A. Houck, PhD, at MedThink SciCom, with support from Ortho Dermatologics.

Once-daily

Seysara®

(sarecycline) tablets

INTRODUCING SEYSARA, A NOVEL ORAL TETRACYCLINE DEVELOPED SPECIFICALLY FOR MODERATE TO SEVERE ACNE PATIENTS AS YOUNG AS 9.[1]

For more information, visit SEYSARA.com

***STUDY DESIGN:** The safety and efficacy of SEYSARA was assessed in two identically designed, 12-week, multicenter, randomized, double-blind, placebo-controlled trials. In both studies, SEYSARA was administered orally once-daily for 12 weeks as 60 mg, 100 mg, or 150 mg tablets, based on patient weight.

***STUDY RESULTS:** Mean absolute reduction (co-primary endpoint) was 15.3 in study 1 (SC1401) and 15.5 in study 2 (SC1402) vs 10.2 and 11.1 in the placebo groups at Week 12, respectively. 21.9% of ITT patients in study 1 and 22.6% of ITT patients in study 2 achieved IGA success (co-primary endpoint; defined as ≥2-point improvement from baseline in IGA scale for inflammatory lesions of acne, and a score of 0 [clear] or 1 [almost clear]) at Week 12 vs 10.5% and 15.3% of patients with placebo, respectively (p<.0001 for study 1 and p=.0038 for study 2).

INDICATIONS AND USAGE

SEYSARA (sarecycline) tablet, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitations of Use: Efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established. SEYSARA has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, SEYSARA should be used only as indicated.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SEYSARA is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS AND PRECAUTIONS

- The use of SEYSARA during **tooth development** (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown).
- ***Clostridium difficile* associated diarrhea (CDAD)** has been reported with nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. If *Clostridium difficile* Associated Diarrhea (antibiotic associated colitis) occurs, discontinue SEYSARA.

WHAT DO I SAY TO PATIENTS FRUSTRATED WITH ACNE?

I SEYSARA®

TOUGH ON ACNE.

- Significant inflammatory lesion count reduction at Week 12, and as early as Week 3[1,*]

EASY ON PATIENTS.

- Convenient once-daily dosing, with 3 weight-based strengths; with or without food[1]

— With a demonstrated safety profile[1] —

- **Central nervous system side effects,** including light-headedness, dizziness or vertigo, have been reported with tetracycline use. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery. These symptoms may disappear during therapy and may disappear when the drug is discontinued.
- **Intracranial hypertension** in adults and adolescents has been associated with the use of tetracyclines. Clinical manifestations include headache, blurred vision and papilledema. Although signs and symptoms of intracranial hypertension resolve after discontinuation of treatment, the possibility for sequelae such as visual loss that may be permanent or severe exists. Concomitant use of isotretinoin and SEYSARA should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension.
- **Photosensitivity** manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using SEYSARA.
- **Bacterial resistance** to tetracyclines may develop in patients using SEYSARA. Because of the potential for drug-resistant bacteria to develop during the use of SEYSARA, it should only be used as indicated.
- As with other antibiotic preparations, use of SEYSARA may result in overgrowth of non-susceptible organisms, including fungi. If **superinfection** occurs, SEYSARA should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

Most common adverse reaction (incidence ≥ 1%) is nausea.

PLEASE TURN THE PAGE FOR BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION.

IGA, investigator's global assessment; reflects the investigator's overall general assessment of the quantity and quality of inflammatory lesions (range 0-4 with 0 being clear and 4 being severe).

ITT, intent-to-treat.

Reference:
1. SEYSARA [package insert]. Exton, PA: Almirall, LLC, 2018.

USSEY0311c 05-2019

almirall

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION FOR SEYSARA® (sarecycline)

This brief summary does not include all the information needed to use SEYSARA safely and effectively. See full Prescribing Information for SEYSARA (sarecycline) tablets for oral use.

INDICATIONS AND USAGE

SEYSARA® (sarecycline) tablet, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.

Limitations of Use: Efficacy of SEYSARA beyond 12 weeks and safety beyond 12 months have not been established. SEYSARA has not been evaluated in the treatment of infections.

To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, SEYSARA should be used only as indicated *[see Warnings and Precautions]*.

CONTRAINDICATIONS

SEYSARA is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS AND PRECAUTIONS

Teratogenic Effects

- SEYSARA, like other tetracyclines, can cause fetal harm when administered to a pregnant woman. If SEYSARA is used during pregnancy or if the patient becomes pregnant while taking SEYSARA, the patient should be informed of the potential hazard to the fetus and treatment should be stopped immediately.
- The use of drugs of the tetracycline-class during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of these drugs, but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported.
- All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued. Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can cause retardation of skeletal development on the developing fetus. Evidence of embryotoxicity has been noted in animals treated with SEYSARA during pregnancy in association with maternal toxicity *[see Use in Specific Populations]*.

***Clostridium difficile* Associated Diarrhea (Antibiotic Associated Colitis)**

Clostridium difficile associated diarrhea (CDAD) has been reported with nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to potential overgrowth of *C. difficile.*

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* should be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Central Nervous System Effects

Central nervous system side effects including light-headedness, dizziness or vertigo have been reported with tetracycline use. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery. These symptoms may disappear during therapy and may disappear when the drug is discontinued.

Intracranial Hypertension

Intracranial hypertension in adults and adolescents has been associated with the use of tetracyclines. Clinical manifestations include headache, blurred vision and papilledema. Although signs and symptoms of intracranial hypertension resolve after discontinuation of treatment, the possibility for sequelae such as visual loss that may be permanent or severe exists. Women of childbearing age who are overweight have a greater risk for developing intracranial hypertension. Patients should be questioned for visual disturbances prior to initiation of treatment with tetracyclines. Concomitant use of isotretinoin and SEYSARA should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension *[see Drug Interactions]*. If visual disturbance occurs during treatment, patients should be checked for papilledema.

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using SEYSARA. If patients need to be outdoors while using SEYSARA, they should wear loose-fitting clothes that protect skin from sun exposure and discuss other sun protection measures with their physician.

Development of Drug Resistant Bacteria

Bacterial resistance to tetracyclines may develop in patients using SEYSARA. Because of the potential for drug-resistant bacteria to develop during the use of SEYSARA, it should only be used as indicated.

Superinfection/Potential for Microbial Overgrowth

As with other antibiotic preparations, use of SEYSARA may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, SEYSARA should be discontinued and appropriate therapy instituted.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 1064 subjects and 1069 subjects with moderate to severe acne vulgaris were treated with SEYSARA and placebo, respectively, for 12 weeks in 3 controlled clinical trials. The only adverse drug reaction that was reported in at least 1% of subjects was nausea, SEYSARA (3.1%) versus placebo (2.0%).

The following additional adverse drug reactions occurred in less than 1% of female SEYSARA subjects: vulvovaginal mycotic infection (0.8%) and vulvovaginal candidiasis (0.6%).

DRUG INTERACTIONS

Effect of Other Drugs on SEYSARA

Oral Retinoids: Tetracyclines may cause increased intracranial pressure as do oral retinoids, including isotretinoin and acitretin *[see Warnings and Precautions]*. Avoid coadministration of SEYSARA with oral retinoids.

Antacids and Iron Preparations: Coadministration with antacids containing aluminum, calcium or magnesium, bismuth subsalicylate, and iron-containing preparations may impair absorption of SEYSARA, similar to other tetracyclines, which may decrease its efficacy. Separate dosing of SEYSARA from antacids containing aluminum, calcium or magnesium, bismuth subsalicylate, and iron-containing preparations.

Effect of SEYSARA on Other Drugs

Penicillin: Similar to other tetracyclines, SEYSARA may interfere with the bactericidal action of penicillin. Avoid coadministration of SEYSARA with penicillin.

Anticoagulants: Similar to other tetracyclines, SEYSARA may depress plasma prothrombin activity, which may increase the risk of bleeding in patients who are on anticoagulant therapy. Decrease anticoagulant dosage when coadministered with SEYSARA as appropriate.

P-Glycoprotein (P-gp) Substrates: Concomitant use of SEYSARA may increase concentrations of concomitantly administered P-gp substrates (e.g. digoxin). Monitor for toxicities of drugs that are P-gp substrates and may require dosage reduction when given concurrently with SEYSARA.

Oral Hormonal Contraceptives: There is no clinically significant effect of SEYSARA on the efficacy of oral contraceptives containing ethinyl estradiol and norethindrone acetate.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary: SEYSARA, like tetracycline class drugs, may cause fetal harm, permanent discoloration of teeth, and reversible inhibition of bone growth when administered during pregnancy *[see Warnings and Precautions and Use in Specific Populations]*. The limited available human data are not sufficient to inform a drug-associated risk for birth defects or miscarriage. Tetracyclines are known to cross the placental barrier; therefore, SEYSARA may be transmitted from the mother to the developing fetus. In animal reproduction studies, sarecycline induced skeletal malformations in fetuses when orally administered to pregnant rats during the period of organogenesis at a dose 1.4 times the maximum recommended human dose (MRHD) of 150 mg/day (based on AUC comparison). When dosing with sarecycline continued through the period of lactation, decreases in offspring survival, offspring body weight, and implantation sites and viable embryos in offspring females occurred at a dose 3 times the MRHD (based on AUC comparison). The potential risk to the fetus outweighs the potential benefit to the mother from SEYSARA use during pregnancy; therefore, pregnant patients should discontinue SEYSARA as soon as pregnancy is recognized.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Lactation

Risk Summary: Tetracyclines are excreted in human milk. Because of the potential for serious adverse reactions on bone and tooth development in nursing infants from tetracycline-class antibiotics, advise a woman that breastfeeding is not recommended with SEYSARA therapy *[see Warnings and Precautions]*.

Females and Males of Reproductive Potential

Infertility: Avoid using SEYSARA in males who are attempting to conceive a child. In a fertility study in rats, sarecycline adversely affected spermatogenesis when orally administered to male rats at a dose 8 times the MRHD (based on AUC comparison).

Pediatric Use

The safety and effectiveness of SEYSARA have been established in pediatric patients 9 years of age and older for the treatment of moderate to severe inflammatory lesions of non-nodular acne vulgaris.

Safety and effectiveness of SEYSARA in pediatric patients below the age of 9 years has not been established. Use of tetracycline-class antibiotics below the age of 8 is not recommended due to the potential for tooth discoloration *[see Warnings and Precautions]*.

Geriatric Use

Clinical studies of SEYSARA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

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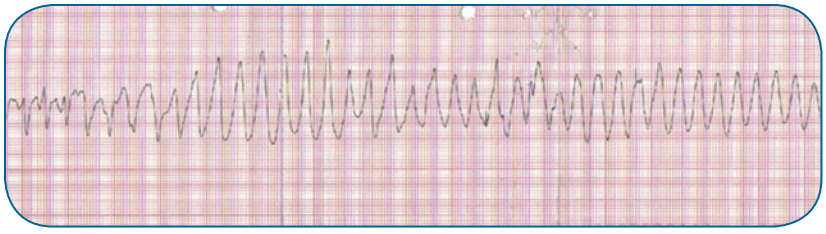
Certification Review

All Those Things Inside the Skin You Might Have Forgotten

By James A. Van Rhee, MS, PA-C

Are you recertifying soon? Start your board review early. Each issue of the JDPA features one board question accompanied by a brief explanation of the answer along with any pertinent test taking tips. Best of luck!

QUESTION: A 40-year-old female, recently diagnosed with prolonged QT interval and being treated with sotalol, presents with a generalized seizure. No family history of cardiac disease. Laboratory testing reveals negative cardiac enzymes serum potassium 3.1 mEq/L and serum magnesium 0.5 mEq/L. EKG rhythm strip (Lead II) is noted below.



Which of the following is the treatment of choice for this patient?

A. IV amiodarone
B. IV magnesium sulfate
C. Synchronized cardioversion
D. Temporary transcutaneous pacing

EXPLANATION: Torsade de pointes is a polymorphic ventricular tachycardia where the QRS complex appears twist around the isoelectric point. Associated with a prolonged QT interval. The disorder may be self-limiting or present with dizziness or syncope. Many drugs are known to prolong the QTc including chlorpromazine, tricyclic antidepressants, macrolide antibiotics, lithium, and sotalol. Treatment consists of correction of any potassium abnormalities along with IV magnesium sulfate. Transcutaneous pacing may be indicated in patients with severe disease. If cardioversion is used it should be unsynchronized direct-current cardioversion. Amiodarone has been linked to QTc prolongation, but rarely associated with significant arrhythmias. Other treatment options include isoproterenol infusion, cardiac pacing, and intravenous atropine.

The correct answer is B.

James A. Van Rhee, MS, PA-C, *is the Program Director for the Yale University School of Medicine Physician Assistant Online Program. Mr. Van Rhee has been involved in physician assistant education for over 20 years. He has served as project director and test item writer for the Physician Assistant Education Association's (PAEA) Physician Assistant Clinical Knowledge Rating Assessment Tool (PACKRAT). He is the author of the Physician Assistant: Certification and Re-certification Review Book and Consulting Editor of Physician Assistant Clinics, both published by Elsevier. For the last fifteen years he has been course director and presenter of the Physician Assistant Board Review, produced live online by Kaplan Medical.*

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OPTIONAL WORKSHOPS

Defensins: Skin-derived Antimicrobial Peptides with Antiaging Properties

By Paula A. Purpera, MSHS, PA-C

ABSTRACT

Established anti-aging recommendations have included topical anti-aging treatment regimens that assist the skin by increasing collagen, elastin, and glycosaminoglycans in the dermis. Most dermatologists and clinicians have used these well established anti-aging products, along with sun protection, for decades. Newer modalities such as the use of growth factors and platelet-rich plasma for rejuvenation have started to show some promise, but no large-scale clinical trials have been performed to date regarding the efficacy of these treatments. There is also some apprehension regarding the safety of growth factors due to possible tumorigenesis or cellular atypia. Recent attention has started to focus on the role stem cells may play in skin rejuvenation, in particular the potential stimulation of our endogenous stem cells by way of defensins. Defensins are antimicrobial peptides that have the capacity to bridge our innate and adaptive immunity. These molecules have inherent antibacterial activity as well as the capability to mobilize cells in the skin and surrounding tissues. Studies have shown that defensins have various properties that may be investigated for rejuvenation purposes. However, more studies are needed in order to fully elucidate the utility and efficacy of antimicrobial peptides in aesthetic medicine.

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Learning Objectives:

1. *Differentiate currently established anti-aging treatments from newer modalities.*
2. *Describe the function of antimicrobial peptides in the skin.*
3. *Describe the mechanism of action of defensins in the skin stem cells.*

INTRODUCTION

Current topical anti-aging treatment regimens work by increasing collagen, elastin, and glycosaminoglycans such as hyaluronic acid in the dermis.[1-2] Most dermatologists and clinicians use established anti-aging products that contain alpha and beta hydroxy acids, vitamin A derivatives, topical antioxidants, and sun protection.[3] Newer modalities such as the use of growth factors and platelet-rich plasma for rejuvenation have also shown some promise, but no large-scale clinical trials have been performed to date regarding the efficacy of these treatments. There is also some apprehension regarding the safety of growth factors due to the fact that some malignant cells have receptors for certain growth factors, which creates the concern for potential tumorigenesis or cellular atypia.[4]

EXOGENOUS STEM CELL USE

Because of the numerous emerging therapeutic indications for stem cell therapy, there has been increased interest in stem cell therapies for anti-aging. Stem cells are undifferentiated or partially differentiated cells that are self-renewing, capable of dividing, and can generate other cell types different from those of the original tissue.[5-6] The use of human stem cells for cutaneous diseases are still in the experimental stages and topical applications are limited to use in burns.[7] Commercially available stem cell skincare products are

usually derived from plant stem cells and there are still questions as to how their effects can be extrapolated to human tissues.[8] Furthermore, there are numerous drawbacks to using plant-derived stem cells in cosmeceuticals such as poor shelf life, non-specificity, and low efficacy.[1,9]

STIMULATING ENDOGENOUS STEM CELLS

Alternatively, the use of pharmaceuticals to modulate and stimulate endogenous stem cell populations are being explored. One such group of molecules are antimicrobial peptides called defensins. Small, cationic peptides known as human defensins are part of the innate immunity and confer protection against bacteria, fungi, or some enveloped viruses by forming a chemical barrier on the skin.[10-11] They also have the capacity to mobilize CD4+ memory cells and immature dendritic cells, indicating that they also have a function in the adaptive immunity. Additionally, defensins have been shown to stimulate migration and proliferation of keratinocytes, accelerate wound closure and skin regeneration, and stimulate fibroblast activity.[12] Numerous studies also show that defensins have the capability to increase cellular proliferation, promote calcium modulated migration of local cells into wounds, and promote collagen synthesis.[13]

DEFENSINS

There are three defensin subfamilies: α-, β-, and θ-defensins. The first two are the most studied and have been shown to have more activity, while θ-defensins were found to be cyclic peptides derived from mutated α-defensin genes. Because of their inherent antimicrobial activity, defensins are currently being investigated as alternatives to antibiotics, because resistance is less likely to occur with these cationic peptides as opposed to conventional antibiotics.[10]

Apart from their antibiotic and chemotactic activity, defensins have also shown their ability to induce Lgr (leucine-rich repeat-containing G-protein-coupled receptor) cell migration and function. Stem cells located directly above the hair follicular bulge, known as Lgr6+ cells, were shown to give rise to all cell lineages of the skin.[14] Since the Lgr6+ cells could potentially produce numerous cell lines, this promotes the growth of new skin cells, that, in contrast to the basal stem cells, would have accumulated less UV radiation exposure, mutation, and damage.[13,15] Additionally, unlike growth factors with their possible link to tumorigenesis, defensins have been shown in several studies to suppress tumor growth as a natural protective immune response.[16-17] β-defensins have also been shown to be involved in the inflammatory cascade. During inflammation, the expression of β-defensin-2 in inflamed skin is induced by IL-1 from resident monocyte-derived cells, which establishes a clear link between infection/inflammation and expression of β-defensins.[18]

A multi-center, double-blind, placebo-controlled clinical study investigating the use of a skincare regimen containing synthetic α-defensins and β-defensins showed increased epidermal thickness, reduction in visible pores, superficial wrinkles, oiliness, pigmentation, and hydration that were statistically significant compared to placebo. This pilot study evaluated clinical, histopathologic, immunohistochemical, and photographic data to determine results.[19] At this time, this is the only study that investigated the utility of defensins for anti-aging.

CONCLUSION

Defensins are antimicrobial peptides that have the capacity to bridge our innate and adaptive immunity. These molecules have inherent antibacterial activity as well as the capability to mobilize cells in the skin and surrounding tissues. Studies have shown that defensins have various properties that may be investigated for rejuvenation purposes. However, more studies are needed in order to fully elucidate the utility and efficacy of antimicrobial peptides in aesthetic medicine.

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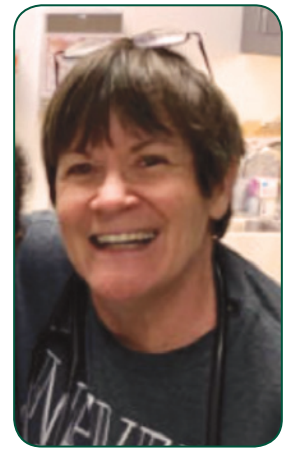
From The Patient's Perspective

Physician Assistant Diagnosed with Melanoma Learns to Make Really Good Lemonade

By Vallerie A. Malkin

If anyone knows cancer, it's physician assistant Barbara Regis. She is a fifty-six year-old fourth-generation health care provider who has been counseling her family practice patients with cancer for over twenty-two years. So when a lesion showed up on her own arm last year, she knew she should probably get to the dermatologist, but like most busy people, she put it off.

Barbara finally got to her dermatology physician assistant to have the new spot, as well as what she felt was a squamous cell carcinoma (SCC) on her face, biopsied and went about her business.



Barbara Regis, Stage III Melanoma Survivor

She still remembers the date and time of the call: It was April 3, 2018, at noon, and she was with her staff sitting on a bench outside her clinic. Her dermatologist said, "I need to talk to you." Alarmed by the tone of her voice and by the fact that the call was coming directly from the dermatologist rather than her medical assistant, Barbara moved away from her colleagues to learn the news. "Number one, you were right," said the doctor, confirming the lesion on her face was indeed SCC. Then, according to Barb, there was a big pause. "Number two is this. You've got a rare form of melanoma and it's aggressive and we're really concerned for you. Let's get you into an oncologist and a surgeon ASAP."

Barbara responded with disbelief: "Say that again?" She knew she had to collect her thoughts so she could see her afternoon patients, but even worse, she had to tell her husband the bad news when she got home. Here she was on the other side of the table after having diagnosed 14-16 melanomas in her career as a health care provider. She has seen how aggressive melanoma could be and that such a diagnosis could be lethal. She had been through this journey with some patients, and she remembers a few that did not make it.

Barbara, an Arizona resident who grew up in Pennsylvania, has no family history of melanoma, nor was she a big sunbather. She and her family used to fish at the Jersey shore but she remembers wearing sunscreen most of the time. Just a year ago she and her husband, Tony, were being teased for being covered up at the pool at their vacation home in Mexico. "I'm just trying to be careful," she recalls telling the neighbors. "I don't want to get skin cancer!"

Family ties and faith in medicine

Telling her father, a retired physician who is now ninety-six years-old, was difficult. He was the reason she went into medicine in the first place, and now she was sick. His response was, "You're in big trouble", Barbara recalls. Her father's sister had died of skin cancer, but

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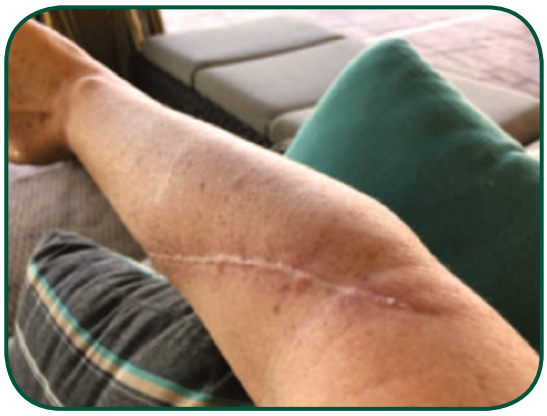
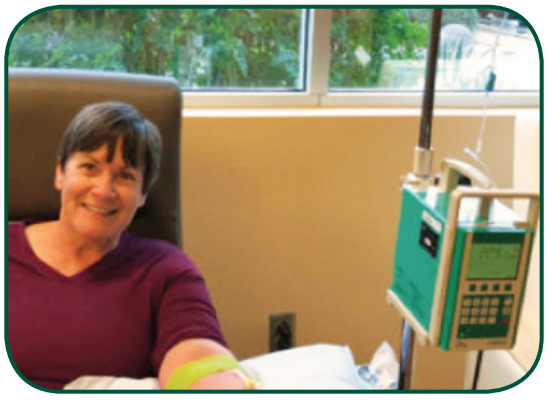
they had never determined what type because the pathology in those days was not as specific. He suspected it might actually have been melanoma and worried he had passed on some sort of gene to his daughter. However, genetic testing revealed no such markers. Barb told her dad, "Treatments are better. I'm not going anywhere. I'm going to work really hard to beat this and do everything my doctors say." She meant it.



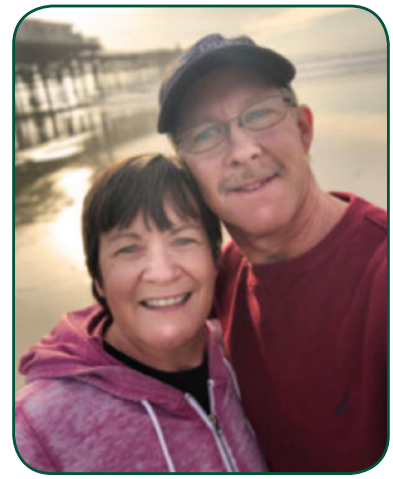
Six months after surgery and SLNB



Immunotherapy with Opdivo at Ironwood Cancer and Research Center

The lesion was removed, and her diagnosis was amelanotic nodular melanoma. Her dermatologist ordered the Castle Test, and the result suggested she had the highest risk for recurrence in the next five years. Along with her surgical excision, Barb had a sentinel lymph node biopsy, which revealed the cancer had metastasized to lymph nodes in her axilla, and she was given a diagnosis of Stage IIIB. She had seen patients fight and lose battles with formidable diseases. She felt lucky that she had a chance to fight. It wouldn't be easy, but Barbara knew that in recent years there have been medical breakthroughs with different therapies and melanoma is no longer the death sentence it used to be. "The chance of me living a full, long life is so much better than even five years ago, that I felt grateful," says Barb.

Barbara has recently completed her 26 treatments of the immunotherapy Nivolumab (Opdivo). She has been lucky, as her side effects have been minimal. She was able to return to work full-time a week after her surgery. Even though the new protocols with Opdivo are monthly, she elected to continue her treatments every two weeks.



Barbara and her husband Tony

She was also lucky to have been diagnosed after January 1 as having Stage III, because insurance would not have approved the treatment otherwise.

"I know deep in my heart that I would have been a walking time bomb had I not qualified for that treatment," she says, "and that's where I feel really blessed." Barbara has had 15 biopsies and all have been negative. There have been unexpected roadblocks; a false positive PET Scan, or in Barb's case, the accidental discovery of an arachnid cyst in her brain that is a fairly good size. She has to now get an MRI every year to make sure it remains stable. Still, Barbara feels lucky that it was discovered and knows it wouldn't have were it not for melanoma. Now doctors can keep an eye on it.

Life does not stop for cancer

After her melanoma diagnosis, Barb was hospitalized four different times. In between treatments, she and her husband had to move her elderly parents from their independent living situation to a group home, then to assisted living, where her mother became ill. Shortly after Barb moved her father back to a group home near her house, her mother died. The family faced another tragedy in February when her brother-in-law died in an airplane crash. After fourteen and a half years, Barbara lost her sidekick, an Old English Sheepdog named Abby, whom she adored and never went anywhere without.

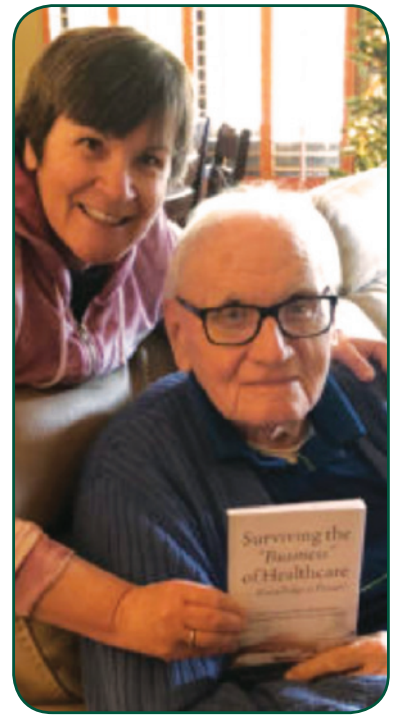
With the help of her husband, Tony, who Barb refers to as her "rock," she was able to keep a positive attitude and focus on getting well despite so many painful setbacks.

"You have two choices in this life," she says, "You feel sorry for yourself or you feel grateful for what you have." In the process, Barb developed what she calls, "survivor's motivation"- "Getting melanoma super-charged my desire to help others," she explains. "I want to try to make a difference."

Staying engaged

Barb is a natural storyteller. Perhaps this gift comes from leading a storied life growing up the daughter of a doctor who practiced medicine out of their home and a mother who supported his business. Back in the day, patients would rap on the door at all hours with all manners of ailments. Once, there was an apartment explosion. Things were never dull.

Barb decided to start a podcast called, "Best of Health" by "Ask the P.A.," more than a year ago on Phoenix Business Radio X. It features stories about providers, advocates, and all types of patients with medical challenges.



Barbara and her Dad

Recently she aired a story about an occupational therapist who started the Motorized Cart Derby for kids with no mobility other than being able to open and shut their eyes. Barb likens the podcast to a chat in real-time at Starbucks. She has discussed her melanoma journey and life as a health care provider.

"It's been really fun to share with people and get out there and talk about things that maybe sometimes aren't really comfortable to talk about but need to be said," she says.

Four years ago Barb started writing a book on health topics called, "Surviving the Business of Health Care" to help make the complex topic of health care easier for people to understand and navigate. Sprinkled inside the book are anecdotes about her parents, and even her beloved dog, Abby, makes an appearance. The book is doing well. She is especially proud of the family stories. "When people ask me who are my heroes, honestly my heroes are my parents. They were amazing examples for me."

Things happen for a reason

After she was diagnosed, Barbara attended a melanoma conference at MD Anderson in Houston, Texas, where she talked to providers and learned about different therapies, studies, and the future of melanoma research. "It was exciting for me to come back and share what I had learned with other melanoma survivors so they know there is hope for us and not to give up," she says.

From there, she got active on social media and through Instagram and Facebook has forged connections with melanoma survivors and their family members all over the world. Her melanoma "buddies" check in with each other on good days and bad. As a health care provider, Barbara can be especially useful to regular people who are confused by the medical language, tests, and treatments. What she can do is help people informally online understand some of the medical information they are barraged with.

She has made countless friends through her melanoma experience, and one woman, Vicki, invited her to her daughter Meredith's cruise ship wedding after she and Vicki began supporting each other during their respective melanoma journeys. Barb says they recently met up in Detroit, had an amazing time, and hope to pay their good fortune forward.

"We all try to help each other and cheer each other on," says Barbara. "Your world opens up with social media, I know people in Australia and England who have come out of the woodwork to support each other." All of these experiences around melanoma have led to what Barbara calls "a groundbreaking passion project" that she will be discussing in the coming months on her podcast. Barb says she wants to leave behind a legacy wherein people thought she really cared and that she had a passion for everyone she touched.

"Part of me at first wanted to feel sorry for myself," says Barb. "I was scared. I made a conscientious decision that I'm going to do everything in my power to not leave any time soon, but if I don't win this battle I want to make sure I have made a huge difference in people's lives." Barbara's most recent PET scan, after completing her treatments May 3rd, was negative and she is currently NED (no evidence of disease). She continues to live fully one day at a time and has learned not to "sweat the small stuff."

"I enjoy the moment", she explains. "I look at it like this: I was given some lemons and I'm learning to make really good lemonade out of them."

TOP 9 REASONS

Dermatology PAs

[or those PAs interested in dermatology]

Should Become a Member of the SDPA

The largest of 26 specialty organizations under the American Academy of Physician Assistants (AAPA), the Society of Dermatology Physician Assistants (SDPA) is a non-profit professional association focused on empowering, educating and advancing PAs currently working in the field of dermatology and those who would like to work in the field.

SOCIETY OF DERMATOLOGY PHYSICIAN ASSISTANTS
SDPA
• EST 1994 •

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The Future of Dermatology

Elevate your career by joining the only association advocating for PAs in dermatology.

BECOME A MEMBER

Journal Club: *Practice Changing Articles for Dermatology PAs*

Use of Eye Shields for Mohs Micrographic Surgery of the Eyelids and Periorbital Area.

Dermatol Surg. 2019 Feb;45(2):210-215. doi:10.1097/DSS.0000000000001722.

Shih S[1], Khachemoune A[2,3]

1. University of Central Florida College of Medicine, Orlando, Florida.
2. Veterans Affairs Medical Center, Brooklyn, New York.
3. Department of Dermatology, SUNY Downstate, Brooklyn, New York.

Background

Internal eye shields are designed for use in periorbital procedures, but their use in Mohs micrographic surgery (MMS) of the eyelids has rarely been reported in the literature.

Objective

The authors aim to discuss different types of internal eye shields as well as their indication, proper use, and potential complications.

Methods and Materials

The authors performed a literature search on PubMed with the keywords "internal eye shield," "corneal shield," "scleral shield," and "periorbital Mohs micrographic surgery" with no restriction on publication time frame due to the scarcity of relevant literature.

Results

Experts seem to agree that use of eye shield for MMS of the eyelids is a reasonable measure to undertake to prevent operative injuries. Although either plastic or stainless steel eye shield can be used, plastic eye shields are often preferred and recommended in procedures where electrosurgical devices need to be used.

Conclusions

Although the authors recommend the use of internal eye shields for MMS of the eyelids for preventing operative injuries, this recommendation (Grade C) is based on very limited evidence (Level 5). More research and higher-powered studies are needed for conclusive evidence and to establish clear guidelines for providers.

From MEDLINE®/PubMed®, a database of the U.S. National Library of Medicine. PreMedline Identifier: 30608286.

Journal clubs are a great way to review and critically evaluate the most current literature impacting the practice of dermatology. For PAs who are new to the practice of dermatology, journal clubs can assist them to become more familiar with advanced medical literature and improve their understanding of current issues within the field. The articles selected for the JDPA Journal Club are meant to be shared and discussed with your colleagues, peers, and collaborating physicians. If you have any articles to recommend for the JDPA Journal Club, please email them to editor@jdpa.org

Dermcast.tv Blog - *Mastering The Surgical Procedure*

By Sarah Patton, MSHS, PA-C

Dr. Mike Swann presented a lecture on mastering the surgical procedure Friday morning November 22nd, 2019 at the SDPA 17th Annual Fall Dermatology Conference in Scottsdale, AZ with the comment, " A solid understanding of anatomy is required to do no harm." He reviewed the "danger zones" of facial anatomy explaining that if, "You stay in the subcutis you can stay out of trouble." This approach can get more challenging in older patients as they tend to have less fat and their fascia can be very thin. He reports damage to the facial nerve is the most devastating permanent result of superficial surgery. Dr. Swann also illustrated the subunits of the nose and lips and expressed accurate anatomical labeling when performing biopsies or surgery on the face. He stressed lymphatic drainage must be understood to evaluate for metastasis.

"A solid understanding of anatomy is required to do no harm."

Next Dr. Swann discussed various surgical techniques. One tip he mentioned repeatedly is the importance of patient positioning. Ideally patients should be in a position where the area in which you are performing surgery is presented in a flat plane. Additionally, you should be as proximal to the patient as you can be. He mentioned performing good surgery is more about, "Doing the simple things" really well rather than learning the "fancy things." He reviewed the ideal length and width ratios for most excisions are 3:1 or 4:1 with longer excisions more commonly needed in the scalp or extremities where "lots of eversion" is needed and "longer is better." The importance of bevel edge was discussed with Dr. Swann reporting incisions should be done with zero bevel, keeping the incision perpendicular to the skin to uniform depth. Dr. Swann illustrated different approaches of the buried vertical mattress deep suture, which he reports as "the most important stitch of a good wound closure."

Dr. Swann ended his lecture with a photo of the three physician assistants, the "best PAs" with whom he works.

Dermcast.tv Blog Post: November 22, 2019
Adapted from the original article

Dermcast.tv is the official online media resource of the SDPA and is your free source for the latest SDPA-related audio podcasts, current dermatology news and research, and videos featuring thought-leaders, procedures, conference highlights, and much more. In addition, Dermcast is the #1 dermatology-related podcast on iTunes! To read more Dermcast.tv Blogs and/or to follow the next live blog from an upcoming SDPA dermatology conference, please visit the Dermcast.tv website at www.dermcast.tv and subscribe today.

Cordran® Tape
Flurandrenolide Tape, USP

IT STICKS WITH THEM, WHEREVER THEY MAY GO.

THE ONLY CLASS 1 HIGH POTENCY CORTICOSTEROID IN A TAPE.[1,2]

CORDRAN® Tape is flexible like athletic tape and offers a transparent, medicated, occlusive skin barrier that can be used for difficult-to-treat areas.[2,3] Visible results have been observed in as little as 1 week.[4]

INDICATION AND USAGE

CORDRAN® Tape (Flurandrenolide Tape, USP) is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses, particularly dry, scaling localized lesions.

IMPORTANT SAFETY INFORMATION

Topical corticosteroids are contraindicated in patients with a history of hypersensitivity to any of the components of these preparations. Use of CORDRAN® Tape is not recommended for lesions exuding serum or in intertriginous areas.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Use over large surface areas, prolonged use, and the addition of occlusive dressings augment systemic absorption. Pediatric patients may absorb proportionately larger amounts of topical corticosteroids and thus may be more susceptible to systemic toxicity.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Patients receiving a large dose applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression, and therapy should be modified or discontinued as appropriate.

Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively for pregnant patients or in large amounts or for prolonged periods of time. Caution should be exercised when topical corticosteroids are administered to a nursing woman.

Local adverse reactions may occur more frequently with the use of occlusive dressings. These reactions are listed in approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis. Reactions that may occur more frequently with occlusive dressings include: maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

Please see Brief Summary of CORDRAN® Tape full Prescribing Information on the following page.

IT STICKS. IT STAYS. IT WORKS.*

*CORDRAN Tape should be applied on clean and dry skin. It should always be cut, never torn. Topical corticosteroids are contraindicated in patients with a history of hypersensitivity to any of the components of these preparations. CORDRAN Tape is not recommended for lesions exuding serum or in intertriginous areas. Replacement of the tape every 12 hours produces the lowest incidence of adverse reactions, but it may be left in place for 24 hours if it is well tolerated and adheres satisfactorily. If irritation or infection develops, the use of CORDRAN Tape should be discontinued and appropriate antimicrobial therapy instituted, as necessary.[3]

USCOT0384b 08-2019

References:
1. US Department of Health and Human Services. *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.* 39th ed. US Food and Drug Administration; 2019. https://www.fda.gov/drugs/informationondrugs/ucm129662.htm. Accessed April 9, 2019.
2. Ference JD, Last AR. Choosing topical corticosteroids. *Am Fam Physician.* 2009;79(2):135-140.
3. CORDRAN Tape [package insert]. Exton, PA: Almirall, LLC, 2018.
4. Weiner MA. Flurandrenolone tape. A new preparation for occlusive therapy. *J Invest Dermatol.* 1966;47(1):63-66.

almirall


LEARN MORE AT
CORDRANTAPE-HCP.COM
Not an actual patient, results may vary.

CORDRAN TAPE BRIEF SUMMARY OF PRESCRIBING INFORMATION

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION FOR CORDRAN® TAPE (Flurandrenolide Tape, USP)

This brief summary does not include all the information needed to use Cordran Tape safely and effectively. See full Prescribing Information for Cordran Tape.

INDICATIONS AND USAGE

For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, particularly dry, scaling localized lesions.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in patients with a history of hypersensitivity to any of the components of these preparations. Use of Cordran Tape is not recommended for lesions exuding serum or in intertriginous areas.

PRECAUTIONS

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions that augment systemic absorption include application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using urinary-free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete on discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, so that supplemental systemic corticosteroids are required. Pediatric patients may absorb proportionately larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see Pediatric Use under PRECAUTIONS). If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatologic infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, Cordran Tape should be discontinued until the infection has been adequately controlled.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression: Urinary-free cortisol test, ACTH stimulation test.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Usage in Pregnancy: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively for pregnant patients or in large amounts or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical-corticosteroid-induced HPA axis suppression and Cushing's syndrome than do mature patients because of a larger skin surface area to body weight ratio. Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma-cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis.

The following may occur more frequently with occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

Manufactured for:
Almirall LLC
Exton, PA 19341.

Revised: 10/2018

USCOT0291 03-2019

almirall

Need a clean slate? How to care for your skin after tattoo removal

Tattoos used to be considered permanent, but thanks to advances in laser technology, dermatologists from the American Academy of Dermatology say today's lasers can get rid of tattoos more safely and effectively, including removing tattoo ink with fewer treatments and treating ink colors that were once difficult to remove. However, while the technology has improved, they say, the results will depend almost entirely on the person performing the service.

"For the best results and to reduce your risk of serious side effects, such as scarring, burns and other wounds, it's important to make sure the person treating you is a physician who is extremely skilled in using lasers and has in-depth knowledge of the skin," says board-certified dermatologist Marie Leger, MD, PhD, FAAD. "After that, it's also important to properly care for the treated skin between sessions, as your skin needs time to heal and flush out the ink."

To care for your skin after each treatment, Dr. Leger recommends the following tips:

1. **Wash the treated area twice a day with water and a gentle cleanser.** Then, use a clean cotton swab to apply petroleum jelly to the area. This will help keep the skin moist so that it will not dry out or form any scabs. To prevent infection, cover the treated area with a dressing until the skin heals.

2. **Protect the treated skin from the sun.** Since the treated skin is more susceptible to sun damage, which can lead to color changes on your skin, keep the treated area out of direct sun exposure. When outdoors, wear protective clothing, such as a lightweight, long-sleeved shirt, pants or a wide-brimmed hat. Once the treated skin is healed, apply a broad-spectrum sunscreen with an SPF of 30 or higher. Look for a sunscreen that contains zinc oxide, which deflects the sun's harmful ultraviolet rays.

3. **Avoid picking at any flaking, peeling, blisters or scabs that form**. Do not pop any blisters, as doing so can cause an infection.

4. **Know what's normal.** After a laser tattoo removal session, you may experience some redness, swelling and blistering as your skin heals. However, if you notice signs of an infection, such as increasing redness and pain, swelling or pus, contact your dermatologist.

"Tattoo removal requires many treatments, with weeks between sessions," says Dr. Leger. "For the best results, follow your dermatologist's instructions for at-home care, and keep all of your appointments for laser tattoo removal, as each treatment removes more ink."

Marie Leger, MD is a board-certified dermatologist at Metro Dermatology, a private practice in New York City. Prior to joining private practice, she was an Assistant Professor of Dermatology at Weill Cornell College of Medicine for two years and at New York University for four years. She completed her dermatology residency at New York University where she also served as chief resident. Dr. Leger attended medical school at the University of Illinois where she was elected to Alpha Omega Alpha, the national medical honors society. She also earned a PhD at the University of Illinois in the Institute of Communications Research, and received her undergraduate degree in molecular and cell biology at the University of California, Berkeley.

Her research interests include tattoo health and removal, technology and health, telemedicine, and international dermatology. She treats a broad range of medical and cosmetic skin conditions, and has particular expertise in autoimmune blistering skin conditions.

Dr. Leger consults with organizations such as the FDA and New York Department of Health and Mental Hygiene about tattoo health and access to isotretinoin for acne. She started the first tattoo center in the US at Cornell University, which she now runs out of Metro Dermatology, and has lectured tattoo artists about skin health, skin cancer detection, and tattoo safety. In addition, she is the founder of a collaborative tattoo removal program at Metro Dermatology with the Legal Aid Society and the Administration for Children's Services in New York City for victims of human trafficking. She is a former host of Doctor Radio on Sirius XM. Dr. Leger is also a founding member of a teaching and research collaboration between the University of Ghana and New York University.

Dr. Leger is from the San Francisco Bay Area and has spent time working and traveling in Mexico City, Central America, and Africa. She speaks Spanish.

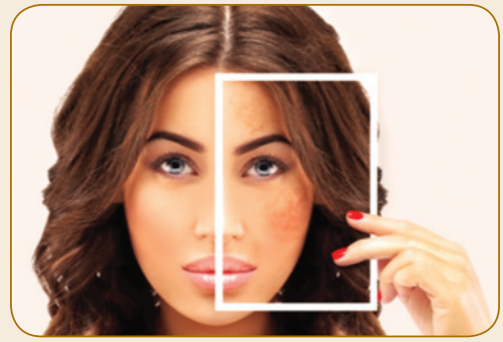
COSMETIC pearls

Dermcast.tv Blog

Defining the Relationship Between Melasma and Hormones

By Martha L. Sikes, MS, RPh, PA-C

Melasma, patchy dark spots on facial skin, develops in women and can cause significant effects on quality of life due to the difficulty in treating the condition. Melasma appears during the reproductive years and is frequently associated with female sex hormones. Oral contraceptives can hasten the development of melasma (as can pregnancy), which suggests that female sex hormones accelerate the development and aggravation of melasma. However, associating melasma definitely with hormones has proved difficult.



A recent study aimed to review the literature on blood levels of hormones in women and men with melasma and to report whether or not a clear correlation can be identified. The study looked at case series and two studies that looked at hormonal levels and melasma in both men and women. Several studies of women with melasma examined the role of hormone levels. One conclusion was that decreased estradiol levels in melasma patients may corroborate the hypothesis that mild ovarian dysfunction might be a factor in the development of melasma.

Other studies noted that female melasma patients had a greater presence of ovarian cysts and androgenic hormones. There were few studies that included men and looked at endocrinology, and the few that exist found conflicting results. One study suggests sun exposure, and family history as the main causative factors of melasma, while others point to the introduction of estrogens or anti-androgen medications as a cause. The authors state that the role of hormones in the onset of melasma in men is contrasting and needs to be verified in studies with larger sample sizes.

The individual case series presented in the review further demonstrate how difficult it is to demonstrate a clear relationship between hormones and melasma. The authors state that while hormonal therapies, pregnancy, and oral contraceptives still present the greatest risk for developing melasma, the role of genetic predisposition and exposure to sunlight are also main factors for melasma development. Despite previous research linking melasma to hormones, we do not have the data to clearly define the relationship. The authors conclude that the literature currently shows that the correlation between melasma onset and hormonal changes in both men and women is not clear.

Dermcast.tv Blog Post: April 16, 2019
Source: Wiley Online
Adapted from the original article

Dermcast.tv is the official online media resource of the SDPA and is your free source for the latest SDPA-related audio podcasts, current dermatology news and research, and videos featuring thought-leaders, procedures, conference highlights, and much more. In addition, Dermcast is the #1 dermatology-related podcast on iTunes! To read more Dermcast.tv Blogs and/or to follow the next live blog from an upcoming SDPA dermatology conference, please visit the Dermcast.tv website at www.dermcast.tv and subscribe today.

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RESULTS WITH JUST A FEW DOSES[1,2]

- With **just 2 doses** at Week 12, 64% and 61% achieved PASI 75 (reSURFACE 1 and reSURFACE 2, respectively)
  - vs placebo: 6% and 6% (reSURFACE 1 and reSURFACE 2, respectively)
- With **just 3 doses** at Week 28, 74% and 70% achieved PASI 75 (reSURFACE 1 and reSURFACE 2, respectively)*

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LIGHTEN THE BURDEN OF FREQUENT DOSING[1,3]

- ILUMYA™ is dosed at Weeks 0, 4, and **every 12 weeks** thereafter

DURABLE SAFETY PROFILE[1]

- **Through Week 64**, the frequency of adverse reactions was similar to that during the placebo-controlled period of the trial, and no new adverse reactions were identified
- ILUMYA™ may increase the risk of infection
- The most common (≥1%) adverse reactions that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea

reSURFACE 1 and 2 were Phase 3, double-blind, placebo-controlled trials of ILUMYA™ given at Weeks 0, 4, and every 12 weeks thereafter. Patients in reSURFACE 1 (N=463) and reSURFACE 2 (N=463) with moderate-to-severe plaque psoriasis who were candidates for phototherapy or systemic therapy were randomized to ILUMYA™ 100 mg or placebo. At Week 28, patients in reSURFACE 1 initially randomized to ILUMYA™ who achieved at least PASI 75 were re-randomized to either continue initial treatment or to receive placebo up to 64 weeks. The co-primary endpoints of both trials were: 1) the proportion of subjects who achieved at least PASI 75 and 2) the proportion of subjects with a PGA 0 or 1 and at least a 2 point improvement, both at Week 12. Other evaluated outcomes included PASI 90/100 at Week 12 and PASI 75 at Week 28. reSURFACE 1 also measured maintenance of efficacy in responders up to Week 64.[1,2]

*These endpoints were considered "other" secondary endpoints in reSURFACE 1 and 2.
All results based on the recommended 100 mg dose of ILUMYA™.
PASI=Psoriasis Area and Severity Index; PGA=Physician Global Assessment.

INDICATION

ILUMYA™ (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity
Cases of angioedema and urticaria occurred in ILUMYA™-treated subjects in clinical trials. If a serious allergic reaction occurs, discontinue ILUMYA™ immediately and initiate appropriate therapy.

Infections
ILUMYA™ may increase the risk of infection. Treatment with ILUMYA™ should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing ILUMYA™ in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILUMYA™ to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and consider discontinuation of ILUMYA™ until the infection resolves.

Pretreatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILUMYA™. Do not administer ILUMYA™ to patients with active TB infection. Initiate treatment of latent TB prior to administering ILUMYA™. Consider anti-TB therapy prior to initiation of ILUMYA™ in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving ILUMYA™ should be monitored closely for signs and symptoms of active TB during and after treatment.

Immunizations
Prior to initiating therapy with ILUMYA™, consider completion of all age-appropriate immunizations according to current immunization guidelines. Patients treated with ILUMYA™ should not receive live vaccines.

Adverse Reactions
The most common (≥1%) adverse reactions associated with ILUMYA™ treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea.

Please see Full Prescribing Information at ILUMYApro.com

References: 1. ILUMYA™ [package insert]. Princeton, NJ: Sun Pharmaceuticals, Inc. **2.** Data on File. Sun Pharmaceutical Industries, Inc. **3.** Rigopoulos D, Ioannides D, Chaidemenos G, et al. Patient preference study for different characteristics of systemic psoriasis treatments (Protimisis). *Dermatol Ther*. 2018;31(3):e12592.

SUN DERMATOLOGY

Brief Summary of Prescribing Information for ILUMYA™ (tildrakizumab-asmn)
ILUMYA™ (tildrakizumab-asmn) injection, for subcutaneous use
See package insert for full Prescribing Information

INDICATIONS AND USAGE ILUMYA™ is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

CONTRAINDICATIONS
ILUMYA is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS
Hypersensitivity: Cases of angioedema and urticaria occurred in ILUMYA treated subjects in clinical trials. If a serious hypersensitivity reaction occurs, discontinue ILUMYA immediately and initiate appropriate therapy *[see Adverse Reactions]*.

Infections: ILUMYA may increase the risk of infection. Although infections were slightly more common in the ILUMYA group (23%), the difference in frequency of infections between the ILUMYA group and the placebo group was less than 1% during the placebo-controlled period. However, subjects with active infections or a history of recurrent infections were not included in clinical trials. Upper respiratory infections occurred more frequently in the ILUMYA group than in the placebo group *[see Adverse Reactions]*.

The rates of serious infections for the ILUMYA group and the placebo group were ≤0.3%. Treatment with ILUMYA should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ILUMYA. Instruct patients to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection or is not responding to standard therapy, monitor the patient closely and consider discontinuation of ILUMYA until the infection resolves *[see Adverse Reactions]*.

Pretreatment Evaluation for Tuberculosis: Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILUMYA. Initiate treatment of latent TB prior to administering ILUMYA. In clinical trials, of 55 subjects with latent TB who were concurrently treated with ILUMYA and appropriate TB prophylaxis, no subjects developed active TB (during the mean follow-up of 56.5 weeks). One other subject developed TB while receiving ILUMYA. Monitor patients for signs and symptoms of active TB during and after ILUMYA treatment. Consider anti-TB therapy prior to initiation of ILUMYA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Do not administer ILUMYA to patients with active TB infection.

Immunizations: Prior to initiating therapy with ILUMYA, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with ILUMYA. No data are available on the response to live or inactive vaccines.

ADVERSE REACTIONS
The following serious adverse reactions are discussed elsewhere in the labeling:
Hypersensitivity Reactions *[see Warnings and Precautions]*
Infections *[see Warnings and Precautions]*

Clinical Trial Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, a total of 1994 subjects with plaque psoriasis were treated with ILUMYA, of which 1083 subjects were treated with ILUMYA 100 mg. Of these, 672 subjects were exposed for at least 12 months, 587 for 18 months, and 469 for 24 months.

Data from three placebo-controlled trials (Trials 1, 2, and 3) in 705 subjects (mean age 46 years, 71% males, 81% white) were pooled to evaluate the safety of ILUMYA (100 mg administered subcutaneously at Weeks 0 and 4, followed by every 12 weeks [Q12W]) *[see Clinical Studies]*.

Placebo-Controlled Period (Weeks 0-16 of Trial 1 and Weeks 0-12 of Trials 2 and 3)
In the placebo-controlled period of Trials 1, 2, and 3 in the 100 mg group, adverse events occurred in 48.2% of subjects in the ILUMYA group compared to 53.8% of subjects in the placebo group. The rates of serious adverse events were 1.4% in the ILUMYA group and 1.7% in the placebo group.

Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the ILUMYA group than in the placebo group.

Table 1: Adverse Reactions Occurring in ≥1% of Subjects in the ILUMYA Group and More Frequently than in the Placebo Group in the Plaque Psoriasis Trials 1, 2, and 3

Adverse Reaction	ILUMYA 100 mg (N=705) N (%)	Placebo (N=355) N (%)
Upper respiratory infections*	98 (14)	41 (12)
Injection site reactions†	24 (3)	7 (2)
Diarrhea	13 (2)	5 (1)

* Upper respiratory infections include nasopharyngitis, upper respiratory tract infection, viral upper respiratory tract infection, and pharyngitis.

† Injection site reactions include injection site urticaria, pruritus, pain, reaction, erythema, inflammation, edema, swelling, bruising, hematoma, and hemorrhage.

During the placebo-controlled period of Trials 1, 2, and 3, adverse reactions that occurred at rates less than 1% but greater than 0.1% in the ILUMYA group and at a higher rate than in the placebo group included dizziness and pain in extremity.

Specific Adverse Reactions
Hypersensitivity Reactions
Cases of angioedema and urticaria occurred in ILUMYA-treated subjects in clinical trials *[see Warnings and Precautions]*.

Infections
Infections were slightly more common in the ILUMYA group. The difference in frequency of infections between the ILUMYA group (23%) and the placebo group was less than 1% during the placebo-controlled period. The most common (≥1%) infections were upper respiratory infections. The rates of severe infections for the ILUMYA group and the placebo group were ≤0.3%.

Safety Through Week 52/64
Through Week 52 (Trials 1 and 3) and Week 64 (Trial 2), no new adverse reactions were identified with ILUMYA use and the frequency of the adverse reactions was similar to that observed during the placebo-controlled period.

Immunogenicity
As with all therapeutic proteins there is the potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to tildrakizumab in the studies described below with the incidences of antibodies in other studies or to other products may be misleading.

Up to Week 64, approximately 6.5% of subjects treated with ILUMYA 100 mg developed antibodies to tildrakizumab. Of the subjects who developed antibodies to tildrakizumab, approximately 40% (2.5% of all subjects receiving ILUMYA) had antibodies that were classified as neutralizing. Development of neutralizing antibodies to tildrakizumab was associated with lower serum tildrakizumab concentrations and reduced efficacy.

DRUG INTERACTIONS
Live Vaccinations
Avoid use of live vaccines in patients treated with ILUMYA *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS
Pregnancy: Risk Summary
Limited available data with ILUMYA use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. Human IgG is known to cross the placental barrier; therefore, ILUMYA may be transferred from the mother to the fetus. An embryofetal developmental study conducted with tildrakizumab in pregnant monkeys revealed no treatment-related effects to the developing fetus when tildrakizumab was administered subcutaneously during organogenesis to near parturition at doses up to 159 times the maximum recommended human dose (MRHD). When dosing was continued until parturition, a small increase in neonatal death was observed at 59 times the MRHD *[see Data]*. The clinical significance of this nonclinical finding is unknown.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data: *Animal Data*

In an embryofetal developmental study, subcutaneous doses up to 300 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks during organogenesis to gestation day 118 (22 days from parturition). No maternal or embryofetal toxicities were observed at doses up to 300 mg/kg (159 times the MRHD of 100 mg, based on AUC comparison). Tildrakizumab crossed the placenta in monkeys.

In a pre- and postnatal developmental study, subcutaneous doses up to 100 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks from gestation day 50 to parturition. Neonatal deaths occurred in the offspring of one control monkey, two monkeys at 10 mg/kg dose (6 times the MRHD based on AUC comparison), and four monkeys at 100 mg/kg dose (59 times the MRHD based on AUC comparison). The clinical significance of these nonclinical findings is unknown. No tildrakizumab-related adverse effects were noted in the remaining infants from birth through 6 months of age.

Lactation: Risk Summary
There are no data on the presence of tildrakizumab in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be present in human milk. Tildrakizumab was detected in the milk of monkeys *[see Data]*.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ILUMYA and any potential adverse effects on the breastfed child from ILUMYA or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of ILUMYA in pediatric patients (<18 years of age) have not been established.

Geriatric Use: A total of 1083 subjects were exposed to ILUMYA 100 mg during Phase 2 and 3 trials. A total of 92 subjects were 65 years or older, and 17 subjects were 75 years or older. Although no differences in safety or efficacy were observed between older and younger subjects, the number of subjects aged 65 and over is not sufficient to determine whether they respond differently from younger subjects.

OVERDOSAGE: In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and administer appropriate symptomatic treatment immediately.

PATIENT COUNSELING INFORMATION: Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide).

Instruct patients and/or caregivers to read the Medication Guide before starting ILUMYA therapy and to reread the Medication Guide each time the prescription is renewed. Advise patients of the potential benefits and risks of ILUMYA.

Hypersensitivity
Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions]*.

Infections
Instruct patients of the importance of communicating any history of infections to the doctor and contacting their doctor if they develop any symptoms of infection *[see Warnings and Precautions]*.

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SUN PHARMA

NOTES from your Office Manager

Electronic Health Records-Risks and Benefits of Storage Alternatives

By Marilyn Schatz, Esq

Since the development of the first electronic medical record system in 1972, electronic health records (EHRs) have become progressively more prevalent throughout the healthcare industry. Today, the clear majority of health records are stored and accessed digitally in the form of EHRs.

Selecting from the various data storage options is a challenging process, one that mandates the exercise of due diligence to assess the capabilities of available storage systems. The major difficulty lies in weighing the relative risks and benefits of each alternative prior to reaching a decision that results in ease of authorized access and HIPAA compliance. Performance, services, customer support, data security, cost, and incident and disaster response are some of the variables that must be carefully analyzed for informed decision-making that yields the most suitable choice for a healthcare practice. It is important to understand where generated data will reside and how chis can potentially impact operations and patient satisfaction.

There are three basic options to select from for the electronic storage of protected health information (PHI): on-site; cloud based; and hybrid. The primary benefit offered by having PHI storage on the premises of a healthcare provider or facility is the ability to maintain greater control over access to and the physical location of EHRs. A wireless internet connection is not required so that there is less risk of downtime or external cyber attacks. The most significant drawback to hosting a server on site is the sizable initial capital investment required for the purchase of equipment and software, as well as the ongoing costs. System management, maintenance, updates, and backups muse be performed on a routine basis by experienced IT staff. The provision of designated physical storage space char offers protection from fire, floods, and other disasters, as well as cooling costs, contribute to overhead. Other factors to consider include: the expense of employing knowledgeable IT support; the potential for physical server HIPAA breaches; the responsibility for performing regular backups; and lack of remote accessibility to data.

Cloud technology involves the internet-based sharing of computing resources, and transmission of data to and from connected devices on demand. A cloud-based system does not involve the burdensome investment in expensive hardware on the premises of a healthcare provider or facility. This option allows for a simplified, flexible, and cost-effective alternative for data storage as leasing fees paid to an off site service provider are typically based on actual storage needs. Data remains accessible by a healthcare practice from any computer with an internet connection. Frequent data back-ups, as well as encryption and automated recovery capabilities, afford better security protections from the potential consequences of a natural disaster or data breach.

However, cloud storage of PHI can potentially compromise the smooth operation of a healthcare practice because access to data is impossible if the internet connection is lost. Data recovery can be time consuming, which may negatively impact the delivery of healthcare services. In addition, lack of control over the server can result in security implications and HIPAA violations stemming from third-party access to PHI. HIPAA specifies that a signed Business Associate Agreement that outlines permitted and required uses and disclosures must be obtained from the chosen data storage vendor.[1]

The option of a hybrid system for the storage of PHI consists of a combination of onsite and cloud-based solutions. Maintaining some onsite server hardware is advantageous because there is no need to rely on continuous access to the internet. The cloud component of a hybrid system enables connectivity from any user location. In addition, data security can be enhanced by backing up PHI to both an on-site server as well as to a cloud system. However, as with any system involving the cloud, reliance must be placed on a service provider for uptime, performance, regulatory compliance, and technical support.

Technological advancements in the collection and storage of PHI have enabled significant improvements in communication among healthcare providers and with patients. The healthcare industry is under increasing pressure to balance these enhancements while maintaining the accessibility and security of PHI. The selection of a dependable data storage solution is essential for the safe and effective handling of PHI, and the avoidance of practice disruptions.

Are you satisfied with an in house structure, or should you reach for the cloud? The pros and cons of internal servers and cloud based systems must be weighed very carefully before choosing an approach char is a good fit for a healthcare practice. Thorough research is crucial to determine which solution best suits individual practice needs. Obtaining guidance and expertise from a skilled technology partner will assist healthcare providers in this demanding undertaking. During the complex process of selecting an EHR storage solution, all issues with the potential for an adverse impact on operations should be thoroughly examined.

REFERENCES:

1.hccps://www.hhs.gov/hipaa/for-professionals/special-copics/cloud-compucing/ index.hem!.

Marilyn Schatz, Esq. *works for Fager Amsler Keffer & Schoppmann, LLP and serves as counsel to MLMIC Insurance Company*

Outside & Inside the 9 to 5...

Interview With AIM's Melanoma Expert: Melissa Wilson, MPAS, PA-C

AIM at Melanoma is pleased to announce that physician assistant Melissa Wilson has joined the AIM team. Wilson will lead the "Ask a Melanoma Expert" program, which replaces AIM's "Ask Our Oncology Nurse" program with more targeted advice and support for those affected by melanoma.

Melissa Wilson, MPAS , PA-C

Melanoma has unique challenges and is not managed like most cancers. Having a melanoma-centric expert on staff gives patients, families, and caregivers invaluable management tools for fighting the illness. Wilson brings a wealth of knowledge and experience to her new role, and boundless enthusiasm for the industry and her patients.

A natural trailblazer, Wilson is proud of her collaborative work as an NCCPA-certified physician assistant senior since 2005 with the distinguished melanoma specialist Dr. John Kirkwood at the University of Pittsburgh in the Cancer Institute Division of Hematology/Oncology, Department of Medicine. Their treatment and research initiatives were so successful that they have been used as a template for other cancer programs throughout the country. Wilson works as lead physician assistant for the Melanoma Program at UPMC Hillman Cancer Center.

Her expertise is focused on acute care in outpatient oncology with research patients and the general melanoma population. She helps patients manage therapy-driven toxicity-related problems and emergencies. She has expertise in biopsies and suturing techniques, cryotherapy, injections, imaging reviews, clinical trial monitoring, and RECIST tumor measurements.

A natural teacher, Wilson has also worked with a multidisciplinary team on patient education and collaboration. She holds appointments at Chatham University Clinical Preceptor where she is an adjunct faculty and has been a cancer care modules lecturer on melanoma since 2013. She also lectured at AIM's melanoma patient symposium in April 2018.

Inspired to her career by her own father's battle with cancer (he is doing well!), Wilson says she will never stop wanting to help patients fight melanoma. She also feels confident that a cure is on the horizon given that melanoma treatments have grown exponentially over the last few years. Wilson looks forward to working closely with AIM to support the melanoma community until the cure for melanoma is found.

We had an opportunity to learn more about Ms. Wilson's role, what inspired her, and what to expect when contacting AIM's melanoma expert. Please see the interview below to learn more about Melissa Wilson and her new and exciting role with AIM.

JDPA: ***What inspired you towards wanting to work in this setting/capacity?***

Ms. Wilson: I have been a PA in a Melanoma Center at the University of Pittsburgh Hillman Cancer Center since 2005, so this opportunity to further educate and engage in a more broad platform with melanoma patients was simply an extension of what I do every day. I have wanted to work in healthcare (and thought I wanted to be a doctor) since I was 3 years old. When my father had a bone marrow transplant in 2002 at the Fred Hutchinson Center in Seattle, I shadowed a woman whom I thought was a fellow, only to find out she

was a PA. Her level of knowledge and autonomy was so advanced that I decided right there I was going to be her when I grew up! I have had amazing mentors, both through other PA's and the physicians in my melanoma center, that I am blessed to say I can be this person to others. One of the most important aspects of medicine is that your patients truly understand what is happening and why, and I like to be able to provide that level of knowledge in laymen terms.

JDPA: ***What do you foresee as being the biggest rewards and/or any challenges you might face in being the "voice" behind the screen? Will there be adjustments from being face to face in the clinical setting?***

Ms. Wilson: I am still in a clinical setting too! I continue to work full time in a melanoma clinic, so this is my second job that I do in my "free" time. I love to help patients especially those who may not have access to a provider to ask the questions that they have, or who want to know things that they feel like they don't understand. I think the most difficult thing for me is not being able to treat patients and give medical advice personally to each patient and taking ownership for the patient care.

JDPA: ***What advice can you offer to providers when they are helping patients navigate a melanoma diagnosis?***

Ms. Wilson: One important aspect of melanoma diagnosis is to make sure to acquire the molecular testing (BRAF, MEK, NF1) on the tumor as it offers different pathways for treatment. Seeing a dedicated melanoma specialist in times of treatment decisions is very important as there are always opportunities for clinical trials, which will help respond to treatment further. But if you are not a melanoma specialist, or even if you are, help the patient know that there is hope. So many innovations are finally coming to light and the lay of the land is much more promising than it has ever been.

JDPA: ***Do you think this approach to support will pave the way for other specialties to provide services in a similar fashion?***

Ms. Wilson: I certainly hope so! I really believe strongly that the PA/NP position is such a positive aspect of clinical medicine. It is such a great "middle" between the physician and the patient and in my experience I have been able to engage with patients on a more basic level, which has really improved our patient satisfaction. Doing posts on social media also has been such a positive experience because it is validated real information that patients can trust to be from a practicing clinical person in the field.

JDPA: ***Do you think it would be successful in regards to other diseases/disorders/specialities?***

Ms. Wilson: Gosh yes. I think that there is so much room for patient education out there. I firmly believe that the best thing that people can be is educated. I believe that the better patients understand what is happening with their condition and treatments, the more compliant and better team you have!

JDPA: ***What should a patient expect if they were to reach out to talk to you as AIM's melanoma expert? Meaning- if a dermatology PA working in a clinical setting were to refer a patient to your services- what should he/she tell a patient to expect from the experience?***

Ms. Wilson: I'm more of a walking encyclopedia in this role. I cannot legally give medical advice, but I can look at photos of moles and say, "Hey that looks worrisome, etc" I can interpret pathology reports and radiology reports and explain all of the medical terminology and what it actually "means" for their diagnosis and risk. I can answer most questions about what options are out there. I can direct people to physicians who specialize in melanoma near to where they live.

JDPA: ***Will you be communicating with dermatology providers or just the patients themselves?***

Ms. Wilson: So far I have been speaking to patients themselves, though I have in the past been a "provider on call" for toxicity for immunotherapy (which was funded through ECOG – Eastern Cooperative Oncology Group) for a few years where I did provide advice to primarily oncologists and dermatologists in regard to adverse events to immunotherapy. However, this seems to be set up primarily to be for patients themselves, but I'm happy to talk to whomever calls!

JDPA: ***Any additional insights/advice/information you would like to share with our readers?***

Ms. Wilson: Educate yourself well regarding your diagnosis, and if you have questions please ask them. We are on a team so the more we understand what is important or bothering you as a patient the better the experience will be for everyone. If you don't feel that your provider is able to make you feel comfortable, ask for help. Call me.

Do You Have Questions About Melanoma?

AIM at Melanoma knows that a melanoma diagnosis can be confusing, but you don't have to handle it alone. That's why our team includes a specialized physician assistant to help you navigate through the entire spectrum of care. Our melanoma medical expert can provide accurate answers to a wide range of melanoma questions on a confidential basis.

We can help you with:

General questions about melanoma prevention, symptoms, and screening, such as, "What should I do to prevent melanoma? What are the symptoms of melanoma? I have a family history of melanoma, should I get genetic testing?"

Questions related to a melanoma diagnosis, treatment, clinical trials, and survivorship, such as, "What does my diagnosis mean? What are the stages of melanoma? What are my treatment options? Could I be eligible for a clinical trial?"

Questions about side effects you might experience during melanoma treatment and questions about will happen during and after treatment.

AIM's medical expert cannot give medical advice or diagnose medical problems.

Our Hours:

Our online form is available at any time, and you can expect answers within 48 business hours.

Who Will I Be Talking To?

You will speak with Melissa Wilson, MPAS, PA-C, AIM's physician assistant who has years of experience helping melanoma patients and their families. Our physician assistant is up-to-date about the latest melanoma treatments and research.

What Can You Help Me With?

When you contact us, our physician assistant can:

- Help you understand your condition
- Help you understand your pathology report or test results
- Explain your treatment options
- Offer suggestions on diet, exercise, or managing side-effects
- Help you understand what your symptoms mean and if you should call your doctor

Can You Give Me a Diagnosis or Prognosis?

We can answer your questions about symptoms but cannot confirm a diagnosis or give you a prognosis.

What If I Am Looking for Melanoma Resources in My Community?

AIM's Director of Community Engagement can refer you to support groups, community social services, or other resources based on your needs. Please contact Brenda Busby, our Director of Community Engagement.

Is There a Cost?

No. AIM's services are 100% free and 100% confidential.

Please submit your message and AIM's physician assistant will get in touch with you within 48 business hours.

JOIN SDPA TODAY

The Society of Dermatology Physician Assistants (SDPA) is a non-profit professional association **committed to empowering, educating and advancing PAs** currently working in the field of dermatology, as well as those interested in working in the field. The SDPA membership currently sits at 3700+, and we fully expect strong growth in the years to come as we continue to provide excellent service and benefits to our members. Turn the page and see what we have to offer...

Please visit us online at www.dermpa.org to learn more about our Society and the benefits of becoming a member.

Contact us at any time at 1-844-DERM-PAS (844-337-6727) or via email at membership@dermpa.org.

SOCIETY OF DERMATOLOGY PHYSICIAN ASSISTANTS

SDPA

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Membership in the SDPA provides all this and more!

Dermatology PA Education

SDPA provides more than 150 hours of Category 1 CME courses at any given time.

Diplomate Fellowship™ Program

The SDPA Diplomate Fellowship™ is the cornerstone of our educational offerings, and the premier training program for Dermatology PAs.

Working with 60+ subject matter experts and testing experts, the program was designed to cover the full range of knowledge every dermatology PA should have to provide exceptional patient care. The full program offers 64.5 hours of AAPA accredited Category 1 CME training, spread out across 22 modules.

CME Conferences

We offer discount registration to two highly rated CME conferences per year, held in varying locations across the country. Our Summer and Fall conferences offer, on average, over 25 Category 1 CME hours each. In addition to excellent educational content, our conferences are the perfect venue to network with your fellow attendees and exhibitors.

JDPA

You'll also receive a complimentary subscription to our quarterly publication, the *Journal of Dermatology PAs* (JDPA), which offers a Category 0.5 CME hour each issue.

Growing, Supporting and Promoting the Dermatology PA Profession

By standing together we will guide the future growth and success of the Dermatology PA profession. Through membership and participation in SDPA, you have a voice at this pivotal time, a voice that will determine the future opportunities of Dermatology PAs and how the profession is viewed in the broader medical community and the public.

Advocacy

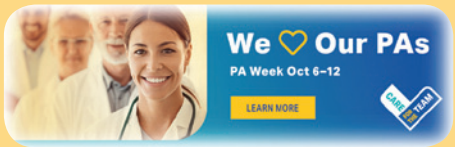
SDPA represents Dermatology PAs to the American Academy of Dermatologists (AAD) and AAPA, as well as state and federal legislators, industry leaders, patient advocacy groups and the local communities you serve.

Our leadership team is proactively involved in issues that have any potential to impact the Dermatology PA profession.

Public Education Campaigns

The Greater Access for Patients Partnership (GAPP) Campaign raised awareness about the nationwide dermatology wait times crisis and sought to improve access to patient care.

The "Thank A Derm PA" Campaign celebrated and highlighted the unique role of the Dermatology PA on the dermatology team. This campaign equipped Dermatology PAs and dermatology practices with easy-to-use tools and resources to show their support and appreciation for the PA profession.



Career Resources

As an SDPA member, you can access our online Career Center to post resumes, search job listings and apply for jobs with a board certified or eligible dermatologist. You can even set up instant email alerts to be notified of new jobs. We also offer an excellent online resource for Dermatologists interested in hiring a Dermatology PA for their practice. Our ***HireADermPA.org*** website provides comprehensive information about the value of adding a Dermatology PA to a practice, as well as hiring best practices.

Connecting with Your Derm PA Colleagues

As a member of SDPA, you are literally part of a "Society." Through interaction with your professional peers, you have access to a limitless resource of knowledge and experience to guide you in your career and to help you better serve your patients.

SDPA Connect

SDPA Connect is our online community site where you can participate in informative online discussions with your peers from around the country about any topic impacting the profession.

SDPA Committees

Much of the work of the SDPA resides at the committee level, and committee participation is the perfect way to get involved in industry leadership. We encourage all SDPA members to consider joining one or more of our committees that interest them.

- Conference Education Planning Committee
- Constituent Relations Committee
- Distance Medical Education Committee
- Legislative Affairs Committee
- Judicial and Ethical Affairs Committee
- Membership Committee
- Publications and Communications Committee
- Public Education Committee

Workplace Excellence
Gratitude

By Matthew Davidson, PhD

In my work as President of the Excellence with Integrity Institute (EII), I have had the opportunity to work with diverse individuals and organizations in their quest to achieve excellence. This column dedicated to workplace excellence explores the organizational, interpersonal, and ethical issues that contribute to (or detract from) individual or organizational excellence within the physician assistant profession. If you have any workplace topics you would like to see covered in the JDPA please feel free to share them with us. Email editor@jdpa.org with any topic ideas or questions concerning the workplace.

If you are not radically grateful every day,
resentment always takes over.
~ Richard Rohr

There are lots of indicators out there today that suggest all is not well in our workplace settings. Burnout is now included in the 11th Revision of the International Classification of Diseases (ICD-11) as an occupational phenomenon. Burnout is defined in ICD-11 as follows: "Burnout is a syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed. It is characterized by three dimensions: feelings of energy depletion or exhaustion; increased mental distance from one's job, or feelings of negativism or cynicism related to one's job; and reduced professional efficacy.

As we think about the very real threat of burnout in the workplace, especially in the healthcare industry where our compassion is drawn upon every day, we do well to remember that we are human beings, not human doings. The tasks we perform every day, no matter how grand or small, require vital energy. Our quest for continuous improvement and efficiency, depend upon harmony within each of us, and solidarity between us. Achieving excellence with integrity requires intrapersonal development (self work) as well as interpersonal development (team work). When we neglect these, we do so to the very real detriment of those whom we are trying to serve.

In reality, some might argue we're not human doings, or even human beings, we're actually spiritual beings having a human experience. According to spiritual author Henri Nouwen, "Burnout is a convenient term for spiritual death." Are you feeling depleted or exhausted - and not just at the end of a long day, but throughout the day? Are you feeling negativity and cynicism - towards those you serve, those you work with, the field in general? Are you feeling a lack of professional efficacy, confidence, and pride? In the various workplace settings we serve, many of us report feeling burned out, stressed out, and maxed out.

The death of vitality, of spirit, of joy - how does this happen? In the immortal words of Ernest Hemmingway, "Slowly and then suddenly." For many of us what precedes burnout is a period of deep engagement where we are all in on the daily challenges that the workplace throws at us. Slowly over time the grind of work wears us down, which can be exacerbated by the many commitments outside of work. Slowly we feel our spirit - the animation, joy, and vitality that once made work so fulfilling and engaging, drying up. And then suddenly, one day we realize the deep engagement has been replaced by a near constant sense that

half our engines are no longer firing. The tasks we once did with ease, and at times even joy, have become drudgery.

So what's the solution? Well, it may be simple, but it's not easy. I have likened burnout to anemia, once you are iron deficient it isn't a matter of popping a few iron pills and watching your levels rise. It takes time. However, there are ways to start restoring your workplace spirit. You can hardly open a workplace journal today that isn't talking about the importance of stress management, technology management, and basic mindfulness. Deep work, rapt attention, focus, and presence - these are just some of the most current social psychology topics that are dominating the literature.

One way to begin to work yourself out of burnout, or even just a disengaged malaise that you might be feeling at work, is to "put on an attitude of gratitude." We often have to "put on gratitude" since at the outset we may feel anything but grateful. Gratitude is a close cousin to love. While we may feel love at first sight - for a person or a vocation - before too long we have to work at it a bit. Love, like the attitude of gratitude, is not something that we simply feel. It is the fruit or the result of our actions. Feeling grateful often does not come easily, especially when we are mad, sad, tired, frustrated, or overwhelmed. We begin to "feel grateful" when we "put on gratitude" by smiling, by silencing the negative voices of doubt and despair, by getting over and beyond ourselves, by affirming and encouraging others, and by letting others support and challenge us.

Some year's back Brother David Steindl-Rast presented a simple, profound, and incredibly popular Ted-Talk entitled, *Want to be happy? Be grateful.* He said, *In daily life we must see that it is not happiness that makes us grateful, but gratefulness that makes us happy.* We all want to be happy. However, we often reverse the order. Ironically, pursuing happiness will often make you unhappy. Happiness ***ensues*** from profound gratitude. So, how do we put on the attitude of gratitude? **Wake up, lighten up, reach out, and look up.**

Wake up: Wake up to the divine within and around us in every moment, even the tough ones that are different than you imagined. Wake up to the beauty and miracle of now. In the workplace, as in many areas of our life, we often fall out of love with the process of preparation, the struggle, the battle, and the journey. We swipe past all of these rich experiences waiting for the one perfect moment, the one highlight, the perfect day, or the completed project. Sadly we often don't wake up to what we have until it's taken from us. Wake up now by putting on the gratitude attitude!

Lighten up: We are all at times gratitude vampires who make everything about us and turn the simplest and best things from gift into drudgery. Apathy means you don't care. Never stop caring! Detachment means you do your best, accept the result, and focus on growing. Too often we make a big deal out of everything. Every exchange with a colleague is a threat to our ego or a test of our absolute value. Every argument or disagreement seems like a crossroad, instead a pause along the journey. We long for the adversity free workplace. However, we often learn and grow more from our adversities and challenges. We must each tell ourselves a thousand times a day: Lighten up! All will be well. All will work out.

Reach out: To paraphrase a famous quote, "Most of us lead lives of quiet desperation." When we struggle we often pull back. Pulling back usually makes things worse, not better. Name the issue; describe the problem; express what is happening and what you want or need from others. Offer a word of gratitude to others early and often. Quickly reach out to others when you are struggling, and even more quickly when you realize they are struggling.

Look up: Sure, this is a call to count our blessings and to pray for the strength to accept what cannot be changed. It is also literally a call to pull up away from and out of the stress we have created for ourselves. A favorite quote says, "People all wrapped up in themselves are a pretty small package." The more we look down at our current struggle (within ourselves or between colleagues) the smaller and more intense things look. If we can simply get a little high ground vantage on things, we can often see that things are not as bad as they seem. We can value the journey and destination. We can often extend the benefit of the doubt to

others and get the precious head-space, and heart-space we need to restore our compassion.

Gratitude researcher Robert Emmons argues that "Gratitude is the recognition that life owes me nothing and all the good I have is a gift." Wake up. Lighten up. Reach out. Look up. Put some humanity back into your workplace culture by attending to the deep need we each have within ourselves to experience harmony and balance.

Many years ago a dear friend said these words to me; he said: "Matt, I appreciate you." It nearly brought me to tears. It was so simple and yet so profound. It is a phrase that I often say to others now. I appreciate those who love me and are patient with me. I appreciate those who see the best in me and help to bring it out. Sometimes it requires "radical gratitude," but I even appreciate people and situations that challenge me, frustrate me, disappoint me, and even anger me. They all help me wake up to my own journey, and to the journey of those around me.

Excellence with Integrity™ INSTITUTE

Matthew L. Davidson, Ph.D. *is the Founder, President, and Director of Education for the Excellence with Integrity Institute (EII), a 501(c)3 nonprofit corporation dedicated to helping individuals and organizations achieve excellence. He is a National Spokesperson for the Business Bureau National Center for Character Ethics. The EII specializes in the development and dissemination of research-based tools for developing the culture and competencies of excellence and ethics in schools, athletics, the workplace, and the home; this is done through professional development workshops & academies, teaching & learning resources, assessment, and consulting services. He is a frequent national presenter and is available for keynote lectures, professional development, retreats, and organizational consulting. He has indicated no relationships to disclose relating to the content of this article. For additional information or to contact the EII, please visit www.excellenceandethics.org.*

Collaborating Physician Corner

American Academy of Dermatology-Choosing Wisely

Part 2 of 2

The ABIM Foundation's Choosing Wisely® campaign is focused on encouraging physicians and patients to talk about medical tests and procedures that may be unnecessary, and, in some instances, can cause harm. To join, a medical society must provide expert guidance on five medical tests or treatments commonly used in its field.

The Academy has identified 10 evidence-based recommendations that can support conversations between patients and dermatologists about treatments, tests, and procedures that may not be needed.

We highlighted recommendations 1-5 in the JDPA Fall 2019 issue and will feature recommendations 6-10 in this issue of the JDPA.

Statement #6: *Do not use systemic (oral or injected) corticosteroids as a long-term treatment for dermatitis*

Explanation: The potential complications of long-term treatment with oral or injected corticosteroids outweigh the potential benefits. Although the short-term use of systemic corticosteroids is sometimes appropriate to provide relief of severe symptoms, long-term treatment could cause serious short- and long-term adverse effects in both children and adults. In extreme cases that have failed to respond to other appropriate treatments, the benefits of systemic corticosteroids must be weighed against these potentially serious risks.

Source:

1. *Yu S, Drucker AM, Lebwohl M, Silverberg JI. A systematic review of safety and efficacy of systemic corticosteroids in atopic dermatitis. J Am Acad Dermatol. DOI: https://doi.org/10.1016/j.jaad.2017.09.074.*
2. *Sidbury R, Davis DM, Cohen DE, Cordoro KM, Berger TG, Bergman JN et al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol 2014;71:327-49.*
3. *Diepgen TL, Andersen KE, Chosidow O, Coenraads PJ, Elsner P, English J et al. Guidelines for diagnosis, prevention and treatment of hand eczema. J Dtsch Dermatol Ges 2015;13:e1-22.*
4. *Usatine RP, Riojas M. Diagnosis and management of contact dermatitis. Am Fam Physician 2010;82:249-55.*
5. *Krejci-Manwaring J, McCarty MA, Camacho F, Manuel J, Hartle J, Fleischer A, Jr. et al. Topical tacrolimus 0.1% improves symptoms of hand dermatitis in patients treated with a prednisone taper. J Drugs Dermatol 2008;7:643-6.*

Statement #7: *Do not use skin prick tests or blood tests such as RAST for the routine evaluation of eczema*

Explanation: Skin prick tests, which are conducted with a needle, or blood tests may help identify causes of allergic reactions including hives or sneezing after exposure to dust or pollen. However, these tests are not useful for diagnosing dermatitis or eczema. For these rashes, when testing is deemed necessary, patch testing with ingredients of products that come in contact with the patient's skin is a better test to look for suspected allergies.

Source:

1. *Sidbury R, Tom WL, Bergman JN, Cooper KD, Silverman RA, Berger TG et al. Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches. J Am Acad Dermatol 2014;71:1218-33.*
2. *Boyce JA, Assa'ad A, Burks AW, Jones SM, Sampson HA, Wood RA et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. J Allergy Clin Immunol 2010;126:S1-58.*

Statement #8: *Do not routinely use microbiologic testing in the evaluation and management of acne*

Explanation: Acne has many contributing factors, of which bacteria are only one part. Microbiologic testing, used to determine the type of bacteria present in an acne lesion, is generally unnecessary because it does not affect management of typical patients with acne. Microbiologic testing should be considered only when acne has failed to respond to conventional treatments, particularly in patients who have already been treated with oral antibiotics..

Source:

1. *Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 Feb 15.*

Statement #9: *Do not routinely use antibiotics for treatment of bilateral swelling and redness of the lower leg unless there is clear evidence of infection*

Explanation: Research has suggested that bilateral lower leg cellulitis is very rare. Patients with swelling and redness of both legs most likely have another condition, such as dermatitis related to leg swelling, varicose veins or contact allergies. To ensure appropriate treatment, doctors must consider the likelihood of diagnoses other than cellulitis when evaluating swelling and redness of the lower legs. Misdiagnosis of bilateral cellulitis can lead to overuse of antibiotics and subject patients to potentially unnecessary hospital stays.

Source:

1. *Weng QY, Raff AB, Cohen JM, Gunasekera N, Okhovat JP, Vedak P, Joyce C, Kroshinsky D, Mostaghimi A. Costs and consequences associated with misdiagnosed lower extremity cellulitis. JAMA Dermatol 2017; 153:141-146.*
2. *Arakaki RY, Strazzula L, Woo E, Kroshinsky D. The impact of dermatology consultation on diagnostic accuracy and antibiotic use among patients with suspected cellulitis seen at outpatient internal medicine offices: a randomized clinical trial. JAMA Dermatol 2014;150:1056-61.*
3. *Hughey LC. The impact dermatologists can have on misdiagnosis of cellulitis and overuse of antibiotics: closing the gap. JAMA Dermatol 2014;150:1061-2.*
4. *Salmon M. Differentiating between red legs and cellulitis and reviewing treatment options. Br J Community Nurs 2015;20:474-80.*
5. *David CV, Chira S, Eells SJ, Ladrigan M, Papier A, Miller LG et al. Diagnostic accuracy in patients admitted to hospitals with J Am Acad Dermatol 2010;62:518-9.*
6. *Levell NJ, Wingfield CG, Garioch JJ. Severe lower limb cellulitis is best diagnosed by dermatologists and managed with shared care between primary and secondary care. Br J Dermatol 2011;164:1326-8.*
7. *Kroshinsky D, Grossman ME, Fox LP. Approach to the patient with presumed cellulitis. Semin Cutan Med Surg 2007;26:168-78.*
8. *Hirschmann JV, Raugi GJ. Lower limb cellulitis and its mimics: part I. Lower limb cellulitis. J Am Acad Dermatol 2012;67:163:e1-12.*
9. *Hirschmann JV, Raugi GJ. Lower limb cellulitis and its mimics: part II. Conditions that simulate lower limb cellulitis. J Am Acad Dermatol 2012;67:177:e1-9.*

Statement #10: *Do not routinely prescribe antibiotics for inflamed epidermal cysts*

Explanation: The overwhelming majority of red and swollen epidermal cysts (ECs) are inflamed but not infected. It is important to confirm infection before treating these cysts with antibiotics. Appropriate treatments for inflamed ECs include incision and drainage or an injection of corticosteroid directly into the cyst.

Source:

1. *Liu C, Bayer A, Cosgrove SE, Daum RS, Fridkin SK, Gorwitz RJ et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant Staphylococcus aureus infections in adults and children. Clin Infect Dis 2011;52:e18-55.*
2. *Diven DG, Dozier SE, Meyer DJ , Smith EB. Bacteriology of inflamed and uninflamed epidermal inclusion cysts. Arch Dermatol 1998;134:49-51.*

To date, 75 national organizations representing medical specialists have joined the conversations about appropriate care. With the release of these recommendations, the campaign will have covered nearly 500 tests and procedures that the specialty society partners say are overused or inappropriate, and that physicians and patients should discuss. For more information on the campaign, visit www.ChoosingWisely.org.

The Academy's Choosing Wisely® list was selected by the AAD's Choosing Wisely® workgroup, who identified areas with the greatest potential for overuse/misuse, a need for quality improvement, and the availability of strong evidence-based research to support the recommendation. The final list was reviewed and approved by the Academy's Council on Science and Research and the Academy's Board of Directors.

Rhofade®
(oxymetazoline HCl)
cream, 1%

Not an actual patient

RHOFADE cream is the #1 prescribed topical treatment for persistent facial erythema associated with rosacea in adults*

*Based on Symphony Health PHAST data recording the number of prescriptions written between July 2017 and October 2019. Data on file. EPI Health, LLC

See results with RHOFADE cream

Unretouched photos of clinical trial subject. Individual results may vary.

At hours 3, 6, 9, and 12 on Day 29 of clinical trials, a ≥2-grade improvement in persistent facial erythema was seen in 12% to 18% of subjects using RHOFADE cream vs 5% to 9% using vehicle. The most common side effects at the application site include: dermatitis, worsening of rosacea pimples, itching, redness, and pain.[1] These are not all the possible side effects of RHOFADE cream. Individual results may vary.

INDICATION

RHOFADE cream is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

IMPORTANT SAFETY INFORMATION AND WARNINGS

WARNINGS AND PRECAUTIONS

Potential Impacts on Cardiovascular Disease
Alpha-adrenergic agonists may impact blood pressure. RHOFADE cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

Potentiation of Vascular Insufficiency RHOFADE cream should be used with caution in patients with cerebral or coronary insufficiency, Raynaud's phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

Risk of Angle Closure Glaucoma
RHOFADE cream may increase the risk of angle closure glaucoma in patients with narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

CONTRAINDICATIONS

There are no contraindications for RHOFADE cream.

ADVERSE REACTIONS

The most common adverse reactions ≥1% for RHOFADE cream were: application-site dermatitis 2%, worsening inflammatory lesions of rosacea 1%, application-site pruritus 1%, application-site erythema 1%, and application-site pain 1%.

For topical use only. Not for oral, ophthalmic, or intravaginal use.
Please see full Prescribing Information for RHOFADE cream at rhofadehcp.com and Brief Summary attached.

References: 1. RHOFADE® cream full Prescribing Information 2018.

EPIHEALTH
Advancing Dermatology

RHOFADE® (oxymetazoline HCl) cream, 1%

BRIEF SUMMARY—PLEASE SEE THE RHOFADE® CREAM PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

INDICATIONS AND USAGE

RHOFADE cream is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

DOSAGE AND ADMINISTRATION

For topical use only. Not for oral, ophthalmic, or intravaginal use.

Prime the RHOFADE cream pump before using for the first time. To do so, with the pump in the upright position, repeatedly depress the actuator until cream is dispensed and then pump three times. Discard the cream from priming actuations. It is only necessary to prime the pump before the first dose.

RHOFADE cream tubes do not require priming.

Apply a pea-sized amount of RHOFADE cream, once daily in a thin layer to cover the entire face (forehead, nose, each cheek, and chin) avoiding the eyes and lips. Wash hands immediately after applying RHOFADE cream.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Potential Impacts on Cardiovascular Disease

Alpha-adrenergic agonists may impact blood pressure. RHOFADE cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

Potentiation of Vascular Insufficiency

RHOFADE cream should be used with caution in patients with cerebral or coronary insufficiency, Raynaud's phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

Risk of Angle Closure Glaucoma

RHOFADE cream may increase the risk of angle closure glaucoma in patients with narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

ADVERSE REACTIONS

Clinical Studies Experience

Because clinical trials are conducted under varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 489 subjects with persistent facial erythema associated with rosacea were treated with RHOFADE cream once daily for 4 weeks in 3 controlled clinical trials. An additional 440 subjects with persistent facial erythema associated with rosacea were also treated with RHOFADE cream once daily for up to one year in a long-term (open-label) clinical trial. Adverse reactions that occurred in at least 1% of subjects treated with RHOFADE cream through 4 weeks of treatment are presented in the table below:

Adverse Reactions Reported by ≥ 1% of Subjects Through 4 Weeks of Treatment in Controlled Clinical Trials

Adverse Reaction	Pooled Controlled Clinical Trials	
	RHOFADE Cream (N = 489)	Vehicle (N = 483)
Application-site dermatitis	9 (2%)	0
Worsening inflammatory lesions of rosacea	7 (1%)	1 (< 1%)
Application-site pruritus	5 (1%)	4 (1%)
Application-site erythema	5 (1%)	2 (< 1%)
Application-site pain	4 (1%)	1 (< 1%)

In the long-term (open-label) clinical trial, the rates of adverse reactions over a one-year treatment period were as follows: worsening inflammatory lesions of rosacea (3%), application-site dermatitis (3%), application-site pruritus (2%), application-site pain (2%), and application-site erythema (2%). Subjects with persistent erythema along with inflammatory lesions were allowed to use additional therapy for the inflammatory lesions of rosacea.

DRUG INTERACTIONS

Anti-hypertensives/Cardiac Glycosides

Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives and/or cardiac glycosides is advised.

Caution should also be exercised in patients receiving alpha-1 adrenergic receptor antagonists such as in the treatment of cardiovascular disease, benign prostatic hypertrophy, or Raynaud's disease.

Monoamine Oxidase Inhibitors

Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no available data on RHOFADE cream use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. A literature article describing intranasal decongestant use in pregnant women identified a potential association between second-trimester exposure to oxymetazoline (with no decongestant exposure in the first trimester) and renal collecting system anomalies. In animal reproduction studies, there were no adverse developmental effects observed after oral administration of oxymetazoline hydrochloride in pregnant rats and rabbits at systemic exposures up to 3 times and 73 times, respectively, the exposure associated with the maximum recommended human dose (MRHD). The estimated background risks of major birth defects and miscarriage for the indicated population are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Following repeated use of oxymetazoline hydrochloride solution nasal spray for the treatment of nasal congestion at a dose 5 times higher than recommended, one case of fetal distress was reported in a 41-week pregnant patient. The fetal distress resolved hours later, prior to the delivery of the healthy infant. The anticipated exposures for the case are 8- to 18-fold higher than plasma exposures after topical administration of RHOFADE cream.

Human Data

No adequate and well-controlled trials of RHOFADE cream have been conducted in pregnant women. Across all clinical trials of RHOFADE cream, two pregnancies were reported. One pregnancy resulted in the delivery of a healthy child. One pregnancy resulted in a spontaneous abortion, which was considered to be unrelated to the trial medication.

Lactation

No clinical data are available to assess the effects of oxymetazoline on the quantity or rate of breast milk production, or to establish the level of oxymetazoline present in human breast milk post-dose. Oxymetazoline was detected in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RHOFADE cream and any potential adverse effects on the breastfed child from RHOFADE cream or from the underlying maternal condition.

Pediatric Use

Safety and effectiveness of RHOFADE cream have not been established in pediatric patients below the age of 18 years.

Geriatric Use

One hundred and ninety-three subjects aged 65 years and older received treatment with RHOFADE cream (n = 135) or vehicle (n = 58) in clinical trials. No overall differences in safety or effectiveness were observed between subjects ≥ 65 years of age and younger subjects, based on available data. Clinical studies of RHOFADE cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

OVERDOSAGE

RHOFADE cream is not for oral use. If oral ingestion occurs, seek medical advice. Monitor patient closely and administer appropriate supportive measures as necessary. Accidental ingestion of topical solutions (nasal sprays) containing imidazoline derivatives (e.g., oxymetazoline) in children has resulted in serious adverse events requiring hospitalization, including nausea, vomiting, lethargy, tachycardia, decreased respiration, bradycardia, hypotension, hypertension, sedation, somnolence, mydriasis, stupor, hypothermia, drooling, and coma. Keep RHOFADE cream out of reach of children.

EPIHEALTH

Advancing Dermatology

Listening To Patients
I Have Seen the Future

By Alan Rockoff, MD

Many patients have seen their long-term physicians retire. When I ask how they like their new doctors, they say, "She's okay, I guess. Quite efficient. Seems thorough. But it's not the same. It's just business. Nothing personal."

Sometimes you have to look backward to look forward. So it's perhaps fitting that I glimpsed the future at my last colonoscopy.

In recent years, I've had such procedures at a local suburban Surgi-Center, with easy access, and plenty of parking.

The woman who checks me in is all business. She scans my insurance cards and hands me a clipboard with a medical history form. Have I ever had cancer? A hernia? Am I pregnant? I wonder whether anyone reads these.

A young woman brings me inside, the first of many new faces. Their roles are murky. All the women are named Katelyn.

In a curtained cubby, the first Katelyn asks me to pack my clothes in a plastic bag and put on a johnny. Then an older man enters, initiating furious multitasking. Katelyn #2 asks me to confirm my name and date of birth, then inserts an IV in one arm, while the old doctor hands me an anesthesia consent form to sign with the other hand. I check many answers very fast, ignore the small-print boilerplate, and sign.

Two more Katelyns hand me other consent forms to sign, one from each side. They make no pretense of explaining them or even telling me what they are for, and I make none of reading them.

They depart, replaced by Ahmed, who rolls me into the next room. He confirms my name and date of birth, and the procedure I am there for. The purpose of these multiple checks is clear, along with dispiriting depersonalization. One could mitigate this with some light banter, but no one bothers. No time.

My physician, whom I actually know, enters, says hello, and exchanges pleasantries. Ahmed asks me to turn onto my left side. IV sedation flows into my veins. The rest is silence.

Some time later I wake up, greeted by another Katelyn. She asks if I am OK, and offers me water or juice and saltines. Noting her Boston Red Sox sweatshirt, I say, "Great game last night," but she does not know what I am talking about. She cares only for football, and plans to fly to Nashville to watch her favorites.

Curtains are closed, and I am asked to dress. Another Katelyn directs me to a chair, where I will await my ride home. Through I try to walk alone, she takes my arm. "We assist everyone," she explains.

As the sedation wears off, I observe. All around me I see movement, brisk and purposeful. Staff crisscross before me from all angles, striding from one task to another, from Prep Room A to Cubby D, walking with or pushing patients from Procedure Room M to Holding Area 8H. None of the staff I've just met recognizes me, or acknowledges doing so.

At last the final Katelyn approaches. She flashes a kind smile as she takes my arm to walk me to the door. I take this for a personal touch, until she explains that she must make sure I don't fall and that I get into the right car. As we pass, no one in the waiting room, staff or patients, takes any notice.

My wife is outside, idling in the correct car. She's brought coffee and a chocolate croissant, which almost makes last night's prep worthwhile. She confirms neither my name nor date of birth.

Altogether, I have been in and out in 90 minutes. In the car, I peruse the handout Katelyn handed me as I exited. Drinking my coffee, I read the post-care instructions and enjoy its full-color pictures. Seldom has my cecum looked more radiant. In The Check-List Manifesto, Atul Gawande describes the outcome improvement that systematized practice can achieve. Data analysis confirms the measurably superior efficacy of such a method.

As for me, I feel like output from one of today's cataract factories: like a car just extruded from an automated wash, with a photo on its front seat of the shiny, Simonized hubcaps included with the Premium Service Package.

The Medical Care of the Future? Okay, I guess. Seems efficient and thorough. Data confirms this.

Just business, though. Nothing personal.

Alan Rockoff, MD *practices dermatology in Boston, MA. He graduated with his medical degree in 1972 from the Albert Einstein College of Medicine in New York and then completed a pediatric internship and residency at Bronx Municipal Hospital Center. Continuing his education, Dr. Rockoff completed a dermatology residency program at the combined program at Boston University and Tufts University. Dr. Rockoff is a Clinical Assistant Professor of Dermatology at Tufts University School of Medicine. He has taught senior medical students and other trainees for over thirty-five years.*

Dr. Rockoff has been named one of Boston's Top Doctors by Boston Magazine for five years. Dr. Rockoff is board certified by the American Board of Pediatrics and the American Board of Dermatology. Dr. Rockoff is a Fellow of the American Academy of Dermatology and a member of the Massachusetts Medical Society and the Massachusetts Academy of Dermatology.

Dr. Rockoff's publications have appeared in a number of journals. He writes a monthly column for his dermatologic colleagues in Dermatology News as well as a blog for the magazine Psychology Today. His first book, "Under My Skin: A Dermatologist Looks at His Profession and His Patients" is available on Amazon and is his second book, "Act Like a Doctor, Think Like a Patient: Teaching Patient-focused Medicine" is available on Amazon and at Barnes and Noble.

From the Desk of...

The SDPA Board of Directors

The SDPA is pleased to announce our *most recent* Diplomate Fellow Members!

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What Do You Want To Read About In The JDPA?

We're interested in knowing what kind of articles SDPA members would be interested in reading more about in order to help improve their practice of dermatology.

Share your content ideas today.
Email them to editor@jdpa.org

JDPA
Journal of Dermatology for Physician Assistants

JDPA Journal of Dermatology for Physician Assistants

INFORMATION FOR AUTHORS – The JDPA is a peer-reviewed publication that delivers innovative clinical, surgical, cosmetic, and professional content exclusively for dermatology PAs. Submissions to the JDPA are peer-reviewed by a panel of experienced dermatology PAs, educational PAs, and dermatologists before articles are accepted for publication.

Manuscripts submitted for publication will be reviewed with the understanding that they are original and have not been submitted elsewhere nor are being considered by other journals. Electronic submissions are accepted and should be sent to editor@jdpa.org.

The five main sections featured in each issue of the JDPA are listed below along with a brief description of the various topics that authors can contribute to. Regardless of the section, all articles must follow the following criteria:

- ***Formatting*** - Times New Roman font, 12 point, double-spaced, left aligned.
- ***Article Order*** - Title, Author(s), Author bios (including disclosures), Text of Article, References, Tables, and Figures
- ***Reference Citations*** - Utilize the AMA Manual of Style, 10th Edition.

DERMATOLOGY PA NEWS AND NOTES

Feature Articles

Write a review about a new or innovative dermatological procedure, device, and/or approach to patient care (500-1000 words).

From The Desk Of…

Write an opinion essay sharing your insight regarding a current "hot item" issue *(e.g., specialty PA credentialing, dermatology access to care, supervising physician relationships, etc.)* or any other topic regarding the field of dermatology (250-1000 words).

CLINICAL DERMATOLOGY

CME articles

Content should be specific to the field of dermatology following any of the following formats:

Study – Original research (clinical or basic science).
Professional issues or health policy papers.
Review – Scholarly review of a topic.

Content length:

6 pages (requires 4 self-assessment Q&A) = .5hr of Cat. I CME.
12 pages (requires 8 self-assessment Q&A) = 1hr of Cat. I CME.

Article should include written learning objectives (3-4 required).

Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

From the Patient's Perspective

Patients' stories published in their own words. JDPA staff can even assist patients with writing their stories (250-1000 words).

Clinical Snapshots

Write a brief written description and clinical facts about an interesting cutaneous anomaly (250-500 words).

Drugs in Dermatology

Write about the current information regarding a particular dermatological medication, drug interaction, or medication side effect/adverse reaction (250-1000 words).

Dermatology Evidence-Based Medicine (derm EBM)

Write a brief, evidence-based assessment of the one or two most relevant studies retrieved to answer a focused clinical question that may have arisen from a real-life situation. A derm EBM is not a comprehensive review of a subject or a synthesis of all the available knowledge (500–1500 words).

SURGICAL DERMATOLOGY

Feature Articles

Write a review about a new or innovative surgical procedure, device, and/or approach to patient care (500-1000 words).

Surgical Wisdom

Write a brief article on a fact or pearl for the surgical setting (250-500 words).

Surgical Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

COSMETIC DERMATOLOGY

Feature Articles

Write a review about a new or innovative cosmetic procedure, device, and/or approach to patient care (500-1000 words).

Cosmetic Pearls

Write a brief article on a fact or pearl for the cosmetic setting (250-500 words).

Cosmetic Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

PROFESSIONAL DEVELOPMENT

Feature Articles

Write an article that explores the professional issues dermatology PAs face such as reimbursement, education, medical trends, contracts, office management, etc. (500-1500 words).

Outside & Inside the 9 to 5

Allow us to share your story of the good work that you do either outside or inside your practice of dermatology. You can write this article yourself or the JDPA staff can interview you to write the article (250-1000 words).

Notes From Your Office Manager

Write a brief article on a fact or pearl for the office setting (250-500 words).

Judicial and Ethical Affairs

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