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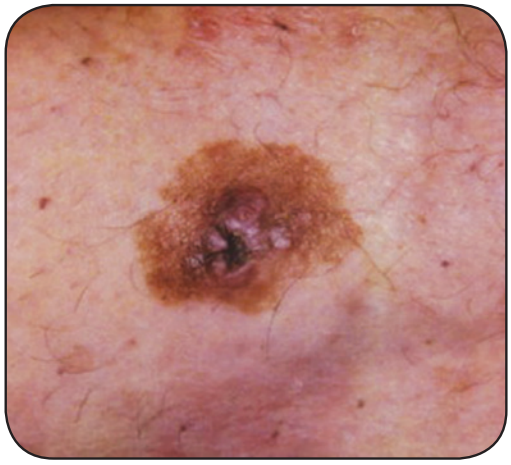
JDPA

Journal of Dermatology for Physician Assistants



Official Journal of the Society of Dermatology Physician Assistants

INDICATION

ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION

ALTRENO is for topical use only. Not for ophthalmic, oral, or intravaginal use.

Skin Irritation: Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

Ultraviolet Light and Environmental Exposure: Minimize unprotected exposure to ultraviolet light, including sunlight and sunlamps. Warn patients with frequent sun exposure and those with inherent sensitivity to sunlight to exercise caution. Use sunscreen and protective clothing over treated areas when exposure cannot be avoided.

Fish Allergies: ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

Adverse Reactions: The most common adverse reactions in clinical trials were application site dryness (4%), pain (3%), erythema (2%), irritation (1%) and exfoliation (1%).

Nursing Women: It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental health benefits of breastfeeding should be considered along with the mother's clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

To report SUSPECTED ADVERSE REACTIONS, contact Customer Service at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on following pages.

References: 1. Altreno lotion [package insert]. Bridgewater, NJ: Ortho Dermatologics, a division of Valeant Pharmaceuticals North America LLC. **2.** Data on file. Ortho Dermatologics, a division of Valeant Pharmaceuticals North America LLC.

Altreno™
(tretinoin) Lotion, 0.05%

Ortho | Dermatologics

BRIEF SUMMARY OF PRESCRIBING INFORMATION

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

ALTRENO™ (tretinoin) lotion, for topical use
Initial U.S. Approval: 1973

INDICATIONS AND USAGE

ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Skin Irritation

Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

Ultraviolet Light and Environmental Exposure

Minimize unprotected exposure to ultraviolet light including sunlight and sunlamps during the use of ALTRENO. Warn patients who normally experience high levels of sun exposure and those with inherent sensitivity to sun to exercise caution. Use sunscreen products and protective clothing over treated areas when sun exposure cannot be avoided.

Fish Allergies

ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

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 clinical practice.

In 2 randomized, double-blind, vehicle-controlled trials, subjects age 9 years and older applied ALTRENO or vehicle once daily for 12 weeks. The majority of subjects were White (74%) and female (55%). Approximately 47% were Hispanic/Latino and 45% were younger than 18 years of age. Adverse reactions reported by ≥1% of subjects treated with ALTRENO and more frequently than vehicle are summarized in Table 1.

Table 1: Adverse Reactions Reported by ≥1% of Subjects Treated with ALTRENO and More Frequently than Vehicle

Adverse Reactions n (%)		
	ALTRENO N=767	**Vehicle N=783**
Application site dryness	29 (4)	1 (<1)
Application site pain[1]	25 (3)	3 (<1)
Application site erythema	12 (2)	1 (<1)
Application site irritation	7 (1)	1 (<1)
Application site exfoliation	6 (1)	3 (<1)

[1]Application site pain defined as application site stinging, burning or pain.

Skin irritation was evaluated by active assessment of erythema, scaling, hypopigmentation, hyperpigmentation, itching, burning and stinging. The percentage of subjects who were assessed to have these signs and symptoms at any post baseline visit are summarized in Table 2.

Table 2: Application Site Tolerability Reactions at Any Post Baseline Visit

	ALTRENO N=760 Mild/Mod/Severe	**Vehicle N=782 Mild/Mod/Severe**
Erythema	51%	44%
Scaling	49%	30%
Hypopigmentation	12%	10%
Hyperpigmentation	35%	35%
Itching	35%	28%
Burning	30%	14%
Stinging	21%	8%

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Available data from published observational studies of topical tretinoin in pregnant women have not established a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are no data on ALTRENO use in pregnant women. The systemic levels following topical administration are lower than with administration of oral tretinoin; however, absorption of this product may result in fetal exposure. There are reports of major birth defects similar to those seen in infants exposed to oral retinoids, but these case reports do not establish a pattern or association with tretinoin-related embryopathy *(see Data)*.

Animal reproduction studies have not been conducted with ALTRENO. Topical administration of tretinoin in a different formulation to pregnant rats during organogenesis was associated with malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) at doses up to 0.5 mg tretinoin/kg/day, approximately 2 times the maximum recommended human dose (MRHD) based on body surface area (BSA) comparison and assuming 100% absorption. Oral administration of tretinoin to pregnant cynomolgus monkeys during organogenesis was associated with malformations at 10 mg/kg/day (approximately 100 times the MRHD based on BSA comparison and assuming 100% absorption) *(see Data)*.

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

Data

Human Data

While available studies cannot definitively establish the absence of risk, published data from multiple prospective controlled observational

studies on the use of topical tretinoin products during pregnancy have not identified an association with topical tretinoin and major birth defects or miscarriage. The available studies have methodologic limitations, including small sample size and in some cases, lack of physical exam by an expert in birth defects. There are published case reports of infants exposed to topical tretinoin during the first trimester that describe major birth defects similar to those seen in infants exposed to oral retinoids; however, no pattern of malformations has been identified and no causal association has been established in these cases. The significance of these spontaneous reports in terms of risk to the fetus is not known.

Animal Data

Tretinoin in a 0.05% gel formulation was topically administered to pregnant rats during organogenesis at doses of 0.1, 0.3 and 1 g/kg/day (0.05, 0.15, 0.5 mg tretinoin/kg/day). Possible tretinoin malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) were observed at maternal doses of 0.5 mg tretinoin/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption). These findings were not observed in control animals. Other maternal and reproductive parameters in tretinoin-treated animals were not different from control. For purposes of comparison of the animal exposure to human exposure, the MRHD is defined as 4 g of ALTRENO applied daily to a 60-kg person.

Other topical tretinoin embryofetal development studies have generated equivocal results. There is evidence for malformations (shortened or kinked tail) after topical administration of tretinoin to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison and assuming 100% absorption). Anomalies (humerus: short 13%, bent 6%, os parietal incompletely ossified 14%) have also been reported when 10 mg/kg/day (approximately 50 times the MRHD based on BSA comparison and assuming 100% absorption) was topically applied to pregnant rats during organogenesis. Supernumerary ribs have been a consistent finding in rat fetuses when pregnant rats were treated topically or orally with retinoids.

Oral administration of tretinoin during organogenesis has been shown to induce malformations in rats, mice, rabbits, hamsters, and nonhuman primates. Fetal malformations were observed when tretinoin was orally administered to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison). In the cynomolgus monkey, fetal malformations were reported when an oral dose of 10 mg/kg/day was administered to pregnant monkeys during organogenesis (approximately 100 times the MRHD based on BSA comparison). No fetal malformations were observed at an oral dose of 5 mg/kg/day (approximately 50 times the MRHD based on BSA comparison). Increased skeletal variations were observed at all doses in this study and dose-related increases in embryo lethality and abortion were reported in this study. Similar results have also been reported in pigtail macaques.

Oral tretinoin has been shown to be fetotoxic in rats when administered at doses 10 times the MRHD based on BSA comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered at doses 4 times the MRHD based on BSA comparison.

Lactation

Risk Summary

There are no data on the presence of tretinoin or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

Pediatric Use

Safety and effectiveness of ALTRENO for the topical treatment of acne vulgaris have been established in pediatric patients age 9 years to less than 17 years based on evidence from two multicenter, randomized, double-blind, parallel-group, vehicle-controlled, 12-week trials and an open-label pharmacokinetic study. A total of 318 pediatric subjects aged 9 to less than 17 years received ALTRENO in the clinical studies [see *Clinical Pharmacology* and *Clinical Studies* in full Prescribing Information].

The safety and effectiveness of ALTRENO in pediatric patients below the age of 9 years have not been established.

Geriatric Use

Clinical trials of ALTRENO did not include any subjects age 65 years and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year dermal mouse carcinogenicity study was conducted with topical administration of 0.005%, 0.025% and 0.05% of a tretinoin gel formulation. Although no drug-related tumors were observed in surviving animals, the irritating nature of the drug product precluded daily dosing, confounding data interpretation and reducing the biological significance of these results.

Studies in hairless albino mice with a different formulation suggest that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect was confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

The genotoxic potential of tretinoin was evaluated in an in vitro bacterial reversion test, an in vitro chromosomal aberration assay in human lymphocytes and an in vivo rat micronucleus assay. All tests were negative.

In dermal fertility studies of another tretinoin formulation in rats, slight (not statistically significant) decreases in sperm count and motility were seen at 0.5 mg/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption), and slight (not statistically significant) increases in the number and percent of nonviable embryos in females treated with 0.25 mg/kg/day and above (approximately the MRHD based on BSA comparison and assuming 100% absorption) were observed.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Manufactured for:
Dow Pharmaceutical Sciences, a division of
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

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

U.S. Patent Number: 6,517,847

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SOCIETY OF DERMATOLOGY PHYSICIAN ASSISTANTS
SDPA
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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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GOING GREEN: Since its inception, the JDPA has utilized eco-friendly printing practices. The JDPA is printed on paper obtained from sustainable forests that meet strict environmental standards. Soy-based inks that have a low environmental impact are used during printing of the journal and the journal is printed using 100% renewable energy. SDPA members may join us in our efforts and opt to receive the JDPA in digital format.

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Managing Editor Jennifer M. Hayden, M.Ed
Copy Editor Douglas Morris
Art Director Angela Simiele
Website Design Terry Scanlon

SALES OFFICE

Physician Assistant Communications, LLC
P.O. Box 416, Manlius NY 13104-0416
Phone (315) 663-4147
PAC@pacommunications.org
www.pacommunications.org

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A United Front

As my children are growing up, I am realizing the importance of having a united front at home. I have learned how important it is to think before I speak, and to choose my words ever so wisely. Sure, when we were married we became a "we" couple, but the "we" partnership of parenthood has shed new meaning to the phrases, "There is no "I" in team," and "There is strength in numbers." Over time, we have recognized the importance and need for the united front of "we" parents.

As an SDPA volunteer through the past several years, the various committees and boards I have worked with have always functioned as "we" organizations. The recognition of what "we" can do as a Society together has been awe-inspiring. "We" have worked together to change our very profession and have helped to shape the role of dermatology PAs for the better. If you pay attention to the language that the SDPA BOD deliberately chooses to use, you will see the use of "we" more often than not. The BOD acknowledges, recognizes, and appreciates the importance of how much "we" can accomplish when "we" stand united and work together.

The use of this very deliberate language can be applied in our clinical settings as well. When we use the inclusive language of "we" when referring to ourselves and our supervising physicians and they in turn do the same when referring to their entire healthcare team (including both the clinical staff and front office staff), our patients are reminded of what great care they are under when they have the united team of "we" caring for them. "We" are all stronger and capable of accomplishing more when utilizing combined and focused attention, and working as one united front.

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

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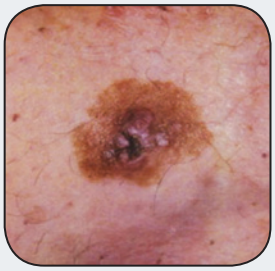

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We look forward to seeing you in Atlanta!

CALENDAR OF EVENTS

2019

JUNE
SDPA Summer Dermatology Conference
June 5 - 9, 2019
Marriott Marquis
Washington, DC

JULY
AAD Summer Meeting
July 25 - 28, 2019
New York, NY

NOVEMBER
SDPA 17th Annual Fall Dermatology Conference
November 21 - 24, 2019
The Westin Kierland Resort & Spa
Scottsdale, AZ

2020

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

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FROM THE SDPA
NEWS & CURRENT AFFAIRS

Dear Colleagues,

It seems like just yesterday that the Society of Dermatology PAs celebrated its 20th year anniversary. This year marks a quarter of a century since founding member, Joe Monroe, stood outside an American Academy of Dermatology Conference with a sign reading, "Are you a PA?". The first meeting had less than 25 dermatology PAs identified in the country. Currently our two conferences each average approximately 600 PA attendees. The SDPA is now the largest specialty organization in the nation.

The SDPA continues to exhibit a booth each year at the American Academy of Dermatology. The March 2019 AAD meeting in Washington, D.C. was no different. Your SDPA leaders sat with members of the AAD Board of Directors to discuss areas that we can work together towards our mutual goals for the profession, patient access, and quality dermatology patient care.

I hope you will be in attendance at the SDPA Annual Summer Dermatology Conference June 6-9, 2019, including the pre-conference day on June 5th. The SDPA's celebration of our 25th year anniversary begins at the SDPA Annual Summer Dermatology Conference on Thursday, June 6th, 2019 at the "Red, White and You!" welcome event at the Sequoia Restaurant, overlooking the beautiful Potomac River in Georgetown.

A few of your SDPA leaders recently attended the AAPA's Leadership and Advocacy Summit in Alexandria, VA. The event kicked off by advocating with legislators on Capitol Hill regarding the critical issues affecting our PA profession. The remainder of the summit included sessions that addressed issues facing the PA profession, best practices for constituent organization leaders, and also advocacy skill-building.

Preceding the conference on Wednesday, June 5th, 2019 the SDPA, in partnership with the AAPA, will host SDPA's Capitol Hill Day. We welcome all PAs from across the country to participate in face-to-face meetings with members of Congress and staff on the key legislative issues that affect our profession and patients. Both novice and seasoned advocates will benefit from and enjoy the SDPA Capitol Hill Day. Don't forget to register.

The philanthropic arm of the SDPA, The Dermatology PA Foundation (DPAF) is now in its 4th year and continuing to grow their outreach in philanthropy, education and research. They are proud to have received a $250,000 research grant from Sun Pharma, which is being used to fund PA-led research into skin disease and PA impact on care in dermatology. Applications are currently open for research grants, so please reach out to the DPAF if you are interested or would like to apply! The DPAF is also gearing up for their 4th annual silent auction to benefit Camp Wonder, and they also sponsor travel for PA volunteers. The auction will open online May 20, 2019 and close June 8, 2019. Items will be available for viewing onsite at the SDPA Summer Conference, as well as online through the Bidding for Good website and app for those not attending. This is a great opportunity to contribute to the DPAF and support patient advocacy, research, and scholarships.

The DPAF and the SDPA are proud to open nominations for awards to recognize exceptional contributions to the dermatology PA profession. These awards will be presented during the SDPA 25th Anniversary Gala. Award categories include: Dermatology PA of the Year, Philanthropic Dermatology PA of the Year, Dermatology Research PA of the Year, and Dermatology PA Educator of the Year.

I am grateful for the PA leaders who have taken the time to pave the way for our profession. There are still some challenges for PAs in dermatology. Our progress ensues because of these PAs who are willing to take action and advocate for change and growth.

We thank those members who took the time to vote in the SDPA 2019 leadership elections. I hope to see your name on a future ballot during leadership elections. In the meantime, there are many areas to serve in your Society. We welcome you and your talents. Let us know where we can plug you in.

Sincerely,

Joleen M. Volz

Joleen M. Volz, MPAS, PA-C, DFAAPA
SDPA President and Diplomate

Dermatology Market Watch

Almirall Announces the Launch of Seysara™

Almirall, LLC recently announced the launch of Seysara™ (sarecycline), a novel tetracycline-derived oral antibiotic developed specifically for the treatment of acne. Seysara™ was approved in October 2018 by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe non-nodular inflammatory acne vulgaris in patients 9 years of age and older, and is now commercially available.

In the two identical Phase 3 clinical trials (SC1401 and SC1402), a significant number of patients receiving once-daily Seysara™ experienced improvement of their acne severity at 12 weeks versus placebo based on the Investigator's Global Assessment (IGA) (21.9% vs 10.1% SC1401; 22.6% vs 15.3% SC1402). Seysara™ also led to a reduction in the number of inflammatory acne lesions at 12 weeks (51.8% vs 35.1% SC1401; 49.9% vs 35.4% SC1402), with significant results seen as early as week 3 (29.6% vs 22.4% SC1401; 28% vs 18.6% S1402).

In clinical trials, treatment with Seysara™ was found to be generally safe and well-tolerated, with low rates of treatment-emergent adverse events (TEAEs) reported in the Seysara™ safety study which followed subjects up to 52 weeks. Patients receiving Seysara™ reported no cases of vertigo or tinnitus and fewer cases of dizziness than seen in the placebo group. Less than one percent of patients experienced photosensitivity or sunburn, and rates of GI issues were relatively low. The most common adverse reaction (incidence ≥ 1%) was nausea. For more information on the Almirall product portfolio please visit www.almirall.us.





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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 35 year-old Type I diabetic presents to the emergency department with a two-day history of vomiting and diarrhea. The diarrhea is watery and without blood, he denies any abdominal pain. He has maintained his usual intake and insulin schedule, but does not monitor his glucose at home. According to the family he is getting confused, but his major concern is that he is still very thirsty. Physical examination reveals temperature 37.5°C (oral), blood pressure 110/68mm Hg, pulse 100/minute and regular, and respirations 20/minute. The patient's lungs are clear, heart regular rate and rhythm, and abdomen is soft and non-tender with normal bowel sounds. Laboratory testing reveals a random serum glucose of 470mg/dl, sodium 132mEq/L, potassium 5.0mEq/L, chloride 98mEq/L, bicarbonate 22mEq/L, and urinalysis reveals specific gravity 1.019, 4+ glucose, trace protein and negative ketones. Which of the following is the most likely diagnosis?

A. Septic shock
B. Diabetic ketoacidosis
C. Severe hyperglycemia
D. Shigella gastroenteritis
E. Hyperosmolar hyperglycemic state

EXPLANATION: Severe hyperglycemia is an elevation in blood glucose without the typically findings noted in diabetic ketoacidosis (DKA). Diabetic ketoacidosis presents with abdominal pain, elevated blood glucose, elevated anion gap metabolic acidosis and the presence of ketones in the blood or urine. This patient only has an elevated glucose level without the other findings consistent with DKA. Septic shock is defined as sepsis that has circulatory, cellular, and metabolic abnormalities that are associated with increased mortality; patients are hypotensive despite fluid resuscitation and have an elevated lactate level. Shigella gastroenteritis presents with high fever, abdominal cramps, and bloody, mucoid diarrhea. Hyperosmolar hyperglycemia state presents in type II diabetes with markedly elevated blood glucose levels and no ketoacidosis: focal neurologic signs may be noted.

The correct answer is C.

James A. Van Rhee, MS, PA-C, *is the Program Director for the Yale University School of Medicine Physician Assistant 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) and is the author of the Physician Assistant: Certification and Re-certification Review Book, published by Elsevier. For the last fifteen years he has been course director and presenter of the Physician Assistant Board Review, which is now being produced live online by Kaplan Medical.*

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
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BECOME A MEMBER

Lymph Node Involvement by Lentigo Maligna Melanoma; *A Retrospective Chart Review*

By, Hillary Finch, CCRP, Tera Purkey, MPH, Glen Bowen, MD, and Mark Hyde, PhD, PA-C

INTRODUCTION

The use of sentinel lymph node (SLN) biopsy in melanoma is currently recommended by the American Joint Commission on Cancer (AJCC) and National Cancer Care Network (NCCN) in certain circumstances. Despite this fact, the relationship between SLN involvement and lentigo maligna melanoma (LMM) has not been extensively researched and existing publications on lymph node involvement by LMM are scarce. There is a need for more information on this relationship, as lymph node involvement is the most important indicator of prognosis and metastasis.[1,2]

Lentigo maligna (LM) is a melanoma in situ (MIS) that occurs on chronically sun-damaged skin. A diagnosis of MIS indicates that the melanoma is contained to the epidermis, but LM indicates that atypical melanocytes are present in the basal layer of the epidermis. While MIS has no direct mortality, this proximity to the vascular layer of the dermis suggests LM is susceptible to invasion and metastasis. Other subtypes of melanoma have been shown to experience growth in two stages: an initial horizontal growth phase, and a second vertical growth phase.[3] During the vertical growth phase, atypical cellular reproduction penetrates into the dermis.[3] At the point that it invades the dermis, LM becomes LMM. As an invasive melanoma of the skin is often aggressive, any advance in prognostication ability is beneficial.

Similar to LM, LMM has been shown to have an increased prevalence on chronically sun exposed skin (i.e. the head and neck region) compared to other cancers.[4] While some research indicates that metastasis to distant lymph nodes is slower in LMM compared to other types of melanomas,[2] LMM metastasis to the SLN has not been extensively researched. The intricate arrangement of cranial nerves in the head and neck area most commonly affected by LMM is a possible explanation for this lack of data.[1] However, LMM is not limited to the head and neck region and SLN biopsy can be successful at other sites, including the extremities and torso. Overall, lymph node involvement in melanomas has been shown to be a strong predictor of overall survival.[1,5] The NCCN recommends sentinel lymph node biopsy in melanoma in the following situations:

» CME

This program has been reviewed and is approved for a maximum of .5 hours of AAPA Category I CME credit by the Physician Assistant Review Panel.

Approval is valid for 1 year from the issue date of April 2018. Participants may submit the self-assessment exam at any time during that period.

This program was planned in accordance with AAPA's CME Standards for Enduring Material Programs and for Commercial Support of Enduring Material Programs.

SDPA members may access the posttest at www.jdpa.org

Learning Objectives:

- *Understand the pathophysiology of lentigo maligna (a type of melanoma in situ on chronically sun exposed skin) and lentigo maligna melanoma*
- *Compare sentinel lymph node involvement rates between lentigo maligna melanoma and other subtypes of melanoma*
- *Consider team based approaches to managing lentigo maligna melanoma when sentinel lymph node biopsy is indicated*

- Tumor depth of 1 mm or greater
- Ulceration
- Mitotic count of 1/mm^2 or greater

Additional situations when sentinel lymph node biopsy should be discussed or considered include:

- Tumor depth >0.75 mm
- Regression
- Angiolymphative invasion

Additional consideration may be given to age, immune status, and clinical course when discussing lymph node biopsy.

This study aims to establish the relationship between lymph node involvement and LMM as well as evaluate the LMM tumor features that may predict nodal involvement. These features, including Breslow depth, mitotic count, ulceration, site, margin involvement, gender, and age, have been studied previously in site-specific melanomas,[1] but no prevailing feature stood out as the primary indicator of nodal involvement.

METHODS

To establish the relationship between lymph node involvement and LMM, we performed a retrospective chart review from 271 LMM tumors with concurrent lymph node biopsy. The evaluated features included Breslow depth, mitotic count, ulceration, site, margin involvement, gender and age, which may predict lymph node involvement. The data included 70 tumors on female patients (25.8%) and 201 tumors on male patients (74.2%). The features were analyzed and conclusions were made based upon these factors in correlation with the lymph node involvement. We used two forms of a multivariate logistic regression model to determine significant indicators of lymph node involvement.

RESULTS

Of the examined data including both male and female patients, the average age was 66 and age did not significantly differ from those with nodal involvement compared to those without nodal involvement. More of the tumors were left sided (n=133, 49.1%) followed by right sided (n+109, 40.2%) and midline (n=29, 10.7%). The most prevelant location of the tumor was 116 (42.8%) facial tumors, followed by 93 (34.3%) tumors on torso and extremities, and 62 (22.9%) tumors on the scalp. Of the examined cases, the average Breslow depth was 1.36 mm (range 0.14-13) and 37 (14.1%) were reported to have ulceration. The average mitotic count was 2/mm^2 (range 0-25) but was missing in 32 (11.8%) cases. Invasive tumor involved the deep margin in 83 (35.6%) cases.

There were 18 (6.6%) cases with nodal involvement. The average Breslow depth in cases with nodal involvement was 2.8mm, which differed from the average in cases without nodal involvement (1.3mm, p<0.001). Following the multivariate logistic regression analysis, each mm increase in Breslow depth increased the odds of nodal involvement by 1.59 times (P=0.005, 95%CI 1.15-2.20) when adjusted for gender, age, ulceration, mitotic count, body site and deep margin involvement. It was determined that males were 4.66 (p=.032, 95%CI 1.14-18.95) times more likely to have nodal involvement compared to females. No other factors were significantly predictive of nodal involvement *(See Table 1)*.

Table 1: Potential Predictors of Lymph Node Involvment by Lentigo Meligna Melanoma

	Odds Ratio (95%CI)	P	95%CI	
Breslow Depth (per mm)	1.59 (1.15, 2.20)	0.005	1.15	2.20
Male	4.66 (1.14, 18.95)	0.032	1.14	18.95
Age	1.00 (0.95, 1.06)	0.955	0.95	1.06
Ulceration	0.59 (0.10, 3.45)	0.557	0.10	3.45
Mitotic count per mm^2	1.24 (0.26, 6.06)	0.787	0.26	6.06
Deep margin involvement	1.41 (0.35, 5.69)	0.622	0.35	5.69

In a second multivariate logistic regression model controlling for the same covariates, the odds of nodal involvement when the Breslow depth was greater than 0.75mm was 4.8 times great than when the depth was less than 0.75mm. This model did not achieve significance (p=.09).

DISCUSSION

Though this study includes a large cohort of

LMM cases concurrent with nodal biopsy, it is still limited by the number of positive nodes, its retrospective nature and inconsistencies in reporting of mitotic rate. This review had a nodal involvement rate of about 7%, which seemed to be best predicted by Breslow depth. Using the cutoff of 0.75mm did not significantly predict nodal involvement. Still, based on these data, Breslow depth remains the most accurate predictor of nodal involvement in LMM. The fact that LMM commonly occurs in cosmetically sensitive and functionally critical locations, it is difficult to balance aggressive surgical treatment and resulting with the potential morbidity.

In our experience, when an LMM is advanced enough to recommend a sentinel lymph node biopsy, a team-based approach may be best. In previous publications 9 mm margins are recommended for LM.[6,7] When invasion is present (LM becomes LMM) at least 1cm margins have been recommended by the NCCN. Anecdotally, there may be some discord between the recommendations and practices of general/oncologic surgery and dermatologic surgery. Our data suggests that lymph node involvement by LMM is similar to other melanomas. As such, finding a middle ground where dermatologic surgeons and general/oncologic surgeons partner to reduce margins, maintain robust pathologic margin evaluation, and offer sentinel lymph nodes can offer the best of both worlds.

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This study was exempted by the IRB at the University of Utah.

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Hillary Finch, CCRP, *earned her bachelor degrees from the University of Utah in Health Promotion and Education and International Studies, and is a Certified Clinical Research Professional. She has indicated no relationships to disclose relating to the content of this article.*

Tera Purkey, MPH, *has a bachelor's degree from Utah State University and an MPH from Westminster College. She has indicated no relationships to disclose relating to the content of this article.*

Glen Bowen, MD, *is the clinical director of the Multidisciplinary Cutaneous Oncology Program for the Huntsman Cancer Institute at the University of Utah. He is board certified in dermatology and fellowship trained in Mohs Micrographic Surgery. He has indicated no relationships to disclose relating to the content of this article.*

Mark Hyde, PhD, PA-C, *is a graduate of Midwestern University PA program in Glendale, Arizona and earned a doctorate in Public Health from the University of Utah. He has indicated no relationships to disclose relating to the content of this article..*

From The Patient's Perspective

An Interview With Aspire Scholarship Recipient, Niki Vora

Ortho Dermatologics offers the Aspire Higher scholarship program for students who have been affected by dermatologic conditions. Through the program, nine students per year receive a scholarship of $10,000. Since 2013, the Aspire Higher scholarship program has awarded 23 scholarships, which has given students a total of $230,000 toward their higher education on campuses nationwide. The Aspire Higher Scholarship program was funded through the Bausch Foundation, which was established in 2017 to improve the lives of patients globally by providing access to safe, effective medicines and by financially supporting health care education and causes around the world.

"Pursuing higher education is an extraordinary milestone in people's lives and at Ortho Dermatologics, we understand that the journey for those living with a dermatologic condition can come with additional personal challenges," said Bill Humphries, executive vice president and group company chairman, Ortho Dermatologics. "For that reason, we are proud to continue the Aspire Higher scholarship program and honor outstanding students who have managed the difficulties of living with a skin condition while focusing on achieving their educational goals."

The JDPA recently interviewed Niki Vora, one of the 2018 Graduate Scholar scholarship recipients about her experience. Niki is currently attending UC Berkeley, studying in the UCSF Joint Medical Program. According to Niki, "This scholarship is incredibly meaningful for me; not only does it generously aid in my educational pursuits, it values the experiences I had as an adolescent with skin conditions which have irrevocably shaped me into who I am today."

JDPA: ***How did you learn about the Aspire scholarship program? Did anyone encourage you to pursue the scholarship?***

Ms. Vora: My dermatologist, Dr. Lemus. She was very encouraging, and thought my story and my interests were in line with the Aspire scholarship.

JDPA: ***What motivated you to apply for the program?***

An Aspire Higher scholarship is available for applicants or current attendees of a two- or four-year college, university or advanced (post-high school) vocational or technical school who have been treated for a dermatologic condition. Scholarships will be awarded to a range of students, with three scholarships available in each of the following categories:

- ***Undergraduate Scholar Awards*** for those pursuing undergraduate degrees
- ***Graduate Scholar Awards*** for those pursuing graduate degrees
- ***Today's Woman Scholar Awards*** for mothers pursuing undergraduate or graduate degrees

To learn more about the scholarship, including eligibility criteria, terms and conditions, and see stories from previous winners, please visit AspireHigherScholarships.com.

Ms. Vora: I applied to the program because I wanted to feel comfortable talking about how atopic dermatitis was a large part of my motivation in pursuing medicine, and has fostered my interest in dermatology as a whole.

JDPA: ***You mention that the scholarship is extremely meaningful to you because it values the experiences you had as an adolescent with skin conditions, which have shaped you into who you are today. Can you please elaborate? What kind of experiences and how did they shape you into who you are today?***

Ms. Vora: As an adolescent with atopic dermatitis, as well as cystic acne and hyperpigmentation, I was often ostracized and bullied for the way I looked. The social and psychological impacts from having a skin disease is different than those we experience with other organ systems; you feel vulnerable and raw because dermatologic conditions are so visible and tangible. My experiences with skin disease growing up resulted in an incredibly low self-esteem that permeated into every aspect of my life. I was uncomfortable having any attention or eyes on me, staying as quiet as I could to just blend in.

It took me years after my skin conditions were under control to gain confidence in myself. Looking back, my experiences growing up with skin disease are one of the main motivating factors for my decision to pursue medicine. At the same time, those experiences taught me to be more empathetic and in the future will make me a more thoughtful physician.

JDPA: ***What degree/program are you pursuing?***

Ms. Vora: I decided to pursue a Masters of Science (MS) and Medical Degree (MD) because I am interested in academic medicine. I recently completed my MS and am now focusing full time on completing my MD degree.

JDPA: ***What are your future goals and/or career aspirations?***

Ms. Vora: My future goal is to become a dermatologist. I really love pediatric and in-patient dermatology in particular.

JDPA: ***Any advice for students considering applying for the scholarship?***

Ms. Vora: Continue applying even if you don't get it the first time!

Niki Vora is currently attending UC Berkeley, studying in the UCSF Joint Medical Program. She recently completed her MS and is focusing full time on completing her MD. She is interested in academic medicine.

Odontogenic Abscess

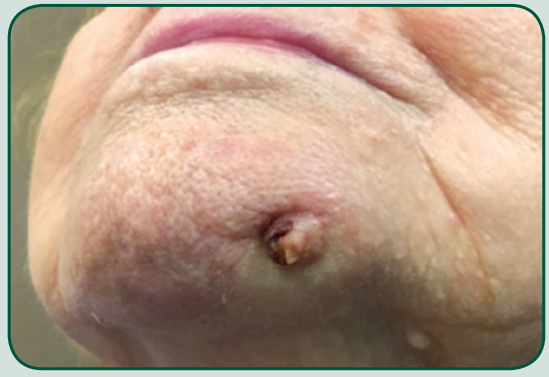
By Archana M. Sangha MMS, PA-C Diplomate
SDPA Secretary/Treasurer

An 89 year-old Caucasian female presented for evaluation of a lesion to her left lower chin. She reports the lesion *(see figure)* had been present for a few months and recently began growing in size two weeks ago. She reported some weeping of lesion but no pain. She denied any mouth or tooth pain. A shave biopsy was performed revealing acute, chronic and granulomatous inflammation. More specifically, there was diffuse dermal infiltrate of lymphocytes, neutrophils, and foamy histiocytes. Brown and Brenn and PASF studies were negative for bacteria or fungal hyphae. These findings were consistent with an odontogenic cutaneous sinus tract (OCST).

Discussion and Treatment

OCSTs are uncommon and often misdiagnosed. They are often caused by periapical infections around root apices as a result of pulpal necrosis, nearby caries, pericoronitis, or traumatic injury. Extraoral sinus tracts usually appear on the mandibular angles, chin, and cheeks. They typically present as an erythematous, non-tender nodule with periodic drainage. Interestingly, patients often deny dental symptoms. This is because the sinus tract provides a route for drainage from the primary odontogenic site. Differential diagnoses include: Squamous cell carcinoma, pyogenic granuloma, foreign body reaction, deep fungal infection, abscess, and sebaceous cyst. Treatment involves eradication of the cause of infection and an immediate referral to a dentist for root canal therapy or tooth extraction. In the case discussed above, the diagnosis was suspected and the patient was immediately started on amoxicillin/clavulanate 875mg/125mg twice daily for ten days. She was also referred to a dentist for next day appointment.

Figure



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Archana Sangha, MMS, PA-C *has been in SDPA leadership since 2012. She received her undergraduate degree in biology from Towson University and went on to earn her Masters in Medical Science and Physician Assistant Studies from Salus University. Prior to being elected as SDPA Secretary/Treasurer, she served as Director at Large and Membership Committee Co-Chair. She enjoys practicing medical, surgical, and cosmetic dermatology in Maryland and Northern Virginia. She has a passion for medical missions and philanthropic work. In her free time, Archana enjoys reading, hiking and traveling.*

IN MODERATE-TO-SEVERE PLAQUE PSORIASIS

DEFY THE LAWS OF PSORIASIS

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)*

RESULTS THROUGH WEEK 64[1]

Based on PASI 75 responders at Week 28 (reSURFACE 1)

- 84% maintained PASI 75*
  - vs 22% placebo

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

64 WEEKS

*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.

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]

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.

ILUMYA™
tildrakizumab-asmn
Injection 100 mg/mL

VISIT ILUMYAPRO.COM

IMPORTANT SAFETY INFORMATION *(cont'd)*

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 brief summary of Full Prescribing Information on next page or visit 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

Fire Safety in Mohs Micrographic Surgery

Dermatologic Surgery. 2019 Mar; 45(3):390-397

Li, JY[1] and Kampp, JT[1]

1. Division of Dermatology, Department of Medicine, University of Washington School of Medicine, Seattle, Washington

Background

Surgical fire is a rare event, but one with potentially devastating patient outcomes.

Patients and Methods

This study was conducted to investigate the incidence, risk factors, and outcome of surgical fires experienced by members of the American College of Mohs Surgeons (ACMS).

Methods

An internet survey was developed and sent to ACMS members. Data collected included total years of experience, total number of cases, typical management of supplemental oxygen, and surgical fires experienced.

Conclusion

Eighty participants contributed data on 886,200 cases of MMS. Nine surgeons (11%) reported at least 1 surgical fire, yielding an estimated incidence of 1 fire per 88,620 cases (0.001%). The most common site of involvement was the scalp (67%). Common ignition sources included monopolar electrosurgical devices (78%) and battery-powered thermal cautery (22%). Fuel sources included towels or drapes, gauze, isopropyl alcohol, aluminum chloride, hairspray, and diethyl ether. Supplemental oxygen was not involved in any of the cases. Five patients suffered singed hair while 4 patients did not suffer any injuries. None suffered any permanent functional or aesthetic deformities.

From MEDLINE®/PubMed®, a database of the U.S. National Library of Medicine. PreMedline Identifier: 30234652.

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.

SURGICAL wisdom

Dermcast.tv Blog -
What Are the Trends In Dermatologic Procedures Performed By Advanced Practice Professionals?

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

Advanced practiced professionals (APPs), such as nurse practitioners (NPs) and physician assistants (PAs) are increasingly billing for procedures performed independent of a supervising physician. Of these procedures, more than half of them are dermatologic.

A recent study looked how the scope and number of dermatologic procedures performed by APPs evolved over a three-year period in the Medicare population. The authors used the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File from 2012 through 2015 to analyze procedures of interest performed in that time period. They looked at biopsies, removals, destructions, repairs, local skin flaps, full-thickness grafts, and patch testing, and calculated the frequencies and percentages billed by APPs (NP, PA, or clinical nurse specialist) and dermatologists for each procedure within the time period.

The results showed that the total frequencies of all examined dermatologic procedures billed by APPs increased significantly each year from 2012 to 2015. APPs most commonly billed destructions of benign neoplasms, biopsies and shaves, and destructions of malignant neoplasms. For each year studied, the number of procedures billed by APPs increased significantly, and at a significantly higher rate than procedures billed by dermatologists, except for simple repairs and full-thickness skin grafts. At the same time, dermatologists' billing rates for the same procedures remained basically stable, except for complex repairs.

The authors note that an increase in the number of APPs appears to be the biggest driving force for increased procedures, which is consistent with the general trend of an increasing number of APPs being employed in dermatology practices. The authors highlight some concerns about the need for appropriate training, credentialing, and oversight as more procedures are performed by APPs, but they also note that transferring such responsibilities to APPs may also reduce wait times and time to diagnosis. The authors state that more research is needed to compare outcomes and safety between specialists, non-specialists, and APPs, in order to weigh the benefits and risks of this trend.

Dermcast.tv Blog Post: October 19, 2018
Source: JAMA Network
Adapted from the original article

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- Statistically significant (65%) improvement of symptoms at day 4 (versus placebo 31% P<0.001)[4]
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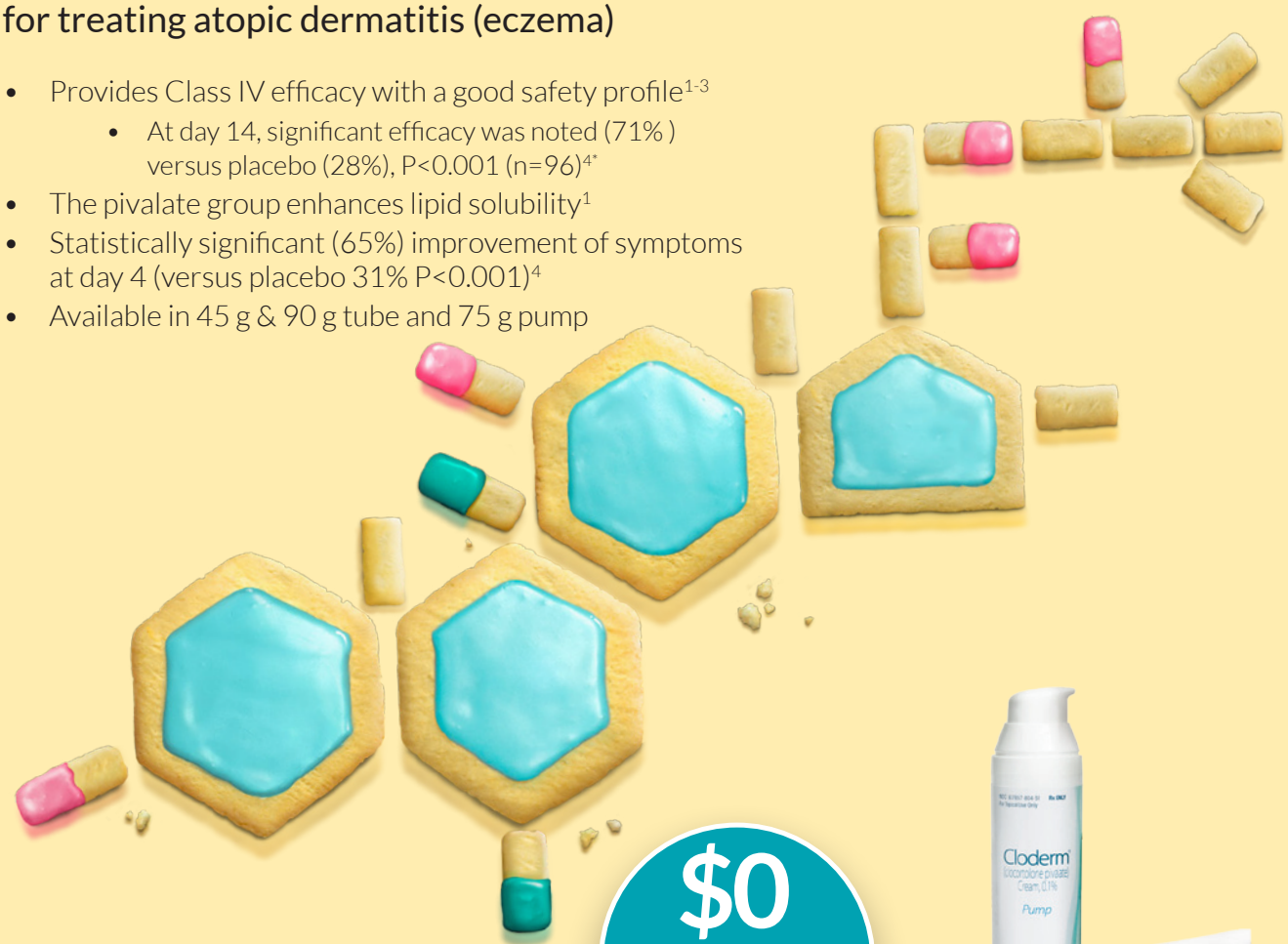

Brief Summary of Package Insert

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EPIHEALTH
Advancing Dermatology

Research Demonstrates Potential of Platelet-Rich Plasma Therapy For Hair Loss

Tens of millions of people in the U.S. experience hair loss, which can have a significant impact on patients' quality of life. There is more hope on the horizon, however, as a growing amount of research indicates that a procedure known as platelet-rich plasma (PRP) therapy can provide effective treatment.[1-4]

"A general body of evidence has recently emerged demonstrating a positive response from PRP treatments," says Jeffrey Rapaport, MD, FAAD, a board-certified dermatologist in private practice in New Jersey. "With consensus forming around treatment protocols, studies are indicating that PRP is a safe, effective hair loss treatment that has the potential to greatly improve the quality of life of millions of people."

PRP therapy originated in Europe more than a decade ago and has been utilized in a variety of medical areas, including orthopedics and dentistry. The procedure involves placing blood drawn from the patient into a special machine that separates red blood cells from plasma, which is rich in platelets that contain growth factors.

In hair loss therapy, the plasma is directly injected into the patient's hair follicles in a process that takes no more than ten minutes, according to Dr. Rapaport. Since the procedure involves only minimal discomfort, he says, patients typically do not require any numbing or downtime following therapy.

After the initial treatment, injections are repeated once a month for the next three months, and then once every three to six months after that. Within the first few months of treatment, patients may notice they are losing less or minimal amounts of hair, Dr. Rapaport says, and soon after, they may begin to see an increase in thickness or eventual regrowth.

While not everyone is a candidate for PRP therapy, Dr. Rapaport says that it has been found to have high success and satisfaction rates in certain hair loss patients, including those with hereditary hair thinning or baldness. He recommends that those considering the procedure consult with a board-certified dermatologist to determine if it's the right option for them, adding that PRP may be used in conjunction with other treatments to give patients the best possible results.

"Since PRP therapy has taken off, there have been a lot of non-dermatologists performing this procedure," Dr. Rapaport says. "Only board-certified dermatologists have the medical training to identify if you are a good candidate, because this treatment will not work for everyone who experiences hair loss. Talk to a board-certified dermatologist to determine which hair loss treatment option is best for you."

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Jeffrey A. Rapaport, MD, PA

Certified by the American Board of Dermatology, Dr. Rapaport is a Phi Beta Kappa recipient from Emory University and a graduate of the Emory University School of Medicine in Atlanta, Georgia. After internship at Emory, he completed his advanced training residency at Thomas Jefferson University, where he served as chief dermatology resident.

A Fellow of the American Academy of Dermatology and of the American Society for Dermatologic Surgery, Dr. Rapaport has consistently been a leader in Aesthetic Surgery. Well-respected by his peers, he often presents seminars on subjects ranging from dermatology to cosmetic surgery. Dr. Rapaport is the holder of three U.S. patents for dermatologic products, and he has been selected as a Top Doctor in the New York Metro Area by Castle Connolly for 8 years. He is currently Emeritus Chief of Dermatology at Holy Name Hospital in Teaneck, New Jersey.

The Medical Director and Founder of the Cosmetic Skin and Surgery Center, Dr. Rapaport has been a practicing dermatologist since 1981. Countless patients have benefited from his talent, experience, dedication, and high standards of excellence.

Dr. Rapaport's papers and book chapters appears in various journals and textbooks.

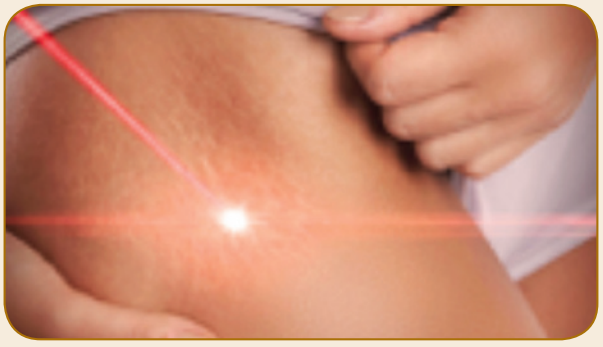
Dermcast.tv Blog

Does Fractional Laser Treatment Improve Stretch Marks?

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

Striae distensae (SD), also known as stretch marks, is a condition that is both distressing to patients and difficult to effectively treat. The currently available treatments are not reliably effective and there is no standard treatment that has been established.

A recent study notes that some laser treatments have shown promise and small clinical improvements in patients. Intense pulsed light (IPL), increases dermal collagen level and leads to skin tightening, while 585nm pulsed dye laser (PDL) can reduce vascularity, which has limited benefit in the treatment of SD albae. Thus far, for mature SD, fractional non-ablative lasers delivered the most consistent results.



In a small single –center clinical trial, authors attempted to further the data by reassessing the safety and effectiveness of fractional, non-ablative 1565nm laser therapy on SD using new objective and subjective assessment tools. The participants were treated three times with a fractional, non-ablative laser in 4-week intervals and clinical outcome was evaluated at baseline, 1-month, and 6-months. Participants also completed subjective questionnaires and objective assessment was done via digital photography and three-dimensional analysis employing PRIMOS! and VECTRA!

The results showed that overall, the use of fractional, non-ablative 1565nm Er: glass laser treatment was an effective and safe treatment of SD. The objective measures showed that skin relief improved significantly throughout the study, the SD lesions improved, and the adjacent skin became more homogenous and appearance was smoothed out. The most significant change was observed between the baseline and 1-month follow-up, and improvement remained at 6-month follow-up. Patients also reported significant changes in life quality.

The authors note that despite the effectiveness of this treatment, in most cases, the SD will remain visible as streaky lesions, and patients' expectations should be managed before therapy.

Dermcast.tv Blog Post: February 18, 2019
Source: Wiley Online Library
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.

NOTES from your Office Manager

Managing Patient Noncompliance

THE RISK:

Patient noncompliance is one of the most difficult challenges for healthcare providers. Noncompliance may include missed appointments and the failure to follow a plan of care, take medications as prescribed, or obtain recommended tests or consultations. The reasons given by patients for non- compliance vary from the denial that there is a health problem to the cost of treatment, the fear of the procedure or diagnosis, or not understanding the need for care. Physicians and other healthcare providers need to identify the reasons for noncompliance and document their efforts to resolve the underlying issues. Documentation of noncompliance helps to protect providers in the event of an untoward outcome and allegations of negligence in treating the patient.

RECOMMENDATIONS:

1. Establish an office policy to notify providers promptly of all missed and canceled appointments. We recommend that this be done on a daily basis.
2. Formalize a process for follow up with patients who have missed or cancelled appointments, tests, or procedures. This process should include recognition of the nature and severity of the patient's clinical condition to determine how vigorous follow up should be.
   a. Consider having the physician or healthcare provider make a telephone call to the patient as a first step when the patient's condition is serious.
   b. If the patient's clinical condition is stable or uncomplicated, staff should call the patient to ascertain the reason for the missed or canceled appointment.
   c. All attempts to contact the patient must be documented in the medical record.
   d. If no response or compliance results, send a letter by certificate of mailing outlining the ramifications of continued noncompliance.
3. During patient visits, emphasize the importance of following the plan of care, taking medications as prescribed, and obtaining tests or consultations.
4. Seek the patient's input when establishing a plan of care and medication regimen. Socioeconomic factors may contribute to the patient's noncompliance.
5. To reinforce patient education, provide simple written instructions regarding the plan of care. Use the teach-back method to confirm that patients understand the information and instructions provided.
6. With the patient's permission, include family members when discussing the plan of care and subsequent patient education in order to reinforce the importance of compliance.
7. When there is continued noncompliance, patient discharge from the practice may be necessary. Please consult your legal team to discuss patient noncompliance and the discharge of a patient.

Outside & Inside the 9 to 5...

Douglas DiRuggiero, PA-C, MHS, DMSc

How the Love of Medical History Led to Being the First and Only PA Named to the Executive Board of the Dermatology Hall of Fame

My dad started collecting stamps and coins when he was a kid and he started me down that path in my early childhood. It was something we enjoyed doing together, attending shows, organizing and cataloging our items, and researching and learning about the people or events depicted in our collection. I guess he's the one who first taught me that historical things have value and should be appreciated. While the seeds were present when I started PA school nearly twenty-five years ago, my specific interest in medical history was truly launched when my grandfather bequeathed to me several medical and pharmaceutical items from his pharmacy career. After receiving a pharmacy degree from Rutgers University in the late 1930's, he entered WWII as an army medic (Battle of the Bulge veteran). He returned from the war and opened his first pharmacy on Maple Avenue in Jersey City, NJ in 1945. He was loved and trusted by the surrounding community for decades. He had a strong sense that I would care for and appreciate several items he had used throughout his career. Hand-painted glass pharmacy bottles, ancient medical dictionaries, and well-used mortar and pestles arrived carefully wrapped in paper--and I was hooked. I knew I could honor him by expanding his collection of medical paraphernalia, using it to enrich my life and medical practice, as well as teach and inspire others.

Douglas DiRuggiero, PA-C, MHS, DMSc

The culmination of my "medical history" pursuits occurred last fall when I researched and delivered a lecture entitled, "Dermatology Greats and the Conditions Which 'Bare' Their Names." After that talk, I was approached and asked to utilize my interests in dermatology history to participate in a newly formed Dermatology Hall of Fame. The Dermatology Hall of Fame was founded to recognize the historical pioneers, revolutionary ideas, and honor the leaders who have distinguished themselves through significant achievements that have advanced the field of dermatology. As an executive board member, I have had a great time working with many living legends of dermatology to develop a list of nominees for the inaugural group to the Hall of Fame. The Board's final nominee list was disseminated to a large cohort of dermatologists across the nation for voting and the following individuals were inducted during a special ceremony at the 2019 AAD conference in Washington, DC:

Marion Sulzberger, MD, Hermann Pinkus, MD, Walter Lever, MD, Naomi Kanof, MD, Albert Kligman, MD, Walter Shelley, MD, Thomas Fitzpatrick, MD, Bernie Ackerman, MD, Stephen Katz, MD, and Charlie Stiefel *(listed in historical order).*

Douglas DiRuggiero, PA-C, MHS, DMSc *works at Skin Cancer & Cosmetic Dermatology in Rome, Georgia. With nearly 20 years of dermatology experience, Douglas enjoys both medical and surgical dermatology, clinical research, publishing, and mentoring. As a nationally-recognized medical lecturer and passionate dermatology teacher, he has been awarded a National Clinical Science Award for published research, Clinical Teacher of the Year by multiple universities, Georgia Humanitarian PA of the year, and was the 2018 recipient of the prestigious Presidential Volunteer Service Lifetime Achievement Award. He completed a doctorate degree in May 2019 and maintains membership in multiple medical societies, notably the American Association for the History of Medicine (AAHM) and the International Society for the History of Medicine (SIHM).*

Douglas has held multiple leadership positions with national dermatology societies, founded the Georgia Dermatology PA Society, and has acted as the President of the New York Society of Dermatology PAs. He was a founding board member of the Dermatology PA Foundation and co-founded a free health care clinic for the homeless in 2005, which continues to serve over 600 patients per month. He has done mission work in Haiti, St. Lucia, Russia, Mexico, and Israel. His wife of 25 years, and their three children, are his most-prized possessions!

Photo - Douglas's grandfather is sitting in first row, far right - in front of a Red Cross Train in Paris, France. Circa 1944

Photos- Part of Douglas's collection of medical bottles and texts

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- If renal impairment exists, MINOLIRA doses may need to be adjusted to avoid accumulations of the drug and possible liver toxicity.
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- Minocycline may cause intracranial hypertension and autoimmune disorders in adults and adolescents. Discontinue MINOLIRA if symptoms occur.
- Minocycline has been associated with anaphylaxis,serious skin reactions, erythema multiforme, and DRESS syndrome. Discontinue MINOLIRA immediately if symptoms occur.
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REFERENCE: **1.** MinoLira Tablets [Package Insert]. Charleston, SC: EPI Health, LLC; 2018.

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Workplace Excellence

Becoming Tough-Minded

Choosing the harder, the better, the more difficult- Part 1 of 2

By Matthew Davidson, PhD

In my work as President of the Institute for Excellence & Ethics (IEE) 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.

When we think about the idea of "toughness," a lot of images may come into our mind: it might be a picture of a body builder pumping some iron, or a fierce collision in sports, or a soldier in battle, or a police officer, a fire fighter, a construction worker. Certainly there's an element of toughness in each of these pictures. But there's toughness that goes beyond the physical, often called mental toughness, and it is, I would argue, the more rare and the more powerful kind of toughness.

When asked about toughness, the famously tough coach Vince Lombardi said, "Mental toughness is many things and rather difficult to explain. Its qualities are sacrifice and self-denial. Also, most importantly, it is combined with a perfectly disciplined will that refuses to give in. It's a state of mind. You could call it character in action." Sacrifice and self-denial, willpower, mindset, character in action - this is the kind of tough-mindedness that is so rare in most every walk of life.

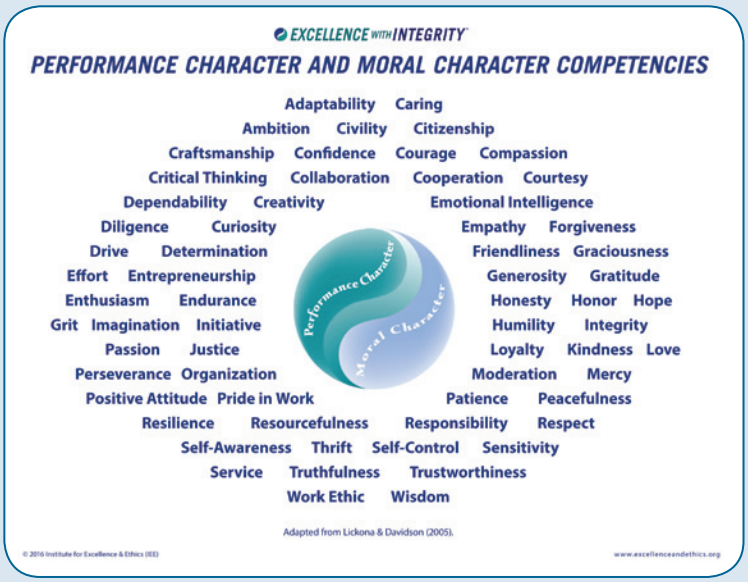
In our work at the IEE we define character as "values in action." We break character into two big components: performance character and moral character. Performance character consists of those values in action, such as effort, self-discipline, and perseverance - that enable us to do our best in any performance environment. Moral character refers to those values that are needed for successful relationships and ethical behavior, such as fairness, honesty, respect, and humility.

So we could argue that mental toughness is character in action. However, it's character in action when the conditions are bad or tough, when putting that character in action is the harder, better, more difficult thing to do, when it requires self-sacrifice and self-discipline, when the short term rewards aren't obvious, and when there are countless reasons to do what would be easier, quicker, or more self-serving. Mental toughness involves sacrifice and selflessness. Becoming tough-minded means choosing to persevere, choosing your attitude, and choosing to continue to give great effort even, and especially, when things aren't coming easy or going well. Kansas basketball coach Bill Self describes the opposite of toughness, saying, "Soft is when you choose the easier path, when the right path is the harder one." Tough then, is obviously choosing the harder, better path even when it isn't the easier one - and it rarely is the easier one.

Toughness: Hard to Develop

Toughness isn't something we inherit: just because your parents or grandparents were tough, doesn't mean you will be. Like all character qualities, you may have some traits of personality and character that naturally predispose you to being tough: you may be naturally self-disciplined or tend to be head strong; but those character qualities are developed through your repeated experiences and your life circumstances. For example, employers and coaches have often observed that they look for

individuals who grew up working on farms or grew up in poverty and difficult life-circumstances. Why? Because these individuals have often developed physical and mental toughness, as they learned to overcome adversity in their circumstances.



In the book *Born To Run,* author Chris McDougall argues that because of where they are located in the brutal terrain of Mexico's Copper Canyons, the Tarahumara Indians have developed the capacity to run hundreds of miles in extreme heat and experience very little signs of stress, injury, or fatigue. So, it's not that they're "born" to run - meaning simply they have a natural gift that makes them better. They may have certain innate abilities passed on genetically. But more importantly, they have become physically and mentally tough by being repeatedly exposed to and by learning to persevere through very tough conditions.

This is the beautiful and difficult truth about toughness: it's often a positive by-product of our negative experiences, our struggles, challenges, disappointments, and past failures. If you think back about what person, experience, or circumstance taught you most about what it means to be tough, isn't it true that at the time they were difficult, challenging, uncomfortable? And, if we are honest with ourselves, we would usually admit that we hated them and that if we could have, we would have gotten out of them!

I think back about some really tough jobs that I had growing up and I think about showing up early, working long hours, pushing through pain and boredom. I can see very clearly how tough I first thought I was, and how quickly my mind gave out - so much sooner than my body. In my mind I would whine and complain and wiggle in search of a way to make it stop. I think about the teachers, coaches, and employers that taught me the most, that I now classify as BOTH my toughest and my favorites! At the time I thought of them as mean, unfair, and unreasonable; but each of them left me with new muscles -mental, physical, and emotional. My character values in action had been shaped and formed and toughened in and through those challenging experiences.

The development of toughness doesn't require a return to "the old days" when we carried water from the stream or chopped wood. Toughness is still needed for and developed from lots of different experiences, challenges, and stresses, which each of us face today. We should also keep in mind that difficult life experiences and hardships can also have a negative impact, especially when one learns to persevere and get through hardship by neglecting or discarding their moral and ethical values. For example, war and poverty and violence can contribute to an unintended negative kind of "toughness."

Three important points: First, we must seek to develop the specific sort of toughness needed for the challenges we most often face and the goals we seek to accomplish. Second, the opportunity for tough-mindedness is often found within the naturally occurring responsibilities and pursuits of our lives. Third, technology and economic prosperity, which make our lives easier, can also cause atrophy of our toughness muscles as many things become generally easier and require less effort.

In a day and age when technology, education, and overall affluence for many, especially in this country have improved the quality and ease of daily life, toughness is becoming a quality that is more and more noticeably absent among the younger generations. Not surprisingly, toughness

is also becoming one of the most sought-after qualities that employers, educators, and coaches want to see in their employees, students, or athletes. For example, Jay Bilas (a former college and professional athlete, college coach, and current ESPN analyst and practicing attorney) devotes an entire book, Toughness, to the exploration of toughness and its essential contribution to the internal fortitude and strength needed to succeed in sport and life. Similarly, research on grit - defined as "perseverance and passion for long term goals", or a form of mental toughness has demonstrated that individuals who possess it consistently overcome failure, adversity, and other barriers to goal achievement.

Matthew L. Davidson, Ph.D. is the Founder, President, and Director of Education for the Institute for Excellence & Ethics (IEE), 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 IEE 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 IEE, please visit www.excellenceandethics.org.

Please be sure to read Part 2 of this series next issue, which will focus on developing a tough-minded mindset and the mindset of motivation.

Listening To Patients
Fungal Failure

By Alan Rockoff, MD

A few months ago I met Ed, still working at 71. "My life's ambition," he said, "has been to help high school science teachers do their job better."

"How's it going?" I asked.

Ed sighed. "I'm still at it," he said. "Let's just say we're not there yet."

I too, dear colleagues, have had a life's ambition, secret until now: I want to eliminate erroneous fungal diagnosis. Or, to put it more pungently, I want to help non-dermatologists (and non-dermatology PAs) to stop treating every roundish scaly rash as ringworm.

Alas, like Ed's, my work is not yet done.

I get reminders of this all the time, but last month the evidence got so overwhelming that I had to take a breath to settle down, and a nip. Ten cases. In twenty-four hours.

1. A 66-year-old woman energetically smeared econazole cream twice daily for weeks for an itchy, lichenified rash on both dorsal feet and ankles. I switched her to betamethasone. The rash was cleared in five days.

2. A 48-year-old woman with scaly patches on both legs. She had no response to terbinafine cream, then to ketoconazole cream, then to oral fluconazole. She was cleared promptly on triamcinolone, once I treated her.

3. A 26-year-old with an erosive vulvar rash lasting month, who had been unresponsive to Nystatin. After I saw her, she spent five days on a steroid and it was gone.

4. A 45-year-old man with lots of sun damage and hypomelanosis on his arms and legs. He had no luck with topical selenium sulfide for TV.

5. A 42-year-old nurse treated for weeks with topical antifungals. She came in with globs of fungus cream sealed in with Tegaderm (to prevent spread). Her roommates wanted to cancel her lease. She was cleared in one week of both rash and Tegaderm. She is now allowed to touch doorknobs.

6. A 27-year-old man with eight weeks of lichenified patches all over his torso. Antifungal creams had not been working. After I treated him, he now knows steroids do!

7. A 25-year-old recent emigre from India, where he was treated for his itchy groin rash with a succession of antifungal creams. He cannot sleep. (Imagine the plane trip from Delhi!) He has lichenified inguinal folds and scrotum. I helped him to be cleared in one week with a topical steroid.

8. A 22-year-old woman with widespread atopic dermatitis. She had no response to antifungals. She had a rash at age two that was called "allergy to shampoo." She too cleared promptly on a steroid I prescribed for her.

9. A 22-year-old man being treated for a scaly, bilateral periocular rash with oral cephalexin. He cleared promptly on a weak of topical steroids I prescribed.

10. A 29-year-old woman who has been suffering for months with "sensitivity" of her vulvar skin that has been diagnosed and treated as "a yeast infection," in the absence of any rash or discharge. Her only visible finding is inverse psoriasis in the gluteal cleft. Guess what clears her up?

And so it goes, and so it has gone, week after week, year after year, decade after decade. Medicine scales Olympus: genomics, immunotherapy, stereotactic surgery. Meantime, the it's-round-but-not-a-fungus problem seems impervious to both education and even to simple

observations that are obvious yet ineffective: if a supposed fungus does not respond to antifungal treatment, then it must be a very bad fungus. If it doesn't respond to yet another antifungal cream, then it must be a really terrible fungus. Deciding that it may not be a fungus at all seems to demand a mental paradigm shift that will have to await a more discerning generation.

In the meantime, patients not only don't get better, but they feel defiled and dirty. They avoid skin contact, intimate and otherwise, and do a lot of superfluous and expensive cleaning of their house and wardrobe. If you doubt this, ask them. If you think I overstate, spend a day with me.

Early in my career I inherited the once-yearly dermatology slot at Medical Grand Rounds at the local community hospital. I spoke about cutaneous fungus, with emphasis on the fact that lots of round rashes are nummular eczema rather than fungus, as well as what it means to patients to be told they are "fungal."

I didn't get much direct feedback, but the Chief of Medicine sprang into action. He canceled the dermatology slot. Not medical enough, I guess.

Ed tells me that many high-school science teachers don't know much science. They teach it because they thought they might like to, or because there was an opening. After Ed hangs up his cleats, there will be plenty of his work left to be done.

But then, there always is.

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...

Sarah B. W. Patton, MSHS, PA-C

Wading Through The FDA's Proposed Sunscreen Guidelines

In 2014, the FDA passed the Sunscreen Innovation Act to provide an "alternative process for the review of safety and effectiveness of nonprescription sunscreen active ingredients". Following up on this, the FDA announced on February 21, 2019 their new proposed regulations on sunscreens. Here are the takeaways and my thoughts:

1. Ingredients - For as long as I have been practicing, providers in the dermatology field have recommended zinc oxide and titanium dioxide as the active ingredients for patients to seek in their sunscreens. These are tried and true in regards to protection and safety. I have often thought back to lifeguards with their noses pasted in white goop, (also known as zinc oxide). How many of these noses were saved from skin cancer with this early use of sunscreen? The proposed guidelines verify that zinc oxide and titanium dioxide are considered **GRASE** or **G**enerally **R**ecognized as **S**afe and **E**ffective by the FDA.

The physical blockers zinc oxide and titanium dioxide function by deflecting and scattering UVA and UVB rays. While dermatology providers have continued to recommend zinc oxide and titanium dioxide, the cosmesis of these products have led to the development of chemical blockers. After all, what good is a medication if it sits in the tube on your patient's shelf? Many individuals, particularly those with more pigment in their skin, complain physical blockers don't tend to rub in to their skin or that these turn the skin "ashy". This has led to the development of chemical blockers. Chemical sunscreens work by absorbing UVB rays (and UVA dependent on the ingredients).

Does this mean that chemical blockers aren't safe because they aren't labeled GRASE? At this time, the FDA reports there is insufficient safety data to label these ingredients GRASE. The FDA is not pulling any of these products from the shelves and I am not recommending patients go and throw away their chemical sunscreens, but to be aware the data needs to be evaluated further prior to giving these sunscreen ingredients the GRASE rating. Unfortunately, as providers, this leaves us in a grey area when it comes to the recommendation of these products to our patients. In addition, the concern is that patients will stop using sunscreens entirely due to confusion over safety concerns. While 12 of the chemical ingredients are under review for GRASE labeling, the FDA has definitively ruled PABA and trolamine salicylate are not GRASE.

Oxybenzone is one of the main ingredients in chemical sunscreens for which there has been increasing concerns in regards to safety. The concern surrounds systemic absorption of this ingredient and any related affects of this for the individual. The other concern is that oxybenzone may be contributing to bleaching of the coral reefs. In 2018, this concern prompted the state of Hawaii to ban the use of oxybenzone, as well as the chemical octinoxate, in sunscreens in their state. A similar law is now being considered in Florida. It is my hope that the FDA proposed changes will better clarify the data on these ingredients so that we may give our patients evidence based answers.

Where does this leave us? Do no harm. For now, as I have been saying for years to patients, if there is a concern with the lack of sufficient data, the rule is to use the physical blockers. They are safe and above all, they work for the protection of the skin from UVA and UVB rays. Additionally, the newer formulations of physical sunscreens with nanoparticles tend to rub in better and many can be found in tinted forms.

2. Formulations - The FDA proposes that dosage forms that are GRASE for use in sunscreens to include sprays, oils, lotions, creams, gels, butters,

pastes, and sticks. Powders are proposed to be included as well. On the other hand, the FDA is proposing wipes, towelettes, body washes and shampoos to be categorized as new drugs. The review of chemical sunscreens will likely play a role in this part of the guidelines, as the majority of spray sunscreens, for example, are chemically based.

3. SPF labeling - The labeling of SPF is confusing. We know that SPF refers to the protection from UVB rays and not UVA rays. We also know that both UVA and UVB exposure leads to skin cancer development. For a long time, consumers would buy chemical sunscreens with a label for example, of SPF 30, with the impression that they were protected against both UVA and UVB rays. Many of the original chemical sunscreens did not have sufficient protection against UVA rays or the protection would degrade over time. This prompted the FDA to require that these sunscreens be labeled as "broad spectrum" if they have BOTH UVA and UVB protection.

Additionally, most patients don't understand what these numbers mean. What patients need to know is that a SPF of 30 blocks 97% of UVB rays. A SPF of 50+ blocks 98% rays. There has been debate about any added benefit of a SPF above 50 and, in my opinion, this debate has not yet been settled. I recommend anyone who is at high risk for skin cancer to use sunscreen with a SPF 50+ and for a person without these risk factors, to use SPF 30+. It is proposed that the changes in labeling will raise the maximum of SPF from SPF50+ to SPF 60+.

Again, it is my hope that the proposed changes by the FDA will allow us as providers to confidently recommend sunscreens based on a wealth of scientific data. We know sunscreen is just one tool in our armamentarium in the protection against sun exposure. Additional measures include avoidance of sun exposure when UV radiation is the highest (between 10:00 AM and 4:00 PM), seeking shade, wearing sun protective clothing, sun protective glasses, and broad rimmed hats.

For the link on the FDA proposed guidelines please visit:

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631736.htm

Sarah B. W. Patton, MSHS, PA-C is in practice in Seattle, Washington specializing in cutaneous oncology where she has worked for over a decade. She also serves as part time didactic faculty for UW MEDEX Physician Assistant Program. She has indicated no relationships to disclose relating to the content of this article.

Collaborating Physician **CORNER**

George J. Hruza, MD, MBA, FAAD, To Assume Presidency of American Academy of Dermatology

Board-certified dermatologist George J. Hruza, MD, MBA, FAAD, will begin his one-year term as president of the American Academy of Dermatology on Tuesday, March 5, at the conclusion of the 2019 AAD Annual Meeting in Washington.

As president, Dr. Hruza will lead the world's largest dermatologic society, representing more than 20,000 physicians specializing in the diagnosis and medical, surgical and cosmetic treatment of skin, hair and nail conditions. He will also hold the same position for the American Academy of Dermatology Association, a sister organization to the AAD that focuses on government affairs, health policy and practice information.

"The health care landscape is evolving, and it's important for dermatology to evolve with it," Dr. Hruza says. "During my time as president, I will work to empower our members to view change as an opportunity and to inspire them to get involved in the Academy's efforts on behalf of their specialty. If we work together and speak with a united voice, we can drive positive development."

When asked about PAs in dermatology, Dr. Hruza said, "The future of dermatology is centered around a team-based care approach with dermatology physician assistants being valued members of that team. I look forward to working with our dermatology physician assistant colleagues as part of the dermatology care team to optimize care for our dermatology patients."

Dr. Hruza earned his medical degree from New York University, where he completed his dermatology residency. He also completed an internal medicine internship at New York Presbyterian Weill Cornell Medical Center, a laser surgery fellowship at Harvard University in Boston and a Mohs surgery Fellowship at the University of Wisconsin-Madison. He has a Master of Business Administration from Washington University in St. Louis.

Dr. Hruza is an adjunct professor of dermatology at St. Louis University. He has written four laser dermatology textbooks and published more than 150 articles.

Dr. Hruza previously served the Academy as a member of the Board of Directors and chair of the Investments Committee. He also is a past president of the American Society for Dermatologic Surgery, the American Society for Laser Medicine & Surgery and the St. Louis Metropolitan Medical Society.

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

Write an article that explores the complex or multifaceted ethical or judicial professional issues that affect the practice of dermatology for PAs (250-1000 words).

To read the JDPA publication's Ethics and Malpractice Statement, please visit www.jdpa.org/write.html.

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