Individualized biologic therapy

JOHN JESITUS | Staff Correspondent

A new study advises selecting biologic therapies for psoriasis based on individual factors such as patients’ comorbidities, preferences and clinical situation, as well as the advantages and disadvantages of particular biologic treatments. The study appears in the February issue of the American Journal of Clinical Dermatology.

Authors led by Jashin J. Wu, M.D., reviewed available evidence to formulate expert-opinion algorithms for comorbidities such as psoriatic arthritis (PsA), tuberculosis and hepatitis B, as well as psoriasis in children and women of childbearing potential.

Few patients present with psoriasis and no other health issues, said Dr. Wu, of Kaiser Permanente Los Angeles Medical Center. Probably the most common comorbidity dermatologists see, he said, is psoriatic arthritis, which affects around one-third of patients with psoriasis. In such cases, Wu et al. recommend the TNF inhibitors adalimumab, etanercept and infliximab, in that order, as first-line options, as all have been shown to inhibit radiographic progression of PsA, as well as other disease signs and symptoms. “The efficacy of TNF inhibitors...”

493,204 unused opioid pills

WHITNEY J. PALMER | Staff Correspondent

When it comes to opioids, neither patient nor provider is equal. Recent research shows distinct differences in who will receive and who will write a prescription.

Despite the nationwide, burgeoning opioid crisis, existing data shows one in five patients with non-cancer, pain-related diagnoses receive an opioid prescription. In dermatology, opioid prescriptions are largely made by dermatologic surgeons. A study published in the March 2018 issue of JAMA Dermatology (DOI:10.1001/jamadermatol.2017.5835) found that 43.1 percent of 12,537 dermatologists followed over the course of one year, wrote between one and 10 prescriptions during this period. But then, 42.3 percent prescribed no claims at all during the study period.

The study also broke down opioid prescribing patterns by region. Dermatologists in the South prescribed 2,77 opioid claims per 1,000 Medicare beneficiaries, compared with 1.60 per 1,000 in the West, 0.89 per 1000 in the Midwest, and 0.83 per 1,000 in the Northeast.

Of those dermatologists who prescribed opioids, each physician processed an average of 63 claims to 61 patients who were given an average of 4.4 days worth of the opioids. This, they said, led to a build-up of unused pills.

“Based on these consumption habits, we calculated that a total of 493,204 pills could be left unused by Medicare patients receiving prescriptions during this period. This is an estimated 13.4 percent of the 3.6 billion opioid pills prescribed to Medicare enrollees in 2014.”

In this month’s issue, we focus on flares associated with plaque psoriasis and atopic dermatitis. Throughout this issue you’ll find content about managing flares from selecting treatment to controlling pruritus.

Image © Adobe/Milan Lipowski

MORE IN THIS ISSUE

Clinical 18
NEUROPATHIC ITCH
Underlying mechanisms understudied with limited treatment options.

Cosmetic 38
COMPLEMENTARY TREATMENTS
Microneedling alone may not be the best route.

Oncology 50
ADD-ON THERAPY
SRT with Mohs for skin cancer recommended for some senior patients.

Business 62
REGULATIONS
How the GDPR may impact patient privacy—in the U.S.

THE PAYER REPORT CARD: Is your payer performing well? Meeting your needs? It may be time to re-evaluate the payer contract. Learn more in this month’s tear out.

PAGE 80
OUR MISSION
Provide practical analysis of recent studies, regulatory updates, techniques, devices and business solutions; and facilitate discussion to optimize practice and improve patient care.

Dermatology Times is guided by a core group of trusted physician experts who provide editorial guidance and expert opinion on issues that affect patients and the practice.

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In recent years there has been surging interest in atopic dermatitis (AD). This is evidenced by the near-exponential growth in the publication of papers dealing with AD (see Figure 1), as well as the now formidable pipeline of medications currently being studied.1

While the pipeline is extremely impressive in terms of potential therapeutic innovations, I’d like to take a step back and briefly look at three areas of advancement in AD from a broader perspective. Underpinning the possibility for these new treatments lies progress in conceptions of the disease, some of which are quite remarkable. I will discuss the microbiome, skin barrier dysfunction, and finally the emerging standard of care in AD.

THE MICROBIOME
The notable dermatologist Paul Unna suggested that the etiology of AD was due to “the inoculation of a germ.” He was far ahead of his time when he asserted that local treatment should “always have in view the destruction of every single germ in the depths of the epidermis”.2 His prescience is remarkable in light of the more than 120 intervening years during which we have, until very recently, largely ignored those germs in the epidermis. The microbiome has gone from more of a fringe topic to something “ripped from the headlines” and is now thought to be seemingly central to the pathogenesis of many diseases, including AD.3 As we have learned more about this microbiota imbalance, the contribution of Staphylococcus aureus has become increasingly clear, including its ability to secrete a toxin that actively contributes to dermatitis.4

Remarkably, these developments have unfolded in the context of a renewed push to heed Unna’s recommendation, perhaps starting with the concept that dilute bleach baths are helpful for AD, possibly by reducing the bacterial burden.5 This story has been significantly complicated, however, by papers showing dilute bleach baths have no effect on Staphylococcus,6 but instead may be anti-inflammatory,7 and perhaps may improve the skin barrier.8 Culminating in a recent paper that frustratingly concludes that bleach baths “do not appear to be more effective than water baths alone”,9 the only certainty is that we still have a lot to learn.

Confusion has opened the door for another controversial approach: mixing a topical antibacterial with a corticosteroid to directly decrease Staphylococcus.10 This approach, popularized by South African dermatologist Dr. Richard Aron, lacks randomized controlled trials, but has a mountain of anecdotal evidence and a small retrospective case series to support its use.11 It remains to be seen if and how this affects skin bacteria, but speaks to the fact that there remain significant unmet needs.

And we haven’t even gotten to the winding story of oral probiotics for both prevention and treatment of AD,12,13,14 or the more exciting new “microbiome transplant” work that suggests a totally different approach for restoring healthy skin flora.15 Suffice it to say, this is a hot topic par excellence, and will likely continue to develop over the next few years.

SKIN BARRIER DYSFUNCTION
Filaggrin is a structural protein in the stratum corneum and plays a critical role in maintaining the skin barrier. The discovery that null mutations in the filaggrin gene (FLG) are associated with AD led to a breakthrough in understanding the pathogenesis of the disease.14 This understanding has become increasingly sophisticated in the past decade, with a recent paper...
“Physicians have been involved ... in almost every biomedical breakthrough.”

Medical societies can support innovation

by STEVE XU, M.D., FAAD, AND MORGAN NGUYEN, BA

Dr. Xu is a board-certified dermatologist and medical director of the Center for Bio-Integrated Electronics at the Simpson Querrey Institute for Bionanotechnology, Northwestern University. He is co-founders of the Advancing Innovation in Dermatology Accelerator Fund. Ms. Nguyen is a medical student at Northwestern University Feinberg School of Medicine.

Successful innovation requires an intimate understanding of underlying unmet clinical needs. Physicians have been involved as critical actors in almost every biomedical breakthrough from imatinib to statins.²

In medical devices, an analysis of 170 pre-market approval patent applications by four large incumbent device companies showed that 11% cited information from physician-founded start-ups, compared to only 4% from non-physician-founded companies.³

Despite interest and potential, clinicians often encounter barriers to developing innovative technologies: Conflict of interests in academic medicine, time and resource limitations, and lack of expertise and experience in product development.

Medical societies offer an influential addition to the innovation ecosystem and are uniquely positioned to address several challenges related to innovation. By recruiting direct physician involvement, these organizations have great potential to be a nexus for innovation. They provide credibility and pooled resources to members, and represent an existing framework that can be adapted to gather and support physicians interested in addressing similar clinical needs.

Societies can address physician barriers to innovation by providing monetary and educational resources to their members. Seed funding, mentorship, and routes for industry collaboration. They also play a key role in knowledge exchange between academia, medicine, and industry. Their annual conferences and contact databases provide a route for physicians and industry to network and collaborate on transformative innovations. Societies represent an opportunity to identify physician-innovators and offer an existing meeting structure to collaboratively address clinical problems in need of innovative solutions.

Here we propose a framework for incorporating innovation into these organizations.

- Identify and prioritize the pressing clinical issues.
- Identify internal accelerators of innovation, such as successful physician-entrepreneurs, industry leaders with connections to academia and vice versa.
- Develop innovation-specific meetings or workshops and innovation education seminars within existing professional meetings.
- Build an education curriculum devoted to innovation literacy to cover topics such as patents, the FDA approval processes, fundraising, successful Small Business Innovation Research (SBIR) applications, and other translational funding opportunities that may be specialty-specific.
- Create seed funding to support early stage ventures.

There are existing examples of medical societies that actively support member innovation. In 2017, the American Medical Association launched the Physician Innovation Network, an online community for physicians and healthcare technology companies.

The Society for Investigative Dermatology identifies innovation as one of its five core values. It maintains an academic/industry partnership database to increase knowledge exchange between researchers and industry leaders. It also hosts an industry partner session at its annual meeting to discuss industry and academia partnerships.

The American Society for Dermatologic Surgery has the Dermasurgery Advancement Fund “to support current and future dermatologic surgeons in continuing their innovative work.”

The annual Dermatology Innovation Forum is held by Advancing Innovation in Dermatology in association with the American Academy of Dermatology. This forum serves to connect physicians with experts in finance, intellectual property and industry. Advancing Innovation in Dermatology has also started a dermatology-focused seed fund—the AID Accelerator Fund—to provide financial support for early-stage ventures to achieve critical commercialization milestones.

The European Society for Dermatological Research is actively forming relationships with industry, scientific foundations, and philanthropies to pool resources that support cutting-edge investigations and innovation. It is developing programs that facilitate and accelerate research innovation by linking the scientific know-how of academic dermatology with the translational and financial resources of industry. “The group’s collaborations demonstrate a model of inclusivity among key players in translational medicine and innovation.”

Innovation requires the active participation of numerous stakeholders. Societies have a tremendous opportunity to support innovation by organizing momentum around specific unmet needs, coordinating effective collaborations with outside partners, and providing critical resources and training to physician-innovators.

CONTRIBUTING AUTHORS: William Ju, M.D., FAAD, is a board-certified dermatologist and founder of Advancing Innovation in Dermatology and co-founder of the Advancing Innovation in Dermatology Accelerator Fund.

References

FINALLY A CLEANSER ADVANCED ENOUGH TO PAIR WITH ADVANCED REPAIR LOTION

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**Eucerin® Advanced Cleansing**
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- Lightweight formula that’s clinically proven to improve the skin’s moisture barrier\(^*\)
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A recent case of the Maryland Board of Medicine weighed whether it was unprofessional to write a prescription for a patient at a restaurant or bar.

In this case, the defendant physician met with a patient at a local restaurant parking lot and wrote a prescription for 100 tablets of an opioid pain reliever. The physician had not taken a history or conducted a physical examination. He also did not document the prescription in his medical records.

A restaurant employee witnessed the event and contacted local law enforcement. The physician was questioned and admitted to writing prescriptions for this patient and others in restaurant parking lots in exchange for $100 per prescription. When asked why he would prescribe in a parking lot rather than in his office, the physician explained that the patient wanted to buy him a beer, so they went to the local restaurant where he wrote the prescription.

The Maryland Board of Medicine disciplined the physician for unprofessionalism. The physician argued there was no legal basis to their finding of unprofessional conduct. He stated that there was no statutory provision, no regulation, and no American Medical Association ethics opinion specifically prohibiting prescribing outside of an office setting.

On appeal, an administrative law court found that the physician’s practice of prescribing and selling opioid prescriptions in parking lots constituted unprofessional conduct in the practice of medicine.

Seeing patients in public greatly reduces the privacy needed to ensure patient confidentiality, the court opined. Nearby individuals can overhear details regarding the patient’s medical history, medications and treatment options. It is also not possible for the physician to conduct a thorough physical examination. The option to perform a thorough medical examination must be available when prescribing opioids.

“Writing prescriptions in exchange for cash in public is a flagrant abandonment of professionalism. This is especially disturbing when the drugs prescribed possess such a high risk for diversion and abuse, such as opioids and benzodiazepines,” the Court wrote. “Selling prescriptions in a public space endangers the public, breaches patient confidentiality, and diminishes the standing of the medical profession in the eyes of the members of the general public.”

How does this relate to Dr. Drug or any dermatologist that sees a patient in a social setting and writes prescriptions for that patient?

Unfortunately, the definition of unprofessionalism is not clear.

Imagine a friend with whom a dermatologist has no previously established doctor-patient relationship mentions particular symptoms. The dermatologist performs a basic exam in public, makes a diagnosis, writes a prescription, and documents this in the patient’s medical record. Or, a dermatologist strikes up conversation with a stranger who upon learning the dermatologist’s profession, mentions symptoms. The dermatologist writes a prescription, tells the person to follow up with his physician, and documents this in the medical record.

Are these scenarios unprofessional? There is no simple answer to Dr. Drug’s situation.
The skin is immunologically, metabolically and biologically active.

Cosmetic efficacy testing

by DR. ZOE DIANA DRAELOS

Dr. Draelos is a consulting professor of dermatology, Duke University School of Medicine, Durham, N.C.

Q. Are cosmetics really tested for efficacy?
I have been asked many times to write a book chapter or a review article on the topic of cosmetics, citing and rating evidence for validity and scientific relevance. One such request involved making a list of all facial moisturizers and then providing the evidence for their efficacy. While I tried very hard to comply with these wishes, the final result did not contain the evidence desired. Why?

There is a lot of excellent testing done in the cosmetics industry, especially by ingredient suppliers who want their new product to be widely used in finished formulations. However, I would say that extensive cosmetic testing is limited by concerns that evidence to support cosmetic efficacy could turn the product into a drug. Remember that the Cosmetics & Toiletries Act was written when the skin was thought to be an inert covering over the body. We now know that the skin is immunologically, metabolically and biologically active. As a matter of fact, it may be one of the most complex structures of the body. So, to provide evidence of cosmetic efficacy, akin to the drug evidence that we are familiar with reviewing, would indeed make the cosmetic a drug. Until the law is updated to allow cosmetics to function beyond scenting and adorning the skin, scientific evidence to document cosmetic efficacy will be lacking. However, there are some widely used standard testing methodologies that are worth examining.

Q. How are cleansers tested in humans?
Cleansers are challenging to test. Next month we will discuss in vitro testing, but I will discuss the most common in vivo cleanser testing technique next. The most commonly used in vivo test for cleanser mildness is the forearm controlled application technique (FCAT) developed by Keith Ertel while at Procter & Gamble, however each company has adapted the test to fit their own internal requirements. This test enrolls human subjects who wet their forearms with warm tap water. A moistened towel is then rubbed in a circular motion over the test bar cleanser for six seconds to generate lather. The lathered towel is then rubbed on the forearm skin in a circular motion for 10 seconds. The lather remains on the application site for 90 seconds and then is rinsed with warm tap water for 15 seconds. The arm is patted dry. The washes are performed twice daily for five days separated by a minimum of three hours. This test controls the amount of cleanser applied, the length of cleansing, and the frequency of testing. It is an exaggerated use test since the cleansing is performed twice daily for a test period of five days. If no irritation is observed with the cleanser under exaggerated use conditions, it is felt to be safe to put the cleanser into the clinic under normal use conditions. This same philosophy is used widely in cosmetic testing.

Q. How are moisturizers tested in humans?
Moisturizer testing is different than cleanser testing because cleansers are assumed to be irritants, but moisturizers are not. The most important attribute to elucidate regarding moisturizer formulations is the duration of the desired effect. For this reason, moisturizers are tested in humans using a regression technique. A panel of individuals with the skin characteristics of the anticipated use population is recruited. The subjects are asked to use the moisturizer on the desired area following the labeled use instructions. Subjects are asked to come back to the research center after one and two weeks of use for visual dermatology grading, subject tolerability assessment, and corneometer testing. The corneometer measures the amount of water in the skin by looking at the skin conductivity of a low voltage current. Since water is the conductor in the skin, increased skin water will be reflected in an increased corneometry reading. A successful moisturizer will demonstrate improvement visible to the dermatologist, no tolerability issues, excellent subject reviews, and increasing corneometry measurements with continued use.

The subjects are then asked to discontinue the moisturizer and return to the research center at a specified time. This is known as the regression portion of the study. Depending on the type of claim being supported, subjects may return at 48 hours, three days, five days, or seven days. Subjects must keep their cleanser unchanged for the entire duration of the study. The length of time after discontinuation that the moisturizer benefits can be perceived is directly correlated to the efficacy of the moisturizer. Regression testing of this type is commonly performed on body moisturizers.
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Epiphany Dermatology is expanding rapidly. Partner with us, and you can focus on your patients. Release yourself from mountains of paperwork and stresses that have nothing to do with providing the best possible skincare.

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THE U.S. FOOD AND DRUG ADMINISTRATION has approved clearance for a new acne treatment that selectively targets sebaceous glands, according to a news release.

Sebacia Microparticles is indicated for use with 1,064 nm lasers, which use photothermal heating of the sebaceous glands to treat mild-to-moderate acne vulgaris.

The product, made by Sebacia Inc., was approved following a randomized, controlled, blinded trial of 168 patients with mild-to-moderate acne. The patients received treatment with laser only or with laser and Sebacia. Those treated with Sebacia Microparticles achieved a 53 percent median reduction in inflammatory lesion count compared to 45 percent of those treated with laser alone, according to the company. At 12 weeks, the study reached its primary endpoint of demonstrating noninferiority. Additionally, 30.1 percent of patients treated with Sebacia Microparticles demonstrated a clear or almost-clear Investigator’s Global Assessment score.

“We have not seen any truly innovative acne therapies developed for more than two decades and with this clearance, Sebacia Microparticles offers a new option for the millions of mild-to-moderate acne sufferers,” Jill S. Wai- bel, M.D., board-certified dermatologist, Miami Dermatology and Laser Institute, said in a statement. She served as a Sebacia clinical trial investigator. “I expect Sebacia Microparticles to further enhance patient and physician optionality while seamlessly integrating into the AAD-recommended polytherapeutic approach to managing acne.”

With the FDA approval and its CE marking, Sebacia Microparticles is now cleared for sale in both the U.S. and the EU.

ALMIRALL ACQUIRES ALLERGAN’S U.S. DERMATOLOGY PORTFOLIO

ALMIRALL HAS CLOSED ON AN AGREEMENT to acquire Allergan’s medical dermatology unit in the United States for $550 million.

The deal, which closed in September, gives Almirall Aczone (dapsone), Tazorac (tazarotene), Azelaic acid) and Cordran (fluorocorticoid), according to a news release. The company also gains a new product, Seysara (sarecycline), a tetracycline-derived anti-biotic with anti-inflammatory properties to treat moderate-to-severe acne vulgaris in patients ages 9 and older. The FDA may approve Seysara in the fourth quarter of 2018.

“The acquisition of the Allergan medical dermatology portfolio…will reinforce and consolidate our position in the U.S., which represents the largest and most profitable dermatology market worldwide,” Peter Guenter, Almirall CEO, said in a statement. “Now as we gain critical mass and growth potential in the U.S. dermatology market, it is also the right moment to look at strategic options for our aesthetics business.”

Allergan will continue to support Almirall during the portfolio transition.

Almirall recently rebranded itself, dropping its former name, Aqua Pharmaceuticals.
CROWN LABORATORIES SECURES AESTHETIC DIVISION WITH BELLUS MEDICAL ACQUISITION

CROWN LABORATORIES has acquired Bellus Medical, allowing the firm to secure a variety of noninvasive aesthetic products, according to a company news release.

The Dallas-based Bellus Medical is being renamed Bellus Aesthetics and represents the new Aesthetics Division of Crown Laboratories. The company produces microneedling protocol SkinFuse, ProGen3M/RegenLab, which are platelet-rich plasma systems; light-activated cream Allumera; and SkinPen, a microneedling device for the treatment of acne scars. SkinPen was the first microneedling device in the United States to be granted clearance by the Food and Drug Administration (FDA) for the facial acne scarring treatment indication, according to the company.

“Bellus has assembled a truly impressive team with an enviable track record of innovation in aesthetics,” Jeff Bedard, president and CEO of Crown Laboratories, said in a statement. “We believe there is tremendous opportunity for us in aesthetics, and with Bellus as the cornerstone of our new division, we expect to expand our portfolio meaningfully in the years ahead.”

Joe Proctor, CEO of Bellus, becomes president of Crown’s Aesthetics Division. He will also join the Crown Board of Directors, according to the news release.

ODAC CONFERENCE RETURNS TO ORLANDO

THE ORLANDO DERMATOLOGY AESTHETIC & Clinical Conference (ODAC), formerly known as Orlando Derm, is scheduled for January 18-21 at the JW Marriott in Orlando.

This year’s meeting will open with presentations from physicians who will address advances in treating skin of color, hot topics in surgical dermatology and cutaneous malignancy, the latest on photodynamic therapy, and a year in review from the Journal of Drugs in Dermatology, among others.

Drs. Eric Bernstein and Jason Pozner will host a panel discussion on “My Top Picks for Laser and Energy Based Treatments.” And, Dr. Joel Cohen will give an overview of facial arterial supply.

During the general session on Saturday, Jan. 19, Dr. Brian Berman will address managing urticaria, which will be followed by talks by Dr. Deirdre Hooper on platelet rich plasma for hair growth and skin rejuvenation; Dr. Andrew Alexander on keloids and disorders of hyperpigmentation in skin of color; and, Drs. Bernstein and Pozner will address advances in non-surgical skin tightening.

On Sunday, January 20, Dr. Jean Bolognia will open the day’s general session with a review of advances in systemic therapies for melanoma.

For more information, visit ODAC online at https://orlandoderm.org

PROSCIA TO EXPAND ITS ARTIFICIAL INTELLIGENCE SOFTWARE LINE

PROSCIA INC., a digital technology company specializing in the development of artificial intelligence applications and software for dermatological pathology, recently secured $8.3 million in an initial round of financing. The funds will allow the company to develop and commercialize applications aimed at “high-volume, high-impact cancers” along with boosting sales of its existing cloud-based digital pathology platform, according to a company news release.

The platform will be used for the launch of DermAI in December 2018, providing artificial intelligence-enabled and disease-specific applications.

“Pathology has been historically underserved by technology, and we believe that powerful software tools will push the boundaries of how modern pathology is practiced,” David West, Proscia CEO, said in the statement. “That’s why this funding is so important. It will allow us to expand the adoption of digital pathology, while creating intelligent systems that will unlock data from tissue to greatly enhance pathologists’ productivity, increase access to care, and improve the way cancer is researched and, ultimately, treated.”

This platform, already used by 300 medical and research facilities worldwide, is designed to integrate with various lab environments, can reduce turnaround times and cut costs, and may allow users to take advantage of imaging and analytics revenue streams.

Flybridge Capital Partners, Emerald Development Managers, Fusion Fund, Razor’s Edge Ventures, Robin Hood Ventures and SoGal Ventures were the venture capital firms providing Proscia the Series A funding.

DR. REDDY’S SELLS CLODERM TO EPI HEALTH

EPI HEALTH has acquired Cloderm Cream (dlocortolone pivalate 0.1 percent) and its authorized generic from manufacturer Dr. Reddy’s Laboratories.

Promius Pharma will be entitled to receive an upfront payment and subsequent future royalties, effective immediately. Financial details of the acquisition were not disclosed.

Cloderm is used for the treatment of various skin conditions such as eczema, psoriasis and allergic reactions.

“The addition of this product to our growing portfolio will support our ongoing efforts to build a successful prescription-branded franchise in the United States,” said Ron Owens, EPI Health president.
Presentation & management of neuropathic itch

While neuropathic pain is a focus of research and drug development, the same cannot be said for neuropathic itch. As a result, the underlying mechanisms of neuropathic itch are poorly understood, diagnosis is challenging, and treatment options are limited.

Since inflammatory cutaneous signs like edema and erythema are characteristic of dermatological itch, and neurogenic inflammation can cause these signs in neuropathic itch as well, dermatologists should understand the underlying pathophysiology.

Neuropathic itch is the result of excess peripheral firing or dampened central inhibition of itch pathway neurons and a symptom of the same central and peripheral nervous system disorders that cause neuropathic pain, such as sensory polyneuropathy, radiculopathy, herpes zoster, stroke, or multiple sclerosis, according to Martin Steinhoff, M.D., M.Sc., department of dermatology and venereology, Hamad Medical Corporation, Doha, Qatar, who authored an article review that was published in *The Lancet Neurology*.

The two conditions can occur simultaneously; however, unlike pain, itch is only felt in the skin or mucosa lining the body’s entrances.

Concomitant sensory loss and gain of function is observed in both neuropathic pain and itch, so a better understanding of the neuroanatomical and pathophysiological similarities and differences between the two conditions might identify existing but underused and novel treatment targets, he notes. To date, standardized case definitions to diagnose and differentiate the subforms of neuropathic itch and validated questionnaires to track symptoms are limited.

Diagnosis is complicated by the fact that different forms of neuropathic itch exist, such as focal vs. widespread and peripheral vs. central, as well as the fact that scratch-induced skin lesions can be mistaken as a primary (e.g., evidence of insect infestation) rather than a secondary symptom.

**COMMON PRESENTATIONS**

*Small fibre peripheral neuropathy* is one of the most common presentations of neuropathic itch and should be considered when patients present with unexplained chronic itch or scratch injuries in the length-dependent pattern on the limbs. It usually starts in the feet and progresses proximally in a length-dependent pattern that sometimes also involves the hands.

Small fibre peripheral neuropathy occurs in approximately 40% of cases of fibromyalgia, and generalized axonopathies trigger more than half of all neuropathic itch presentations.

_Focal mononeuropathies or oligoneuropathies_ that damage the small fibres within spinal nerves, plexi, or nerve roots are the major cause of focal neuropathic itch, Dr. Steinhoff writes. Itchy patches, which correspond to the cutaneous distribution of the damaged nerves or root, are most common on the head, upper torso, or arms, and are less common below the waist.

_Compressive radiculopathy_ due to lateral spinal stenosis is the most common cause of brachioradial pruritus (the more distal patches), particularly after midlife. The second most common cause of truncal radicular neuropathic itch is herpes zoster, particularly at cervical and upper thoracic levels. Diabetic microvascularopathy should also be considered in patients with focal truncal neuropathic itch, as this requires prompt initiation of disease-specific treatment.

_Ganglionopathies_ (neuronopathies) cause non-length-dependent itch or itchy patches, and other sensory and radicular symptoms, neuropathic pain and proprioceptive ataxia. They can relate to cancer (particularly small-cell lung cancers),...
FOR ADULTS WITH PLAQUE PSORIASIS

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The efficacy of Class 1 halobetasol with safety proven for up to 8 weeks of dosing¹,²

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POTENT TO SUPERPOTENT CLEARANCE¹:

Continued results 4 weeks post treatment¹

Significant symptomatic relief as early as week ²

No increased epidermal atrophy observed through 8 weeks of treatment²

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, hypopigmentation and allergic contact dermatitis. Some local adverse reactions may be irreversible.

STUDY RESULTS: 36.5% of patients in trial 1 and 38.4% in trial 2 achieved treatment success at week 6 (primary endpoint) vs 6.1% and 12.0% of patients with vehicle, respectively (P<0.001 in both trials)³.

STUDY DESIGN: The safety and efficacy of BRYHALI Lotion were assessed in 2 prospective, multicenter randomized, double-blind, phase 3 clinical trials in 430 adult patients with moderate to severe plaque psoriasis. Patients were treated with BRYHALI Lotion or vehicle lotion, applied once daily. Primary efficacy endpoint was treatment success evaluated at week 6. Secondary efficacy endpoint was treatment success evaluated at weeks 2, 4, 6, and 12 (4 weeks post treatment). Tertiary efficacy endpoint was a 2-grade improvement from baseline at each time point for the individual signs of psoriasis (erythema, plaque elevation, and scaling)³.

¹Treatment success was defined as at least a 2-grade improvement from baseline in the Investigator’s Global Assessment score, and a score of “clear” or “almost clear” (primary endpoint at week 8).³


Indication
BRYHALI™ (halobetasol propionate) Lotion, 0.01% is a corticosteroid indicated for the topical treatment of plaque psoriasis in adults.

Important Safety Information

Warnings and Precautions
- BRYHALI Lotion has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis during treatment or upon cessation of treatment; periodic evaluation may be required.
- Systemic effects of topical corticosteroids may also include Cushing’s syndrome, hyperglycemia, and glucosuria.
- Children may be more susceptible to systemic toxicity when treated with topical corticosteroids.
- Local adverse reactions may include atrophy, striae, telangiectasias, hypopigmentation, and allergic contact dermatitis. Some local adverse reactions may be irreversible.
- Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma. If visual symptoms occur, consider referral to an ophthalmologist.
- Use an appropriate antimicrobial agent if a skin infection is present or occurs, and if prompt response is not seen, discontinue use until infection has been adequately treated.
- Discontinue BRYHALI Lotion if allergic contact dermatitis occurs.

Adverse Reactions
- The most common adverse reactions (≥1%) were upper respiratory tract infection, application site dermatitis, and hyperglycemia.

To report SUSPECTED ADVERSE REACTIONS, contact Customer Service at 1-800-321-4576 or FDA at 1-800-FDA-1088.

Please see Brief Summary of full Prescribing Information on following page.

Ortho Dermatologics

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DISCOVER MORE AT BRYHALI.COM
BRYHALI™ (halobetasol propionate) Lotion, 0.01% is indicated for the topical treatment of:

**INDICATIONS AND USAGE**

Initial U.S. Approval: 1990

BRYHALI has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Systemic effects of topical corticosteroids may include reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment with the topical corticosteroid. The potential for hypothalamic-pituitary-adrenal (HPA) axis suppression with BRYHALI was evaluated in a study of 19 adult subjects with moderate to severe plaque psoriasis involving ≥20% of their body surface area (BSA). HPA axis suppression was reported for 1 (5.6%) subject at Week 4 and for 3 (15.8%) subjects at Week 8. All 3 subjects had normal HPA axis suppression test with discontinuation of treatment [see Clinical Pharmacology in full Prescribing Information].

Because of the potential for systemic absorption, use of topical corticosteroids, including BRYHALI, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent corticosteroids, use over large surface areas, occlusive use, use on an altered skin barrier, concomitant use of multiple corticosteroid-containing products, liver failure, and young age. An adrenocorticotropic hormone (ACTH) stimulation test may be helpful in evaluating patients for HPA axis suppression. If HPA axis suppression is documented, attempts to gradually withdraw the drug, reduce the frequency of application, or substitute a less potent topical corticosteroid may be considered. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Systemic effects of topical corticosteroids may also include Cushing’s syndrome, hyperglycemia, and glucosuria. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to corticosteroids. Pediatric patients may be more susceptible than adults to systemic toxicity from the use of topical corticosteroids due to their larger surface-to-body mass ratios [see Use in Specific Populations].

**ADVERSE REACTIONS**

Local Adverse Reactions

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and milia. These may be more likely with occlusive use, prolonged use, or use of higher potency corticosteroids, including BRYHALI. Some local adverse reactions may be irreversible.

Concomitant Skin Infections

Use an appropriate antimicrobial agent if a skin infection is present or develops. If a favorable response does not occur promptly, discontinue use of BRYHALI until the infection has been adequately treated.

Allergic Contact Dermatitis

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Consider confirmation of a clinical diagnosis of allergic contact dermatitis by appropriate patch testing. Discontinue BRYHALI if allergic contact dermatitis occurs.

**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 randomized, double-blind, multicenter, vehicle-controlled clinical trials, 426 adults with plaque psoriasis were treated with BRYHALI and had post-baseline safety data. Subjects applied BRYHALI once daily for up to eight weeks. Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with BRYHALI and more frequently than in vehicle-treated patients.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>BRYHALI (N=284)</th>
<th>Vehicle (N=142)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Application Site Dermatitis</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td>1%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

There are no available data on BRYHALI use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproduction studies, increased malformations, including cleft palate and omphalocele, were observed after oral administration of halobetasol propionate during organogenesis to pregnant rats and rabbits. The available data do not support relevant comparisons of systemic halobetasol propionate exposures achieved in the animal studies to exposures observed in humans after topical use of BRYHALI.

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 to 4% and 15 to 20%, respectively.

**Data**

**Animal Data**

Halobetasol propionate has been shown to cause malformations in rats and rabbits when administered orally during organogenesis at doses of 0.04 to 0.1 mg/kg/day in rats and 0.01 mg/kg/day in rabbits. Halobetasol propionate was embryotoxic in rabbits but not in rats. Cleft palate was observed in both rats and rabbits. Omphalocoele was seen in rats but not in rabbits.

**Lactation**

There are no data on the presence of halobetasol propionate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production after treatment with BRYHALI.

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BRYHALI and any potential adverse effects on the breastfed child from BRYHALI.

**Clinical Considerations**

Advise breastfeeding women not to apply BRYHALI directly to the nipple and areola to avoid direct infant exposure.

**Pediatric Use**

Safety and effectiveness of BRYHALI in pediatric patients under the age of 18 years have not been evaluated.

Because of higher skin surface area to body mass ratios, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing’s syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse reactions including striae have been reported with use of topical corticosteroids in infants and children [see Warnings and Precautions].

HPA axis suppression, Cushing’s syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema [see Warnings and Precautions].

**Geriatric Use**

Of 284 subjects exposed to BRYHALI in clinical trials, 61 subjects were 65 years or older. Clinical trials of BRYHALI did not include sufficient numbers of subjects age 65 years and older to determine whether they respond differently from younger subjects.

**NONCLINICAL TOXICOLOGY**

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term animal studies have not been performed to evaluate the carcinogenic potential of halobetasol propionate. Halobetasol propionate was not genotoxic in the Ames assay; in the sister chromatid exchange test in Chinese hamster somatic cells, in chromosome aberration studies of germlinal and somatic cells of rodents; or in a mammalian spot test. Positive mutagenicity effects were observed in a mouse lymphoma gene mutation assay in vitro and in a Chinese hamster micronucleus test.

Studies in rats following oral administration of halobetasol propionate at dose levels up to 0.05 mg/kg/day indicated no impairment of fertility or general reproductive performance.

**PATIENT COUNSELING INFORMATION**

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

Dow Pharmaceuticals 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 Numbers: 6,517,847 and 8,809,307

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Based on 9652102 November 2018 BRY.0095.USA.18
Diagnosis is based primarily on recognizing clinical characteristics of specific neuropathic itch syndromes...

Martin Steinhoff, M.D., M.Sc., Hamad Medical Corporation, Doha Qatar

Neuropathic itch presentation and management FROM PAGE 18

infection, or autoimmune disease, and imaging with contrast or cerebrospinal fluid analysis can help confirm these diagnoses.

Post-ganglionectomy ulcers were often misdiagnosed as being caused by deprivation of axonally transported nutritive trophic factors (trigeminal trophic syndrome), but then excessive and often painless scratching was recognized as the correct cause, Dr. Steinhoff writes. The para-midline nasal or the cheek is the characteristic location of the lesion after trigeminal ganglion or lower root injury, and the tip of the nose is usually spared. Non-trigeminal facial neuropathic itch can indicate lesions of the nervus intermedius of the cranial nerves VII or IX, or of the cervical spinal nerves C1 or C2, he adds. Herpes zoster is the most common cause of cranial neuropathic itch, and the forehead and anterior scalp are most commonly affected.

In diseases of the central nervous system, any type of lesion of the itch pathways in the spinal cord or brain can cause somatotopic neuropathic itch, including stroke, intramedullary neomyelitis, intramedullary tumors, transverse myelitis, and spinal cord injury. Opioids and brain infections, such as Creutzfeld-Jakob disease, can induce neuropathic itch, and neuropathic itch can present alone or with other symptoms such as colocalising sensory loss or weakness suggesting a neurologic origin.

The time between the onset of neuropathic itch or neuropathic pain can range between a few months to a few years after an event like a stroke, Dr. Steinhoff writes. The para-midline nasal or the cheek is the characteristic location of the lesion after trigeminal ganglion or lower root injury, and the tip of the nose is usually spared. Non-trigeminal facial neuropathic itch can indicate lesions of the nervus intermedius of the cranial nerves VII or IX, or of the cervical spinal nerves C1 or C2, he adds. Herpes zoster is the most common cause of cranial neuropathic itch, and the forehead and anterior scalp are most commonly affected.

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- More user-friendly features
- Better treatment experience

Significant improvements across patients

**Telangiectasia**
- Baseline
- 3-month follow-up

**Rosacea**
- Baseline
- Post 2 treatments

Photos are unretouched. Patient treated with Vbeam Prima; individual results may vary. Photos courtesy of E. Victor Ross, MD.

Photos are unretouched. Patient treated with Vbeam Prima and contact cooling; individual results may vary. Photos courtesy of Konika Patel Schallan, MD.

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High efficacy shown in self-inject PsO biologic

JOHN JESITUS | Staff Correspondent

The TNF alpha inhibitor certolizumab pegol (Cimzia, UCB) has achieved the highest response rates seen in phase three trials of self-injectable biologics for psoriasis, according to a study published online in the Journal of the American Academy of Dermatology (JAAD).

Certolizumab pegol was approved in May by the FDA for adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

The CIMPASI-1 and CIMPASI-2 trials showed that week 16 improvements in Psoriasis Area and Severity Index (PASI) and other measures persisted, and in some cases improved, through week 48. In pooled analysis, week 16 PASI 75 response rates for 200 mg and 400 mg doses were 76.7% and 82.0%, versus 70.7% and 83.6% at week 48.

Also at week 48, depending on study population (CIMPASI-1, CIMPASI-2 or investigators’ pooled analysis) and dose, 52.7-72.6 percent of patients achieved physician global assessment (PGA) scores of clear or nearly clear (0/1), including at least a two-point improvement from baseline. PGA 0-1 response rates at week 16 ranged between 47.0 percent (200 mg, CIMPASI-1) and 71.6 percent (400 mg, CIMPASI-2). PASI 90 response rates, reported only until week 16, were 35.8-55.4 percent.

In two separate multi-site trials whose results were published in the JAAD online on April 13, 2018, investigators randomized patients with moderate-to-severe psoriasis to treatment with certolizumab pegol 400 mg every two weeks, certolizumab pegol 200 mg every two weeks (after 400 mg loading doses at weeks zero, two and four) or placebo. At week 16, any patients on active treatment who had achieved PASI ≥ 50 continued at their original dose through week 48. Placebo-treated patients who had achieved PASI 50-74 at week 16 switched to certolizumab pegol 200 mg every two weeks (after loading doses). During the first 48 weeks of the ongoing study, injections were performed by study personnel who were not involved in any other study procedures.

While CIMPASI-1 results and pooled results revealed that the 400 mg dose generally performed better than 200 mg, CIMPASI-2 results showed no significant difference between the doses. In CIMPASI-1, for example, week 16 PASI 75 response rates were 66.5 percent (200 mg) and 75.8 percent (400 mg). The corresponding figures in CIMPASI-2 were 81.4 percent and 82.6 percent.

Investigators could not explain why CIMPASI-2 showed no significant differences between the two certolizumab pegol doses. “Several demographic and baseline clinical characteristic differences between the two studies were observed. However, there is no clear evidence to indicate these differences affected clinical outcomes across the studies,” wrote the authors of the study which was led by Alice Gottlieb, M.D., Ph.D., of New York Medical College at Metropolitan Hospital, New York.

Previous studies have suggested that patients with prior biologic exposure experience lower efficacy than biologic-naïve patients do in clinical trials. In CIMPASI-1 and CIMPASI-2, several demographic and baseline clinical characteristic differences between the two studies were observed. However, there is no clear evidence to indicate these differences affected clinical outcomes across the studies.”

Alice Gottlieb, M.D., Ph.D., and colleagues, New York Medical College at Metropolitan Hospital, New York
Most meds switched without much discussion

JOHN JESITUS | Staff Correspondent

A new methotrexate usage survey shows that most patients with arthritis do not discuss medication modification strategies with their doctors.

The survey study was conducted by the Canadian Arthritis Patient Alliance (CAPA) and presented in June at the European Congress of Rheumatology/European League against Rheumatism (EULAR).

“Methotrexate is one of the first drugs that people are typically prescribed, sometimes with other drugs, when diagnosed with inflammatory arthritis, said Nathalie Robertson, a co-author of the study.

The survey, of 363 patients, also showed that 80% of patients do not discuss medication modification strategies with their healthcare providers. “That was a surprise. It makes you wonder why people would not want to talk to their doctor. Is it because the doctor is too busy? Do they think that if the doctor has prescribed the medication, there must be a way for them to figure it out themselves? CAPA is working to understand the answers to such questions,” Ms. Robertson said.

Half of respondents agreed with the statement that they “do not like taking methotrexate, but it helps me manage my arthritis.”

Patients reported avoiding milk or lactose, gluten, red meats, acidic, spicy or greasy foods, and alcohol. Other adaptation strategies include taking methotrexate with folic acid, or taking methotrexate before bed or on weekends, Ms. Robertson said. Additionally, “Some people take it on a full stomach. Some people drink lots of water; some might split a dose.”

RESOURCE FOR PATIENTS

In early 2018 CAPA released a web resource featuring patient-derived tips and tricks for methotrexate use, in English, French and Spanish. This tool offers suggestions in areas such as diet and schedule modification. The tool’s intent is to tell patients that there are modifications, such as dose splitting, that they should discuss with their doctors, and others they can control on their own, said Ms. Robertson. As of early June, the web resource had drawn more than 600 visits.

References


Inadequately controlled atopic dermatitis burden

BOB KRONEMYER | Staff Correspondent

Patients with moderate-to-severe atopic dermatitis are at high risk of having inadequate disease control, according to a cross-sectional study in *JAMA Dermatology*.

“It was surprising that despite treatment of moderate-severe disease with our traditional systemic treatment, over half of patients felt like their disease was not adequately controlled,” said Eric Simpson, M.D., of Oregon Health and Sciences University, Portland, Maine and the study’s corresponding author. “This identifies the need for improved systemic therapy for atopic dermatitis, prior to the approval of dupilumab.”

Dr. Simpson was inspired to undertake the study to better understand the burden of adult atopic dermatitis in a population from a clinic rather than a trial population.

The study used data from six academic medical centers in the United States, which collected information from a patient self-administered internet questionnaire.

1,519 adults patients with atopic dermatitis were stratified by disease severity as mild or moderate-severe using the Patient-Oriented-Scoring Atopic Dermatitis (PO-SCORAD).

Compared to patients with mild atopic dermatitis, patients with inadequately controlled disease reported a significantly higher DLQI score (54.1 vs. 27.6) in areas such as work, social activities, and sleep.

Over half of patients felt like their disease was not adequately controlled. The study sought to clarify the burden of atopic dermatitis in adults.

---

**Dermatology Life Quality Index (DLQI)**

- **MILD** (< 20)
  - (n=689)

- **MODERATE/SEVERE** (21-50)
  - (n=830)

- **CONTROLLED** (< 11)
  - (n=82)

- **INADEQUATELY CONTROLLED** (23+)
  - (n=103)
Atopic dermatitis burden in adult patients

(n=689), patients with moderate-to-severe disease (n=830) reported more severe itching and pain, greater sleep adverse events, higher prevalence of anxiety and depression, and greater health-related quality-of-life impairment.

Patients with moderate-to-severe disease who were treated with systemic immunomodulations or phototherapy within the past seven days were further stratified as having adequate or inadequate disease control.

In all, 22.3% (n=185) of patients with moderate-to-severe disease were treated with the above treatment protocol, of whom 55.7% (n=103) considered themselves inadequately controlled.

Patients with inadequately controlled atopic dermatitis were younger than those with controlled disease: 44.6 years vs. 49.8 years.

However, there were no differences between the controlled and inadequately controlled group for age of onset, disease duration or use of topical therapies and any systemic treatments.

The pruritus numerical rating scale (0 to 10, with 0 being no itch and 10 being worst imaginable itch within the past 24 hours) was 2.0 for mild disease, 5.9 for moderate-to-severe disease, 5.4 for moderate-to-disease patients treated with immunomodulations or phototherapy who felt their disease was controlled, and 6.9 for inadequately controlled treated patients.

Patients with moderate-to-severe disease also experienced more days per week with itchy skin compared to mild disease: 5.7 vs. 2.7. Also, itch duration greater than half a day: 22.8% of moderate-to-severe patients vs. 2.9% of mild patients.

Pain severity was also higher among moderate-to-severe patients (3.3 on a scale of 0-10, compared to 0.9 for mild disease), and for inadequately controlled vs. controlled disease (3.2 vs. 4.7).

In addition, moderate-to-severe patients were more likely to have trouble sleeping: 3.9 vs. 1.1, based on the PO-SCORAD visual analog scale (VAS), as well as longer sleep latency (38.8 minutes vs. 21.6 minutes), more frequent sleep disturbances (2.6 nights in the past week vs. 0.4 nights) and greater need for over-the-counter sleep medication (39% of patients vs. 21%).

Sleep problems rated “much” or “very much” interfered with daily function much more often in patients with moderate-severe atopic dermatitis: 24.3% vs. 6.8% for mild disease.

Likewise, mental health symptoms of anxiety and depression were reported by 50.2% of patients with moderate-severe disease compared to 27.3% with mild disease.

The mean Dermatology Life Quality Index (DLQI) scores were also higher in patients with moderate-severe disease (9.2 vs. 2.9), and among patients with inadequately controlled as opposed to controlled disease (13.4 vs. 9.3).

For item 7 on the DLQI, 14.0% of moderate-to-severe patients reported that their disease prevented work or study compared to only 2.6% of mild patients. Similarly, the percentages were 27.2% and 18.3% for inadequately controlled and controlled disease, respectively.

“In contrast to studies that have reported few differences in the burden between mild and moderate/severe AD, the current study reports a significantly greater burden of moderate/severe AD across all outcomes compared with mildly affected patients,” the authors wrote.

These differences may be due to sample size limitations of the other studies or from differences in assessing disease severity.

“Clinicians need to explore more thoroughly how the disease affects their patients on a day-to-day basis. Such exploration will likely lead clinicians to offer more aggressive forms of therapy to help alleviate patient suffering,” he said.

Disclosures: Dr. Simpson is a consultant for Regeneron Pharmaceuticals and Sanofi.

Reference

Could the skin lesion you’re seeing... actually be a deadly blood cancer?

Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is an aggressive and deadly hematologic cancer with skin lesions that may be mistaken for other skin disorders.1,2

WHO ARE PATIENTS WITH BPDCN?

- ~85-90% present with skin lesions2-4
- ~75% are men2,5
- Typically between 60-70 years of age, but all ages can be affected2,5

Plasmacytoid dendritic cells (pDCs) invade the dermis where they proliferate, resulting in skin lesions that take the form of 1-3,6:
- Nodular lesions (73%)
- Bruise-like macules (12%)

Research has uncovered key markers, including α123, that allow for the proper diagnosis of BPDCN.6*

When biopsying skin lesions, ask your pathologist to test for α123. Refer patients early.

*BPDCN diagnosis can include other markers, such as α4, α56, TCL1, and α303 (BDCA2).7

First approved biologic in derm to carry suffix

BOB KRONEMYER | Staff Correspondent

Quick Takes

Biologic tildrakizumab-asmn approved with suffix as differentiator from future biosimilar versions.

The suffixes carry no meaning, but will help to ensure patients receive the correct product and assist in accurately tracking orders, prescribing and dispensing of biosimilar products.

Tildrakizumab-asmn (Humya, Sun Pharmaceuticals), the interleukin (IL)-23-inhibitor biologic approved for treating moderate-to-severe psoriasis, is the first originator biologic in dermatology to adopt the 2017 FDA-mandated “asmn” suffix. It behooves dermatologists to understand this naming convention as new biologics and biosimilars become available.

This four-letter nomenclature has been used to identify biosimilars in dermatology since 2016.

The U.S. Food and Drug Administration introduced guidance in January 2017 recommending that all biological products include an FDA-designated suffix to help patients and physicians accurately discern between biologic products, related biologic products and biosimilars; facilitate pharmacovigilance when tracking biologic ordering, prescribing, and dispensing; and to minimize inadvertent substitution of products that have not been determined to be interchangeable.

Last November, the FDA added four-letter meaningless suffixes to two newly approved biosimilars outside of dermatology: emicizumab-kzwh (Hemlibra, Roche) for hemophilia and vestronidase alfa-vjbk (Mepsevii, Ultragenyx Pharmaceutical) for the rare inherited condition Sly syndrome.

Pharmaceutical companies can propose a maximum of 10 suffixes for their product, as long as they are not perceived as confusing. The suffixes are a combination of four letters that carry no meaning, and the FDA makes the final selection.

In a June 2018 article in the American Journal of Clinical Dermatology, first author Eric Yang, M.D., of the department of dermatology at the University of California, San Francisco, and colleagues note that “adoption of this nomenclature by this newly approved drug demonstrates an anticipated increased role of biosimilars in dermatology.”

Simon Lowry, M.D., head of Medical Affairs and chief medical officer for Sun Pharma, notes, “The assigned meaningless suffix ‘asmn’ is used to differentiate our originator biologic from future biosimilar versions of tildrakizumab.”

Tildrakizumab-asmn was approved by the FDA in March 2018 for the treatment of adults living with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

“There is a need for additional treatment options for people living with the persistent nature of moderate-to-severe plaque psoriasis,” Dr. Lowry tells Dermatology Times.

The approval of tildrakizumab-asmn was supported by data from two multicenter, randomized, double-blind, placebo-controlled trials (reSURFACE 1 and reSURFACE 2) in which 926 patients with moderate-to-severe chronic plaque psoriasis were treated with tildrakizumab-asmn, etanercept (reSURFACE 1) or placebo. In reSURFACE 1, 74% of patients treated with tildrakizumab-asmn 100 mg achieved 75% skin clearance at week 28 after three doses. In addition, 84% of patients who continued receiving tildrakizumab-asmn 100 mg maintained PASI 75 at week 64 compared to 22% of patients who were re-randomized to placebo.

Further research from a long-term pooled analysis found that 9 out of 10 patients on tildrakizumab-asmn who achieved PASI 75 at week 28 maintained their skin clearance after three years of treatment.

“Over the three-year period, the drug was well-tolerated with a low rate of adverse events of interest,” Dr. Lowry says.

The three most common adverse reactions associated with 100 mg dosing are upper respiratory infections, injection site reactions and diarrhea.

Dr. Lowry says the IL-23 genetic pathway is present in numerous autoimmune diseases, including psoriatic arthritis and ankylosing spondylitis, for which the company is currently conducting phase 2 studies with tildrakizumab-asmn.

Disclosure: Simon Lowry is an employee of Sun Pharma.

Reference

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Infliximab is more effective at clearing skin lesions, followed by adalimumab and then etanercept.


Psoriasis with psoriatic arthritis

Psoriatic arthritis affects one-third of psoriasis patients. In these cases, Dr. Wu prefers TNF inhibitors as first-line options in this order:

- **FIRST**: Certolizumab Pegol
- **SECOND**: Ustekinumab
- **THIRD**: Infliximab

If TNF inhibitors fail in these cases, the second-line treatment includes IL-17 inhibitors:

- Secukinumab
- Ixekizumab
- Brodalimumab

If IL-17s fail, third-line treatments include IL-12/23 inhibitors:

- Ustekinumab

**FOODS THAT TRIGGER SKIN FLARES**

Gluten-containing foods may trigger flares in some patients.

[bit.ly/2r7GV2R](bit.ly/2r7GV2R)

**TOPICAL THERAPY IN PSO AND AD**

Best practices for topical therapy uses in psoriasis and atopic dermatitis.

[bit.ly/2FHLNj](bit.ly/2FHLNj)

**IT MAY BE TIME FOR ACT II IN AD RESEARCH**

Dupilumab is a proven treatment for AD, so where do we go from here?

[bit.ly/2NyUMbt](bit.ly/2NyUMbt)

**For Further Reading on the Topic**

1. **Opioids**
   - Neuropathic Itch
   - [bit.ly/2r7GV2R](bit.ly/2r7GV2R)

2. **Switching Meds**
   - Opioids
   - [bit.ly/2FIHLNJ](bit.ly/2FIHLNJ)

3. **Biologic Naming**
   - Opioids
   - [bit.ly/2NyUMbt](bit.ly/2NyUMbt)

**LIMITATIONS TO THE STUDY**

The study did not include IL-12/23 inhibitors guselkumab and tildrakizumab. When these recommendations were written, there was little data for guselkumab, which was FDA-approved in July 2017, and tildrakizumab, which is not yet approved. The study authors are planning to update algorithms to incorporate these and other recently approved biologics.

Reference

Telangiectasias in systemic sclerosis

WAYNE KUZNAR | Staff Correspondent

More than 90% of patients with systemic sclerosis (SSc) have at least one telangiectasia (TA), and the median number of TAs in this patient population is 30. Most TAs are distributed on the face, hands, and upper part of the trunk, according to French researchers.

Findings from a cross-sectional study of 106 adults who fulfilled American College of Rheumatology/European League Against Rheumatism criteria for SSc revealed that 37.2% of TAs were located on the face, 26.4% on the hands, and 17.1% on the upper trunk. Study results appear in JAMA Dermatology.

In addition to describing the distribution of TAs, the authors also sought to characterize clinical manifestations of TAs in SSc, focusing on severe vascular manifestations. As well, a TA score was calculated.

More than three fourths (78.3%) of the 106 patients included were women and 72.6% had limited cutaneous SSc. Ninety-eight patients (92.5%) had at least one TA, including 55 (51.9%) with at least one TA greater than 5 mm. The median numbers of TAs was 30, the median number of TAs greater than 5 mm was one, and the median TA score per patient was five. There was a positive, significant correlation between the total TA number on the whole body and TAs on the face, on the upper limbs, and on the hands.

On multivariable analysis, the total TA number was independently associated with male sex, pulmonary hypertension, history of pulmonary embolism, an increase in glomerular filtration rate $P = 0.04$), and an increase in soluble endoglin level. Soluble endoglin is an angiogenic of various vascular pathologies, including SSc, the authors noted.

The number of TAs on the whole body, the hands, and the hands and face, and the TA score, were significant indicators of the presence of pulmonary hypertension. The TA score was also significant.

“TA number on the hands and/or face was well correlated with the total TA number and could be useful to identify patients with SSc who require closer monitoring for pulmonary hypertension,” according to the investigators.

Reference

Opioids: Study suggests that females receive more opioid prescriptions than men

FROM PAGE 1

Findings from a 2014 Pain Research & Management study (Pain Res Manag, 2014 Jul-Aug; 19(4): 179–185) noted 26.6 percent of all prescriptions written by dentists were for opioids. The JADA study indicates that rate has fallen to 10.8 percent, however, making dentists’ contributions to the opioid prescription rate the lowest among healthcare providers.

Their study was based on a review of 891,720 Medicaid claims data from 13 states (from Jan. 1, 2013 and Sept. 30, 2015) in which 209,296 patients, 23.4 percent, received an opioid prescription within 14 days of diagnosis. The patient groups receiving the most prescriptions were 19-to-29-year-olds (30.3 percent), females (65.8 percent), non-Hispanic whites (57.8 percent), and those receiving care from emergency department providers (36.8 percent). Additionally, 48.4 percent of patients ages 30-to-39 also received an opioid prescription, but only 11 percent received a prescription from a dentist.

Researchers also identified 25 percent of both non-Hispanic white and African-American patients filled opioid prescriptions; however, Hispanic patients received prescriptions at a lower rate—10 percent.

And, even when investigators controlled for age, race or ethnicity, and healthcare provider type, women were still more likely to fill opioid prescriptions for dental diagnoses than were men.

The findings contradicted results from the Pain Research & Management study that examined opioid prescribing habits among physician specialties. Those results noted 44 percent of men, compared to 40 percent of women, received opioid prescriptions for orthopedic pain.

Study results also revealed the healthcare provider type affected who received an opioid prescription. Emergency room providers accounted for the most opioid prescriptions. Data analysis showed African-American and non-Hispanic white patients were more likely to receive an prescription post-diagnosis in an emergency department than Hispanic patients were (OR, 1.69; 95% CI, 1.59 to 1.81 and OR, 2.03, 95% CI, 1.91 to 2.16, respectively). In addition, African-American patients were 30 percent more likely to receive an opioid prescription from a dentist than were non-Hispanic white patients and three times more likely than Hispanic patients.

Overall, the investigators said, these results mirror the results of other healthcare disparities studies.

“Our findings reiterate racial and sex disparities in prescription provision that are echoed in medical diagnoses,” they wrote. “In medicine, these differences have been attributed to various factors, including the suggestion that the healthcare provider’s own unconscious biases and cultural differences between the healthcare provider and patient have an influence.”

FROM PAGE 1
Complementary treatments

Microneedling pairs well with other aesthetic approaches to optimize outcomes

JOHN JESITUS | Staff Correspondent

Quick Takes

Microneedling pairs well with other procedures, but clinicians should learn nuances of each to avoid adverse effects.

Microneedling is inexpensive and is easily incorporated into clinical practice.

To reduce adverse effects, laser treatments and microneedling should be timed at monthly intervals.

Microneedling cannot match the tissue-tightening effects of lasers, but it addresses issues ranging from stubborn wrinkles to stretch marks, quickly and cost-effectively, according to an expert who spoke at the summer Cosmetic Bootcamp held June 21-24 in Aspen, Colorado. Rather than competing, she added, microneedling and laser treatments often complement each other.

Although fractional ablative lasers have bridged the efficacy-versus-downtime gap between traditional CO2 lasers and non-ablative lasers, said Tina S. Alster, M.D., no laser can treat severe perioral rhytides successfully. She is director of the Washington Institute of Dermatologic Laser Surgery and clinical professor of dermatology at Georgetown University in Washington, D.C.

Along with micro-wounding, microneedling creates controlled macro-wounding that spurs healing in the way that tilling a field increases its yield, Dr. Alster explains. Microneedling is also inexpensive, combines well with other procedures and incorporates easily into any clinical practice, she said.

Dr. Alster prefers microneedling devices with disposable tips and as many needles as possible. Drum-shaped needle rollers are hard to clean, and their permanent needles dull quickly, she explained.

For perioral rhytides and other indications, Dr. Alster frequently offers what she calls simple microneedling, without radiofrequency assistance, or adjuvant cosmeceuticals delivered through the microscopic channels. Based on a March 2018 *Dermatologic Surgery* article she co-authored, Dr. Alster offered the following technical tips:

- Don’t overdo the gliding gel. “Put just enough on the skin to permit a smooth gliding action of the microneedling tip across the skin, but not so much that excess gel interferes with the device’s motor.”
- Use manual traction for smooth needle delivery. “If you’re dragging the device over loose skin, the needles can drag or get caught. Your assistant can stretch the skin taut—or you can use your non-dominant hand to do so — during treatment.”
- Hold the device perpendicular to the skin so the needles penetrate the surface at 90°.
- Perform multidirectional passes. “I move the microneedling tip back and forth, up and down and diagonally across the treatment area. Some practitioners perform circular motions. It’s important to avoid treatment in the same direction so that patients don’t end up looking like they have stripes.”
- Watch for early pinpoint bleeding as a clinical endpoint. “Severely photodamaged skin often bleeds immediately, while fibrotic skin or scars, particularly in non-facial areas, may require several passes to elicit pinpoint bleeding.”

**Dr. Alster**

**meeting COVERAGE**

**COSMETIC BOOTCAMP**

June 21-24, 2018

Aspen, Colorado

**1a, b.** 40-Year-old male patient shown before (left) and one month after (right) second microneedling treatment for atrophic nose scarring.

Photos: Tina Alster, M.D.
Bringing Molluscum Contagiosum to Light

While as many as 1 out of every 5 healthy children contract molluscum contagiosum, this disease and the patients it affects receive very little attention.¹ Quality of life can be negatively affected by a molluscum infection.² Children with the disease may become stigmatized and experience teasing, embarrassment, and social isolation. Up to 82% of parents and caregivers express moderate to great concern about molluscum.³ Lesions may be mostly asymptomatic, but reports indicate that patients do complain about itching, burning, and tenderness.³

Although lesions can resolve within 6 to 9 months, patients typically have the infection for 13 months, and some infections can persist for 2 years or more.²,³ Treatment at the time of diagnosis provides the best chance of decreasing the number of lesions and spread of the disease.³

No current FDA-approved treatment option addresses the problem of successfully treating molluscum.

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References
Thread lifts or surgery?

Patient expectations important when selecting a midface approach

JOHN JESITUS | Staff Correspondent

Thread-lifting techniques have evolved to provide satisfactory short-term results, particularly in the midface, according to an expert who presented at summer Cosmetic Bootcamp held June 21-24 in Aspen, Colorado. However, he added, thread lifting often works best in conjunction with other procedures such as fat injections and fat contouring. Even at its best, thread lifting cannot approach the results or longevity of specialized surgical results.

Choosing between thread lifts and surgical lifts requires knowing what patients want, and how long they want results to last, said Providence, Rhode Island-based plastic surgeon Patrick Sullivan, M.D. For patients who want to be ready for a near-term event, with little postprocedural downtime, he explained, thread lifts may suffice. But if patients can tolerate a longer recovery in pursuit of more beneficial and durable results, the pendulum swings toward surgery.

After the original non-resorbable barbed sutures became available, many patients who had undergone the procedure elsewhere presented at his practice with threads protruding through their skin. “Those hooks don’t seem to do the job as well as some of the other technologies,” Dr. Sullivan said.

The cone-and-suture structure of the Silhouette InstaLift (Sinclair) is much more effective. In the perioral area, the bidirectional cones seem better able to lift and hold tissue in position. Over time, the polyglactin (glycolide/L-lactin or PGLA) material of which they are made resorbs into the body, forming a temporary filler, as polymethylmethacrylate does.

For perioral lifting, he marks three parallel entry points in the mid-cheek, which correspond to exit points in the upper cheek and perioral area. He then guides a long 18-gauge needle approximately 5 mm under the skin’s surface to the upper-cheek exit point.

“You can see the different cones being brought through this one entrance site. This opening is not even made with a knife.” Then he returns to the central entry point with the other end of the needle and anchors the other end of the suture in the perioral region. “It’s very important to feed those cones in perfectly so they don’t cause any tethering.”

Next, gentle upward pushing across the length of the thread provides medial and lateral lifting as one locks the cones into place.

“You can see this lifting, right on the table, which I find very satisfying.” Nobody knows how long InstaLift results last, so he suggests curbing expectations. “The limited results I get are very different from what I get from surgery.”

Patient selection is critical. One patient he treated underwent surgical blepharoplasty, then decided three days later that her face needed lifting. But she had to return to work the following week.

“When you have somebody who wants something extra to better match their upper face, the InstaLift is a possibility to consider.” For this patient, he said, the procedure provided modest lifting in the perioral area, and with threads along the jawline as well, but nothing in the neck.

“A better candidate might be someone who wants more at the same time,” he said.

For example, one patient wanted an...
eyelid lift and fat injections to raise her cheeks and pre-jowl sulcus. “We also removed some fat from the jowl at the same time. When you combine treatments, that’s a better approach,” Dr. Sullivan said.

For this patient, he first inserted threads extending from the mid-check to exit points in the peri-orbital area. “As we mark those out, we can really get a feel for what we want to lift. Then you can create the other exit points back up against the hairline,” he said.

The neck is more challenging to treat with Instalift because patients find the postauricular exit openings less comfortable than preauricular ones. Beyond six weeks the results for this procedure are unimpressive.

For one female patient he treated, the Instalift facelift worked very well initially. “But when she returned 1.5 years later, we didn’t see any improvement. Then you get into the value proposition, because each thread costs $150,” Dr. Sullivan said.

However, he said that combining facial thread lifting with procedures such as blepharoplasty and fat injections gives patients affordable.

Regarding adverse event, none of his patients have experienced tethering that lasted beyond five days. “But it has been reported. Some people say you have to make sure that the area of the central entrance point is very smooth, because tethering can last months,” Dr. Sullivan said.

Poor candidates for neck thread lifts include those with subplatysmal fat, which one can detect when patients swallow. “If you can feel that fat pull away from you, then it’s probably deep to the platysma and more difficult to get with something like Kybella (deoxycholate, Allergan),” he said.

Such patients are better candidates for procedures such as surgical neck lifting and contouring, he said. “And if they are concerned about their face as well, the superficial muscular aponeurotic system (SMAS) lift can be very effective if done by the right surgeon. Surgical results vary greatly between surgeons.” A female patient for whom Dr. Sullivan performed an extended SMAS lift maintained very good results nearly eight years later, he said.

Other contraindications to thread lifts include heavy jowls, and deflation of the pre-jowl sulcus or posterior jawline. “A thread is not going to put enough volume in those locations. So fat injections, or one of the other synthetic materials, would be helpful there,” he said.

Men with thick, heavy skin and little subcutaneous fat also make poor neck thread-lifting candidates. For a male bodybuilder with thick platysmal bands, Dr. Sullivan performed a full-width transection of the platysma, keeping incisions very low on the neck so the muscle incision would not be visible under the skin since the patient had no fat.

Nearly 2.5 years later, Dr. Sullivan said, the patient maintained an improved jawline and a far better lift than threads would have provided. “Additionally, in his neck region, we were able to get control of the platysma, and you couldn’t see any area where we did the full-width division inferiorly. Thus there are no scars visible at all from all of his face and neck surgery. His result is very natural, and that is just what he wanted.”

**Disclosures:** Dr. Sullivan reports no relevant financial interests.

**Microneedling complements other aesthetic treatments from page 38**

Sometimes she treats beyond the pinpoint bleeding, depending on lesional severity. Application of ice water-soaked gauze between passes immediately stops bleeding with minimal pressure. Once bleeding stops, she applies a few drops of Soothe HC Arnica Recovery Balm (A Method).

For patients with minimal perioral rhytides and surrounding photodamage, she frequently performs microneedling followed immediately by full-face nonablative (or, for more extensive photodamage, ablative) fractional resurfacing.

To reduce the risk of adverse events, she does not perform laser treatment over areas that have been microneedled. She recommends combination microneedling and nonablative laser treatments at monthly time intervals.

However, applying preservative-containing cosmeceuticals too soon after microneedling or nonablative resurfacing can lead to granulomas. Therefore, Dr. Alster advocates waiting until patients have returned to their regular skincare regimen (usually one week post-treatment) before applying additional cosmeceuticals. During that week, patients use her A Method post-care kit, which includes a gentle, nonirritating cleanser, a daytime moisturizer with a nonchemical sunblock and evening moisturizer.

For atrophic scars, traditional pulsed CO2 lasers can provide significant and lasting improvements with one treatment. But to avoid post-treatment mismatches in skin color or texture, laser treatment must be delivered to entire cosmetic units. With microneedling a small area of...
Opioid prescriptions post surgery

By Liset Hiltom

STUDIES PUBLISHED THIS YEAR suggest prescribing 20, 30 or more opioid pills post-rhinoplasty might be significantly more than most patients need. Limiting the number of opioids prescribed after rhinoplasty might decrease opioid-related addiction and death.

In a retrospective review of 173 cosmetic and functional rhinoplasty patients, facial plastic surgeons report prescribing an average 28 tablets, ranging from 5 to 40 per patient. In addition, more than 11% of patients didn't fill narcotic prescriptions, and only two patients required refills, according to the research letter published September 6, 2018, in JAMA Facial Plastic Surgery.

"Although the optimal number of tablets required to manage postoperative rhinoplasty pain is unclear, these data suggest that patients experienced less pain than was anticipated," the authors write. "With the current opioid epidemic, the anus is on surgeons to critically examine postoperative pain management practices.

A study evaluating 62 rhinoplasty patients that was published in January-February 2018 in JAMA Facial Plastic Surgery suggests over-prescribing is a reality and offers an optimal post-rhinoplasty prescribing regimen. The case series analysis reveals that while facial plastic surgeons initially prescribed 20 to 30 hydrocodone-acetaminophen combination tablets, patients used only an average 8.7 tablets, or 40% of those prescribed after surgery. Nearly three-quarters of the patients studied used fewer than 15 opioid tablets. Three of the 62 patients needed opioid refills. A lesson learned from this study about rhinoplasty suggests surgeons can start by prescribing 15 opioid pills, according to the study's senior author Russell W. H. Kridel, M.D., a fellowship-trained facial plastic surgeon who practices in Houston, Texas.

"If anybody is not managed by the 15 pills, it's a good idea to see that patient, to see why the patient's pain requires more opioids," says Dr. Kridel, a past president of the American Academy of Facial Plastic and Reconstructive Surgery.

It's important for surgeons to avoid over-prescribing for reasons beyond the risk of patient abuse or addiction, he says. Dr. Kridel and coauthors cited a 2011 study by Maxwell JC in Drugs and Alcohol Review that found 71% of opioid abusers receive the drugs through methods of diversion and 55% of those get pills via friends or family members who were prescribed the drugs and have left-over pills.

Surgeons should also talk with their rhinoplasty patients before surgery to learn patients' pain tolerance and opioid use in previous surgeries, to better determine how many opioids a person might need. The surgeon should educate patients that it's important that they taper off of opioids and start acetaminophen as soon as possible to prevent abuse or addiction.

"We prefer acetaminophen to ibuprofen, which has the potential to increase bleeding," Dr. Kridel points out. Surgeons can and should verify patient opioid use histories by accessing individual state prescription drug-monitoring programs, according to Dr. Kridel.

The point of our paper is that we shouldn't just pick a figure and prescribe that," Dr. Kridel says. "I think every doctor who does a certain procedure can do a study that looks at how many pills that doctor prescribes and asks 20 patients or so how many they used. If it turns out that they're using less than prescribed, surgeons can start with the lower number.

The CDC reports that prescription and illicit opioids are the main driver of drug overdose deaths today, with 42,249 people dying from these drugs in 2016.

References
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Superficial radiation therapy complements Mohs in older patients

WHITNEY J. PALMER | Staff Correspondent

Quick Takes

Superficial radiation therapy is an appropriate option for treating elderly patients with nonmelanoma skin cancers on the lower extremities, data shows.

A recent review looked at the effectiveness and safety of using SRT on basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) lesions on lower extremities in older patients. The investigators reviewed the medical records of 105 patients with 151 biopsy-proven cancers in a retrospective study. The average patient age was 82.5 years, and the average BCC and SCC lesions measured 1.08 cm and 1.27 cm, respectively. Patient co-morbidities included use of anticoagulants, thyroid disease, poor circulation, diabetes, stasis dermatitis, and immunosuppression.

Lower limb lesions received an average dose of 5019.34 cGy and an average time-dose fractionation of 101.91. Most patients had 50 kv, but three had 70 kv. The majority (89%) received three fractions weekly. Thirty-two percent had a follow-up period of more than four years; 30% for three years; 20% for two years; and 17% for less than two years. The overall success rate was 97.3%. All but four lesions (one BCC and three SCC) were cleared.

This approach is unique, according to Joe Sardano, chief executive officer of Sensus Healthcare, the company that produces SRT, largely because of its benefits. SRT requires no anesthesia or cutting, and it causes no pain, no bleeding, and no scarring.

Consequently, it appears to be a good option for skin cancer patients over age 65 who are diabetic or who take beta blockers. Diabetic patients are more susceptible to post-surgical infections, and beta blocker patients bleed more easily, delaying healing.

“Due to the loss of elasticity, older patients require more stitches,” he said. “Eighty percent of skin cancers occur on the neck and face, making healing and scarring from surgery an experience many would like to avoid.”

SRT requires no anesthesia or cutting, and it causes no pain, no bleeding, and no scarring. Consequently, it could be a good option for skin cancer patients over age 65 who are diabetic or who take beta blockers.”

Joe Sardano, CEO Sensus Healthcare

Each treatment lasts roughly 40 seconds, and most patients receive 2 to 3 weekly treatments for 3 to 4 weeks. Ultimately, Mr. Sardano said, results demonstrate SRT is a viable option to add to the therapy arsenal for this older patient group.

“We haven’t introduced this product as one to replace Mohs surgery. It’s a very good complement to a Mohs surgeon’s practice,” Mr. Sardano said. “If you’re looking to provide patients with a total solution set of options, then having this device available for older patients who are on beta blockers or who are diabetic makes a lot of sense.”

“
Podcast Series

Scar repair options for breast cancer survivors

Using CO₂ technology to minimize scarring from reconstructive surgery

The results of reconstructive surgery for breast cancer survivors typically include physical and emotional scars. What options do dermatologists have to help patients improve the appearance of scars, while addressing other uncomfortable symptoms?

In this podcast, Lesley Clark-Loeser, MD, FAAD discusses her use of fractionated CO₂ lasers to repair surgical scars in breast cancer survivors.

Listen to this podcast at dermatologytimes.com/laser-tech
Surgeons defer procedures during early pregnancy

Promp management of skin cancer lesions is stressed for pregnant patients in a recent article in the *Journal of the American Academy of Dermatology*, but whether it’s applied in clinical practice is unknown.

Researchers with the University of Texas Southwestern surveyed members of the American College of Mohs Surgery to analyze the management patterns of basal cell carcinoma (BCC), squamous cell carcinoma (SCC), and melanoma in pregnant and lactating women. They also explored how intra- and peri-operative practices are modified in pregnancy and lactation, and presented their findings at the American Society of Dermatologic Surgery in Phoenix, Arizona.

“The association between pregnancy and melanoma has been controversial with prior evidence suggesting that pregnant patients have a worse prognosis,” said Era Murzaku, M.D., chief dermatology resident at UT Southwestern and lead study author. “Our results were quite compelling. We found that 80% of dermatologic surgeons change their clinical practice based on a patient’s pregnancy or lactation status.”

They were significantly less likely to perform surgical interventions in the first trimester compared to the second and third trimesters, primarily because of fear of legal repercussions, followed by fear of harm to the developing fetus, and limited safety data in pregnancy and lactation.

Surgical intervention during pregnancy was mostly likely to be performed for melanoma (95% of surgeons) and least likely to be performed for basal cell carcinoma (45%), with squamous cell carcinoma falling in the middle with 67% likeliness.

Decisions on surgery were made with less hesitation for lactating women, and the surgeons surveyed said they would be much more likely to perform surgical procedures for basal cell carcinoma, squamous cell carcinoma, and melanoma in lactating women.

“All in all, pregnant and lactating women should be surgically managed in a similar manner to their non-pregnant counterparts. Optimal timing of surgery is the second trimester, although surgery can safely be performed under local anesthesia during any trimester,” Dr. Murzaku said.

She noted that the American Academy of Dermatology recently published consensus guidelines supporting the safe use of lidocaine with epinephrine in pregnant and lactating patients. Post-operative antibiotics, when indicated, should also be selected with pregnancy and lactation status in mind. Commonly used antibiotics such as penicillin and cephalosporins are safe in pregnancy and lactation. In general, pregnancy and lactation status should not delay management of skin cancers.

Where anesthetics are concerned, the majority of their survey respondents (66%) used a local anesthetic without epinephrine in pregnant patients, which Dr. Murzaku said could be in response to a study that suggested an increase in malformations in infants whose mothers were exposed to epinephrine during the first trimester. There is also concern about the vasoconstrictive effects of epinephrine on placental blood vessels leading to decreased uteroplacental blood flow.

In terms of antibiotics, one-third of dermatologic surgeons were less likely to prescribe it to pregnant and lactating patients. Dr. Murzaku’s team sent anonymous surveys that were answered by 123 ACM members. They concluded that pregnancy and lactation status does impact and could potentially delay surgical management of skin cancers.

Reference
PET-CTs for melanoma lack benefit, study indicates

PET-CT is often ordered reflexively when clinicians are concerned about melanoma metastasis, but the potential for harm from false positive results is not always weighed.

A study to evaluate the usefulness of PET-CT in staging patients with stage II melanoma was conducted at Duke University Medical Center, with a retrospective review of all patients who were imaged over an 11-year period, from 2005 to 2016. The abstract was presented last week at the American Society of Dermatologic Surgery annual meeting in Phoenix.

“We frequently observed that PET-CTs performed for melanoma in our institution were of less utility than we may have hoped,” said study author Adam Brys, M.D., a second-year dermatology resident at Duke Hospital. He has a special interest in melanoma.

Costs of healthcare modalities are also crucial to consider, as avoiding unnecessary tests allow better utilization and distribution of limited resources to those patients who truly would benefit from such tests,” he added.

A total of 225 patients had a PET-CT scan within three months after their initial melanoma diagnosis. More than half received the scan in conjunction with a sentinel lymph node biopsy, while some palliative cases chose to forego the biopsy. Out of these, 89 patients had stage II melanoma. Metastasis was detected in only one patient, who had an ulcerated primary melanoma with a Breslow thickness of 7 mm. So the authors concluded that staging with PET-CT in patients with stage II melanoma rarely provides information that is likely to change management.

The study focused on both stage II and III melanoma, as patients with advanced stage II disease often have a better five-year survival rate than patients with less advanced stage III disease.

“For example, a very thick melanoma with no nodal metastasis has a worse prognosis than a thin melanoma with minimal, but positive, nodal involvement,” Dr. Brys said.

In a separate presentation at ASDS, the authors also presented data on patients with stage III melanoma who presented with occult positive lymph nodes that were detected only through sentinel node biopsies.

He pointed out that current guidelines, based on moderate strength data and some consensus, recommend no imaging in patients with stage II melanoma, although they state it should be considered in patients with AJCC stage IIIA melanoma and obtained in other stage III melanoma cases.

Patients with new symptoms suggestive of metastatic disease and patients with clinically detected, palpable lymph nodes should undergo imaging. But for asymptomatic patients with thin melanomas, cross-sectional imaging will not provide benefits.

However, further study is warranted to identify strategies for accurately predicting which patients would be most likely to benefit from baseline staging PET-CT, and to determine more precise prognostic factors, such as gene mutations or precise thickness, that may be predictive of the utility of PET-CT.

“It should be noted that certain clinical trials may require baseline imaging. And of course, exceptions certainly exist to all guidelines and recommendations,” Dr. Brys said.

Reference
SCC mortality high in patients with HS

Incidence of squamous cell carcinoma in hidradenitis suppurativa is very rare, with fewer than 100 cases in published records. However, the mortality rate is very high, so it must be treated aggressively, according to John Kohorst, M.D., who spoke at the American Society for Dermatologic Surgery annual meeting in October.

Dr. Kohorst, of Mayo Clinic in Rochester, Minn., undertook a study to calculate the incidence within one county in Minnesota over a period of 37 years, from 1976 through 2013.

Previously, the only epidemiological data on occurrence was from a 2001 review of the Swedish National Cancer registry of hospitalized patients over a 32-year period, which identified five patients with the condition out of 2,119 patients with hidradenitis suppurativa.

He and his colleagues examined clinical characteristics, pathology findings, and postoperative outcomes, and assessed whether HPV could be involved in the pathogenesis, since a previous study detected high risk of human papilloma virus (HPV) in such cases. They found 12 patients who were identified through medical records and the Rochester epidemiology project, of which nine were men, and 11 were of Caucasian descent.

All cases involved gluteal, perianal, or perineal skin. Seven out of 12 patients had post-operative squamous cell carcinoma recurrence, which caused death in these patients, despite being treated with surgical excision, and aggressive surgical and radiotherapeutic intervention. Three other patients died of unknown causes, but it was not associated with high-risk or low-risk HPV, so unlike the previous study, the Mayo researchers found no link to HPV. They concluded that this condition was more common in men with chronic gluteal, perianal and perineal hidradenitis suppurativa.

“This study is relevant now and in the future, because of the very high mortality rate of SCC and also because of newer HPV observations in SCC,” Dr. Kohorst said. “HPV has been noted especially recently to occur in several subtypes of SCC, such as verrucous SCC, as well as SCC locations — oral, perianal/digital, and cervical. Our study, however, did not find an association with HPV infection, as was reported in a previous series.”

The researchers noted that mean duration of HS before SCC development was 28.5 years (with a range of 15-53 years). Although HS is more commonly prevalent in women than in men, Dr. Kohorst said disease severity has been correlated with older age, male sex, and smoking history. In their study of 590 patients, most patients with surgical disease were men (57%). And nine out of twelve patients with SCC in HS were men, which he said concurs with the data from other published reports where almost all patients were men.

“Though rare, invasive SCC arising in HS carries a very high risk of death,” he said. “It is re-assuring to note that it is infrequent, but if detected it must be treated very aggressively.”

Reference
PODCAST SERIES

Treating Rhinophyma

Where can patients turn when initial treatments fail?

For patients with rhinophyma, the condition affects not only appearance, but may also decrease nasal valve function. What solutions are available to treat this patient population when oral and topical agents are not effective?

In this podcast, Matthew Mahlberg, MD offers perspectives on making the move to treat rhinophyma with physical modalities such as CO₂ laser technology.

listen to this podcast at dermatologytimes.com/laser-tech
While no cure exists for cutaneous lymphoma except for bone marrow transplants, “there is still a need to find new treatments (such as monoclonal antibodies).”

Martine Bagot, M.D., Ph.D., Saint Louis Hospital, Paris

New treatments for cutaneous lymphoma

Targeted monoclonal antibody therapies offer hope for patients

GALADRIEL BONNEL, PH.D., FNP | Staff Correspondent

Bone marrow transplant still the go-to treatment for cutaneous lymphoma.

Three potential new treatments offer hope for patients.

Trials are underway for pembrolizumab, brentuximab and mogamulizumab.

Cutaneous lymphomas are rare, heterogeneous diseases, even though most patients present with Sézary syndrome. Survival is stage-related, meaning that patients with an advanced stage of disease have a poor prognosis.

At the European Academy of Dermatology and Venereology (EADV) Congress this week in Paris, Dr. Martine Bagot, professor and researcher in the dermatology and Inserm U976 research departments of Saint Louis Hospital in Paris, emphasized that no cure exists for these patients except for allogeneic bone marrow transplantation, “nevertheless there is still a need to find new treatments.”

NEW HOPE
She shared examples of treatments which represent new hope for cutaneous lymphoma patients using targeted monoclonal antibodies, which we know either augments the patient’s immune system (as in melanoma), or destroys the tumor T-cells as specifically as possible. In the future, Bagot says, the ideal treatment would combine these.

ANTI-PD-1 (PEMBROLIZUMAB)
A small phase two, single-arm study in 24 patients with mycosis fungoides and Sézary syndrome stages IB-IV treated with an anti-programmed death-1 (PD-1) agent (pembrolizumab) showed an overall response rate of 38%. However, it was difficult to predict which patients would respond to treatment, and a worsening effect (skin flare reaction) occurred in 40% of patients. According to Dr. Bagot, other types of monoclonal antibodies still need to be developed.

BRENTUXIMAB VEDOTIN
Dr. Bagot then described an open-label randomized phase three multicenter trial among 131 patients with CD30-positive cutaneous T-cell lymphomas (published in 2017). Patients were randomized to receive brentuximab vedotin (an anti-CD30 antibody–drug conjugate approved to be used after at least one previous systemic therapy) or physician’s choice (methotrexate or bexarotene). Progression-free survival was higher and quality of life was most improved for patients receiving brentuximab vedotin. A notable side effect was peripheral neuropathy, which is reversible but may take time. “So this is treatment is not definitely curative, but maybe not to be used long-term because of toxicity,” she said.

MOGAMULIZUMAB
Results from a humanized anti-C-C chemokine receptor 4 (CCR4) antibody, mogamulizumab (approved in the U.S. but not yet in Europe), have been recently published in an open-label phase three randomized controlled trial. Patients were randomized to receive mogamulizumab or vorinostat. Progression-free survival and global response were better, Dr. Bagot said, particularly in patients in an advanced stage. She also states that the commonly reported adverse events are well-known.

Dr. Bagot highlights that other trials are underway, and that these are exciting drugs which may prove useful in the future treatment of cutaneous lymphomas.

Reference
Pr. Martine Bagot, M.D. “Cutaneous lymphomas” (abstract #D2T01.1H), EADV 2018 Meeting, Paris, France, September 14, 10:10-10:40a.m.
For patients with large skin areas affected by actinic keratoses (AK) and severe photodamage, daylight photodynamic therapy preceded by ablative fractional laser as opposed to microdermabrasion was found to be significantly more efficacious in clearing actinic keratoses at three months, according to a prospective, randomized study.

The study, which appeared in the *British Journal of Dermatology* on August 17, consisted of 18 patients, all of whom were treated in two side-by-side treatment areas randomized to either microdermabrasion followed by daylight photodynamic therapy (MD-dPDT) or ablative fractional laser followed by dPDT (AFL-dPDT).

AFL-dPDT treated areas achieved an AK clearance rate of 81% versus 60% for MD-dPDT. Furthermore, AFL-dPDT led to fewer new AKs and superior improvement in dyspigmentation and skin texture.

Co-investigator Emily Wenande, M.D., Ph.D., and a fellow in the department of dermatology at Bispebjerg University Hospital in Copenhagen, Denmark where the study was conducted between August and November 2016, says the study describes the first head-to-head comparison of the two different physical skin pretreatments — microdermabrasion and ablative fractional laser — as methods to enhance the efficacy of dPDT therapy for AK and severely photodamaged skin.

“In patients with large areas of field cancerized skin and multiple hyperkeratotic AKs, many topical field treatments demonstrate unsatisfactory efficacy, in part, due to insufficient penetration of topically applied photosensitizers,” Dr. Wenande says. “A range of physical skin pretreatments, such as curettage, microneedling, microdermabrasion and AFL have been used in the clinic to enhance photosensitizer delivery during photodynamic therapy. Unfortunately, not enough evidence exists on their relative efficacy or tolerability.”

For the first time, the investigators demonstrated that AFL-dPDT attained superior clearance of AKs and improved appearance of photodamage/cosmesis compared to MD-dPDT. However, local skin reactions in the days following treatment were also intensified using AFL-dPDT.

Bispebjerg University Hospital was also the site of a previously published study in *JAMA Dermatology* in 2017 that compared a range of physical skin pretreatments and their impact on photosensitizer uptake and local skin responses in healthy volunteers.

“In that study, we found that AFL, and, to a lesser extent, microdermabrasion, provides high protoporphrin (PpIX) fluorescence and more intensified skin reactions compared to pretreatment with microneedles, curettage and nonablative fractional laser,” Dr. Wenande says.

Based on the previous study, the investigators had an initial indication that AFL might be more effective than microdermabrasion for increasing photosensitizer uptake/effects. “But for improvement in photodamage, we were struck by the noteworthy impact AFL-dPDT had on skin texture and dyspigmentation compared to MD-dPDT,” Dr. Wenande says.

Patients also preferred AFL-dPDT over MD-dPDT because the AFL pretreatment procedure was less painful. Increased intensity of the local skin responses to AFL-dPDT was however also observed, with three patients treated on the chest developed culture-verified local staph infection.

“Overall, we concluded that while efficacious in patients with difficult-to-treat, severely photodamaged skin and multiple AKs, both MD-dPDT and AFL-dPDT treatments were more aggressive than standard dPDT,” Dr. Wenande says.

Two study limitations are the small sample size and short follow-up time.

Despite dPDT combined with AFL being a potent and effective treatment for AK and photodamaged skin, increased local skin reactions may limit its use in some patients.

“Future studies should pursue adjusting AFL and PDT parameters to maintain a high degree of efficacy with less downtime, in order to target a larger patient population,” Dr. Wenande says.\[Disclosures: Galderma Nordic provided a research grant.]

**References**


**Quick TAKES**

Daylight photodynamic therapy preceded by ablative fractional laser was found to be more effective than microdermabrasion followed by PDT at clearing AK.

A previous study indicated that microdermabrasion and ablative fractional laser would be effective for increasing photosensitizer uptake/effect.

While ablative fractional laser was found to be more effective, both pretreatments were more aggressive than standard photodynamic therapy.
European GDPR impacts U.S. patient privacy

Bob Kronemyer | Staff Correspondent

**Quick Takes**

EU regulation on data protection has put pressure on U.S. legislators and regulators to heighten protections within our own borders, experts say.

The experience of EU firms, consumers, healthcare providers and patients with GDPR over the next few years will factor into experts’ recommendations for reform here in the U.S.

The European Union’s (EU) General Data Protection Regulation (GDPR), which went into effect May 25, 2018, is designed to harmonize data privacy laws across Europe, protect and empower all EU citizens’ data privacy, and reshape the way organizations across the region approach data privacy, according to the education website eugdpr.org.

The website states that GDPR’s mention of “personal data” encompasses “any information relating to an identifiable person who can be directly or indirectly identified in particular by reference to an identifier.

This definition provides for a wide range of personal identifiers to constitute personal data, including name, identification number, location data or online identifier, reflecting changes in technology and the way organizations collect information about people.”

Organizations not in compliance face hefty fines.

The ramifications for healthcare organizations, both abroad and in the United States, are significant. Here’s some valuable information.

“Physicians and healthcare facilities should be aware that healthcare records are more valuable than credit card data.”

Foad Nahai, M.D., F.A.C.S., Emory University School of Medicine, Atlanta

**1. IS GDPR APPLICABLE TO U.S. PRACTICES?**

The GDPR, technically, only applies to the EU, says Anthony Orlando, Ph.D., of the College of Business Administration, California State Polytechnic University, Pomona.

“But, in practice, it has had a significant effect on the U.S., as multinational corporations have adopted similar policies in both regions for simplicity and to minimize the risk of violating the rules when they conduct cross-border business,” he tells Dermatology Times.

Dr. Orlando is also the lead author of a new article entitled “The New Privacy Crisis: What’s Health Got to Do with It?”, which was published online in the American Journal of Medicine on October 24. In the article he notes that the GDPR’s central philosophy is to notify consumers about what companies are doing with their data, require their explicit consent, and allow consumers to view and delete the data they don’t want.

In contrast, the Health Insurance Portability and Accountability Act (HIPAA) only applies to healthcare providers and insurance plans and their “business associates,” but that technologic innovation has opened the gates to further access of information, including fitness trackers and direct-to-consumer genetic testing services.

“HIPAA does not apply to any of these digital actors,” Dr. Orlando wrote.

**2. WHAT ARE THE IMPLICATIONS OF GDPR FOR U.S. PRACTICES?**

In an editorial about the GDPR and data breaches in the Aesthetic Surgery Journal, Foad Nahai, M.D., F.A.C.S., of the department of surgery at Emory University School of Medicine in Atlanta, notes that “the widespread adoption of GDPR privacy standards by international companies may be a case of the ‘Brussels effect,’ in which European laws and regulations are used as a global baseline.”
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Study: Market competition impacts generic pricing

BOB KRONEMYER | Staff Correspondent

Market competition plays a role in controlling the costs of medications, according to a recent analysis. Topical dermatologic formulations associated with more than six manufacturers were found to cost less than those associated with only one or two manufacturers.

Over the past decade, drug prices for commonly prescribed dermatologic medications have exceeded the rate of inflation and reimbursement. In a retrospective cost analysis of the most commonly prescribed topical dermatologic generic drugs published online in JAMA Dermatology, researchers explored the association between drug price and market competition among the most commonly prescribed topical generic medications in dermatology.

“Our study helps us understand some of the reasons that we have seen dramatic increases in the costs of topical medications over the past several years,” says principal investigator Arash Mostaghimi, M.D., M.P.A., M.P.H., of the department of dermatology at Brigham and Women’s Hospital in Boston.

Previous research by Dr. Mostaghimi and his associates demonstrated a large increase in the price of topical steroid medications over the past few years. “This has resulted in increased costs for Medicare and for individual patients,” Dr. Mostaghimi tells Dermatology Times. “We wanted to evaluate whether reduced market competition may play a role in these higher prices.”

Studies have shown a role for robust generic market competition in reducing drug prices among non-dermatologic medications, the authors wrote. However, the connection between competition and the costs of topical dermatologic generic drugs has not been assessed.

The investigators used the National Average Drug Acquisition Cost (NADAC) database to identify the price per unit for 166 topical dermatologic formulations, representing 70.5% of the total Medicare Part D dermatologist-coded claims for 2015.

Annual drug prices were collected for the years 2013 to 2016, with inflation-adjusted for 2016. The three most widely used topical dermatologic generic drugs by Medicare beneficiaries were formulations of topical steroids (56%), acne and rosacea medications (17.2%) and antifungal medications (16.4%).

Drug formulations with only one or two manufacturers during the study period showed a 12.7% median increase in price, while those formulations with more than six manufacturers had a 20.5% median decrease in price.

More specifically, formulations with one or two manufacturers were 20.6% more expensive than those with three or four manufacturers; 19.5% higher than with five or six manufacturers; and a staggering 33.2% higher than with more than six manufacturers.

“There was a statistically significant inverse association between the percentage change in drug price and median number of manufacturers,” the authors wrote.

Price discrepancies were particularly alarming for the 65 generic topical steroids. Formulations by one or two manufacturers had a 67.8% higher median cost compared to three or four manufacturers; 65.3% higher than for five or six manufacturers; and 62.2% higher than with more than six manufacturers.

Moreover, when the number of manufacturers remained unchanged between 2013 and 2016, formulations with one or two manufacturers had a 25.2% higher median drug price than formulations produced by three or four manufacturers; a 35.5% higher drug price than formulations from five or six manufacturers; and a 32.1% higher price than formulations from more than six manufacturers.

In addition, roughly 25% (n=28) of the topical dermatologic generic medications increased in price by more than 100% during the study period, and about 8% (n=9) increased in price by more than 500%.

Of these nine medications that rose in price by more than 500% from 2013 to 2016, more than half (n=5) were formulations of clobetasol. And three of the medications had price increases that exceeded 900%: econazole nitrate cream 1%, clobetasol ointment 0.05% and hydrocortisone solution 0.1%.

Based on the study’s findings, the authors advocate robust market competition to control the costs of generic drugs produced by a limited number of manufacturers.

“The FDA should continue to advance policies that reduce barriers to market entry for generic manufacturers,” Dr. Mostaghimi says. “Allowing importation of foreign medications for drugs with fewer manufacturers may curtail costs. Policies to automatically substitute the cheapest same-class, same-vehicle agent for a given prescription may allow patients to have access to cheaper medications without delays.”

The authors acknowledge, however, that one possible reason for the disconnect between the number of manufacturers and drug price is that drug prices do not adjust immediately after a change.
Steps to mitigate cyber risk

JOSEPH E. GUIMERA | Contributing Author

Quick Takes

The use of cloud-based platforms to send, receive and store patient data in teledermatology adds security risks.

Steps to minimize mobile use risk include password protection, encryption, anti-malware software and remote data deletion programs.

To minimize risk with cloud-based platforms, assess the vendor’s level of security using the questions here as guidelines.

One often-cited benefit of teledermatology is convenience. The patient can connect with his or her dermatologist by smartphone, tablet, or computer at any time and from anywhere, and receive personalized treatment.

But teledermatology’s heavy reliance on mobile devices and use of cloud-based platforms to send, receive, and store patient data create additional security risks. The patient’s active role in the process adds further complications.

MOBILE DEVICES

While mobile devices facilitate communication between patient and provider, they are also aggressively targeted by cybercriminals, as they often lack even basic security. Mobile devices frequently lack password protection or firewalls, have out-of-date operating systems and applications, and are unencrypted. Downloaded apps may contain malware or security vulnerabilities. Mobile devices are also easily lost or stolen. The use of mobile devices on unsecured wireless networks presents another security risk.

Several steps can be taken to minimize the risks of mobile devices:

- Regularly update the operating system and installed apps.
- Enable password protection and use strong passwords or biometric authentication.
- Enable encryption to make the data on the device unreadable.
- Install a firewall to protect against unauthorized connections.
- Install anti-malware and antivirus software to protect against malicious applications, viruses, spyware, and malware attacks.
- Install a remote wiping program to delete data in case the device is lost or stolen.
- Avoid connecting to unsecured wireless networks.

While it is common for many providers to use their personal devices for practice business, using dedicated devices is more secure.

CLOUD-BASED PLATFORMS

Most teledermatology practices use a third-party, cloud-based platform to communicate with patients and store and access patient data. These cloud-based platforms offer many benefits, including simplicity of use (patients and providers can create an account and access the platform often with just a username and password), lower costs (pay a monthly fee rather than having to buy and maintain in-house servers and software), flexibility, and access from anywhere.

But as with mobile devices, with these benefits come security risks.

Using a cloud-based platform means that you are using a third-party’s software to access data stored on that third-party’s server, rather than on your own computer.

Hosting data with a third-party vendor increases risk, as the vendor is itself subject to data breaches, account hijacking, insider threat, malware, denial of service attacks, and data loss.

Using these platforms requires clear understanding of the vendor’s security. To determine a vendor’s level of security, consider these questions:

- Does the vendor maintain its own servers or lease space on another vendor’s server?
- Is the patient data stored on one server or is it spread over several servers?
- Does the vendor offer dedicated servers, or will the practice share a server with other organizations?
- What are the vendor’s security policies and procedures?
- Does the vendor regularly patch and update its software and vulnerability protection?
- Has the vendor suffered any data breaches in the past, and if so, how has it responded?
- Is the vendor insured against data breaches?
- Will the vendor’s employees have access to patient data, and under what circumstances?
- Will the vendor provide a service level agreement that covers information security and privacy, network and data access, threat and risk analysis, disclosure and breach reporting requirements, and provides for auditing or verifying compliance?
- Is patient data fully encrypted while stored on the vendor’s servers?
- Does the platform use end-to-end encryption for transmitting data?
- Does the platform use secure logins for both provider and patient with unique identifiers (rather than just a username) and multi-factor authentication (rather than just a password)?
- Does the platform allow a user’s access to be restricted or limited?

A RISK-BASED APPROACH

Every teledermatology practice is different, both in operation and objectives. The risks outlined above are general risks that may apply differently to each practice. Creating an effective cybersecurity program requires understanding and addressing the specific risks to a practice. This can be accomplished by following three steps:

1. CONDUCT A CYBER RISK ASSESSMENT

Similar to a HIPAA risk assessment, a cyber risk assessment examines four areas:

- What assets need to be protected?
- What are the threats to those assets?
- What are the practice’s vulnerabilities to the identified threats?
- What would be the effect of a realized threat to those assets?

The results of the assessment can be used to prioritize risk and determine what areas require the greatest allocation of resources.
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2. CREATE STRONG POLICIES AND PROCEDURES
Once the risks are identified, create written policies and procedures detailing how to protect the practice from security threats. Common policies include:

- A mobile device policy (whether use of personal devices is permitted or prohibited, what security must be installed on devices, etc.)
- Staff access policy (who can access what data, and for what reason)
- Physical security policy (building access, file storage, servers)
- Network security policy (email spam filters, firewalls, anti-virus, anti-malware)
- Roles and responsibilities of staff

As cyber threats are constantly evolving, cyber risk assessments and policies and procedures should be regularly reviewed, at least once a year.

3. PROVIDE MEANINGFUL TRAINING TO STAFF AND PATIENTS
Once completed, the policies and procedures should be shared with all staff, and used as a basis for educating staff on cybersecurity. The goal is to enable staff to understand and recognize security threats, understand how the policies and procedures relate to threats, and be aware of their responsibilities in protecting against threats.

As patients represent a security risk themselves through their potential use of unsecured personal devices, unsecured networks, or weak or shared passwords, they should also be regularly educated on the security measures the practice takes to protect their medical data, and how they can help protect their own data. This education can be started as a part of patient intake, and followed up with a short video or handout.

No cybersecurity program is completely secure, but following a risk-based plan can help mitigate the additional cybersecurity threats faced by a teledermatology practice.

Disclosures: Joseph E. Guimera is an attorney and founder of Guimeralaw Cybersecurity Advisory where he helps organizations plan, build, and execute cybersecurity programs. He can be reached at jguimera@guimeralaw.com.

Prevent cyber attacks: Don’t overlook the human element

By DEBRA A. SCHUTE

Practices typically focus on technological tools and interventions to prevent cyber attacks — 83% of physician practices report they have experienced some form of cyber attack, including phishing, hacking, and employee theft of electronic protected health information (ePHI), according to a study from the American Medical Association and Accenture, a digital strategy and consulting company.

While antivirus software and firewalls do play a critical role in cybersecurity, the human element should not be overlooked, says Uday Ali Pabrai, chief executive officer of ecfirst, a cybersecurity company. Most organizations have not done enough to improve individuals’ cyber-literacy, thus weakening practices’ readiness overall, he says.

Before your practice becomes a cybercrime statistic, consider the following ways to strengthen your defenses:

EXPLAIN THE STATISTICS
Practices must convince employees that training is integral to protecting patients, the practice, and the employees’ jobs, says Brian Yeaman, M.D., a solo primary care physician in Oklahoma and health IT expert.

Even a minor security incident can cause substantial business disruption, Dr. Yeaman says. And it’s not unheard of for disgruntled patients to make privacy or security complaints without merit, says Kate Borten, a Massachusetts-based security and privacy consultant. “I worked with one office in which a patient angry about his bill made a privacy complaint as a means of wigging out of financial responsibility,” she says.

Because there was a complaint, HHS investigated and therefore required the practice to provide copies of all of its policies, procedures, and evidence of staff training. “Through no fault of its own, the practice was really on the spot [to prove compliance],” Borten says. “Practices have to convey to employees that it doesn’t take much to become involved in an investigation and they need to be prepared.”

SELECT A SECURITY OFFICER
Success starts at the top. Therefore, it’s crucial that practice leadership and security officials be devoted to protecting the organization from cyber-threats, says Borten.

First, practices of all sizes should recognize that they are required to have a privacy official and a security official. Borten advises appointing practice privacy and security officials (who can be the same or separate individuals, according to HIPAA regulations) who welcome the role. “You really want somebody who cares, who’s interested in privacy and security, and who will go out and actually seek information to understand his or her responsibilities.”

Security personnel should be provided with some work time to fulfill those responsibilities, Borten notes. Those duties include developing training content, which may be in the form of slides, paper handouts, or other media that can be shown to HHS in the case of an audit or complaint.

REDUCE INTERNAL RISKS
Especially in small practices, the trustworthiness of employees can be easily taken for granted. However, a 2018 survey from Accenture found that 18% of healthcare employees said they would be willing to sell confidential data to unauthorized individuals. Furthermore, about a quarter of those surveyed said they knew someone in their organization who had sold their login credentials or similar information.

To create an environment that protects your practice, Dr. Yeaman recommends, for example, shutting down USB ports on all equipment to prevent individuals from downloading data onto another device. Network activity monitors should also be set to track any aberrant patterns that could signal inappropriate activity.

While anonymous reporting of suspected data misuse or noncompliance with security policies can be challenging, it’s essential that leadership supports reporting without retaliation, says Borten.

Reporting procedures should be included in training, she says. Both the HIPAA privacy and security rules require that covered entities have a written process for discovering and reporting even suspected misuse or breach of patient information.
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in market concentration.

Nonetheless, because of alleged collusive practices among oral and topical generic drug manufacturers, the authors urge authorities and lawmakers to remain vigilant to prevent anticompetitive activities like price fixing by drug manufacturers.

“Given the association between drug price and market competition, police changes aimed at destining the need for physicians to devote time monitoring drug costs. Physicians should continue to be aware of the heterogenous increases in drug price,” Dr. Mostaghimi says. “If a cheaper drug will work, it should be substituted for the more expensive medication when possible.”

One of the limitations of the current study is that the NADAC pricing database relies on voluntary national surveys, which may not fully represent all retail pharmacies in the United States. Future studies may also benefit from a longer study period.

Further, by limiting the study to Medicare prescribing, popular drugs for younger patients like acne medications were likely not captured for analysis.

Going forward, Dr. Mostaghimi and his colleagues are evaluating other factors that impact drug costs.

Disclosures: Dr. Mostaghimi reports no relevant financial disclosures.

Reference


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Therefore, Dr. Nahai encourages healthcare professionals to be cognizant of the GDPR standards and their potential impact.

“Given the increasing awareness of privacy risks in the United States, the GDPR has put pressure on U.S. legislators and regulators to heighten protections within our own borders,” says Dr. Orlando in the interview. “Against this pressure, the U.S. must weigh the value of data collection and information sharing to spur beneficial innovations. The experience of EU firms, consumers, healthcare providers and patients with GDPR over the next few years will factor into experts’ recommendations for reform here in the U.S.”

### IS GDPR A GOOD IDEA?

“Believe there is a step in the right direction,” Dr. Orlando says. “Currently, too few consumers and patients understand how much of their personal health information is at risk and in what ways it can be used to harm them. The GDPR makes an important distinction for ‘data concerning health,’ which cannot be processed without either the data subject’s explicit consent or a necessity to provide healthcare or protect public health. As we point out in our article, however, the GDPR does not address several other risks associated with personal health information, nor does it protect consumers who do not understand what they are consenting to. In some cases, transparency might not be a sufficient safeguard.”

### WHAT OTHER STIPULATIONS OF GDPR SHOULD CLINICIANS BE AWARE OF AND HOW BEST CAN THEY NAVIGATE THOSE MEASURES?

“In this rapidly evolving world of technological innovation, clinicians should consult legal counsel to ensure that their data collection, protection, usage and sharing procedures comply not only with the letter of the law but also with the best practices prescribed by the U.S. Department of Health and Human Services, as well as leading data privacy experts, such as the Future of Privacy Forum,” Dr. Orlando says. “It is not only important for their own liability but also for the efficacy of the medical profession, as this attention to patient privacy increases public trust in the healthcare system,” Dr. Orlando says.

“It has been reported that 95% of all breaches of enterprise networks enter through a spear phishing attack (an email with a malicious attachment or link),” writes Dr. Nahai, who is also editor-in-chief of Aesthetic Surgery Journal. “Physicians and healthcare facilities should be aware that healthcare records are more valuable than credit card data.”

Fortifying vulnerable systems with numerous antivirus engines can dramatically increase malware detection rates. Besides preventive technology, “You and virtually every member of your staff, as well as your software consultants need to be actively engaged in the war against security breaches,” Dr. Nahai writes.

### WHAT ARE FUTURE CONCERNS ABOUT PATIENT PRIVACY?

“These issues will not go away. They are only going to grow in importance as the technology improves,” Dr. Orlando says. “The support of the medical community is critical to ensure an ethical, inclusive, productive balance is struck between innovation and privacy for generations to come.”

Disclosures: Dr. Orlando reports no relevant financial disclosures.

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demonstrating regional variability in filaggrin processing that may actually begin to answer one of the “holy grail” questions in dermatology: why AD appears in some areas (such as the cheeks of infants) rather than others.15

Building on this concept of barrier dysfunction as “leaky skin”, the stakes have been raised by the increasingly clear notion that the ineffective skin barrier of AD may directly lead to the development of allergic sensitization (so-called transepidermal sensitization) in animal models.16 In humans, it is strongly suggested to be equally true,17-20 and further trials are ongoing to verify this hypothesis.19

In the meantime, practical clinical guidelines have changed based on this notion: while previous guidance suggested delaying introduction of allergenic foods into the diet of high-risk children, those with AD are now encouraged to eat peanuts between the ages of 4-6 months of age (making sure to first allergy test those with severe AD and/or egg allergy). This has been shown to significantly decrease the development of peanut allergy.20,21

Perhaps most exciting, however, is the idea that skin barrier dysfunction is so central to AD, that artificial augmentation of this barrier may actually prevent the development of AD in the first place, not to mention the secondary diseases such as food allergy as discussed above. Two studies have demonstrated cutting the development of AD in high-risk patients by some 30-50% with moisturization.22,23 The implications of these trials are ongoing to verify this hypothesis.19

In the years ahead, we will see a different understanding of AD and its burden. The history of dermatology has been one of ever increasing co-morbidities to AD. In recent years, we have seen the realization that AD is a systemic disease, and that many organs are affected by AD. This understanding has been bolstered by the realization that the treatment of AD, while important, is not the only reason we need to treat AD. The quality of life issues associated with AD are so significant that many patients consider their quality of life worse than that of a patient with advanced cancer.24

A NEW STANDARD OF CARE

All of these advancements in understanding and therapies are leading to a new standard of care: raising the bar so that the goal—for those who have missed the prevention window—is to get patients clear, keep them clear safely, and maximize improvements in quality of life. In the past several years, the significant, perhaps shocking to the uninitiated, impact on quality of life of AD has been further elucidated.25-27 Detrimental effects on sleep, work, school, leisure activities, and psychological well-being have all been described, with more recent papers also reporting a majority of patients experiencing pain in addition to the itch as yet another burden.28

An increasingly nuanced understanding of the pathogenesis of psoriasis has developed over the past decade, altering its perception from an unpleasant rash that patients must tolerate, to a truly systemic disease that is effectively treated with safe, incredibly effective agents. This decade of psoriasis has allowed for a new bar to be set in terms of therapeutic expectations.29 Finally, similar leaps in understanding AD are occurring and, as such, we must ensure that the aggressive approach to psoriasis is likewise followed with AD as our treatment armamentarium begins to fill in.

After many decades of darkness, we enter into a new era of AD armed with new knowledge and new tools that will hopefully bring light.

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Ortho Dermatologics launches tretinoin lotion

Ortho Dermatologics has launched ALTRENLO LOTION (tretinoin 0.05 percent) for the treatment of acne vulgaris in patients ages 9 years old and older, marking the first time tretinoin has been available in a lotion formulation.

Altreno Lotion was approved by the FDA in August following the conclusion of two multicenter, randomized, double-blind, vehicle-controlled phase three studies. Altreno Lotion demonstrated statistically significant reductions in inflammatory and noninflammatory lesions compared to vehicle, according to the company. Altreno Lotion resulted in significantly greater efficacy compared to vehicle for treatment success, defined as at least a two-grade improvement from baseline and clear-to-almost clear in acne severity by Evaluator Global Severity Score.

The most common adverse reactions were erythema, pain, dryness, irritation, and exfoliation. These occurred in 11 percent of patients and greater than vehicle. The lotion is provided in a formulation with hyaluronic acid, collagen, and glycerin.

"Altreno Lotion has demonstrated the efficacy of a tretinoin with a proven tolerability profile. Greater tolerability may help improve adherence to skin care regimens, which may ultimately lead to better patient outcomes," said Joshua Zeichner, M.D., director, Cosmetic and Clinical Research in Dermatology, Mount Sinai Hospital, New York City.

FOR MORE INFORMATION: ortho-dermatologics.com

Alaffia launches Baobab Rooibos

Alaffia, a maker of socially responsible and cruelty free skin care products, has launched the BAOBAB ROOIBOS COLLECTION, a collection of facial and other skin care products for dry skin.

The collection, which is based on the use of antioxidiant and vitamin C-rich baobab and rooibos oils, includes four products:
- The Dry Skin Cooling Gel Hydration Mask containing prickly pear, watermelon, and apple extracts.
- The Dry Skin Cleanser, an enriched cream cleanser with fermented holy basil, known for calming and brightening properties.
- The Dry Skin Day Crème designed to be used daily to hydrate, fortify, and balance skin. It contains baobab and rooibos, watermelon fruit extract and rose geranium oil.
- The Dry Skin Oil Concentrate for day and night use. It includes melon seed, lavender and geranium oils.

“Our new Baobab Rooibos Collection provides an effective yet luxurious, all-day hydration regimen for consumers with extremely dry skin," said Danya Fields, Alaffia’s senior vice president of marketing and product development. "We developed this collection of face care products after seeing voids in the marketplace and hearing our consumers’ concerns about sensitive, tight, uncomfortably dry skin that is prone to showing signs of aging, stemming from dehydration.

FOR MORE INFORMATION: alaffia.com

Cutanea Life Sciences launches Xepi Cream

In November, Cutanea Life Sciences announced the launch of XEPI (oxefoxacin) Cream 1%, an FDA-approved treatment for impetigo in pediatric and adult patients.

It is the first new topical prescription treatment for impetigo in the last 10 years.

Xepi is a non-fluorinated topical quinolone indicated for the treatment of impetigo due to Staphylococcus aureus and/or Streptococcus pyogenes. It is applied topically twice daily for five days.

Impetigo, a highly contagious bacterial skin infection commonly treated by dermatologists and pediatricians, most often affects infants, young children and those involved in close contact sports or living in enclosed environments. It is estimated to account for approximately 10% of the skin problems treated in pediatric clinics in the U.S.

Xepi has been shown to be active against most isolates of S. aureus (including methicillin-resistant isolates) and S. pyogenes, both in vitro and in clinical infections. In clinical trials, it was found to be negligibly absorbed, safe and well tolerated in pediatric and adult patients.

FOR MORE INFORMATION: cutanea.com

Sonoma Pharmaceuticals launches Ceramax

In October, Sonoma Pharmaceuticals launched CERAMAX SKIN BARRIER LOTION. The lotion is also currently available as a cream.

“We continue to receive positive physician and patient feedback on our current Ceramax cream, which we launched two years ago," said Tom Devine, Sonoma Pharmaceutical’s dermatology division general manager. “We are now expanding this product line for those patients who prefer prescription-level barrier protection benefits in a lighter lotion formula.”

Both Ceramax products contain skin-enriching technology that helps manage dry itchy skin, minor skin irritations, rash and inflammation caused by various skin conditions, including atopic dermatitis and allergic contact dermatitis. This technology contains selected lipids and a lipid precursor designed to easily penetrate the layers of the skin by blending with the natural lipid building blocks.

Ceramax lotion is now available with a physician prescription throughout the United States.

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There are several factors to consider when deciding to keep or terminate a payer contract. Underperformance by a payer often offsets a better fee schedule. Here are five reasons to consider terminating or renegotiating an agreement.

Overflowing Appointment Schedules
If you have more patients than you have room or time, you have leverage with payers that make up five percent or less of your revenues. Let the payer who pays least know they need you more than you need them. Make your issues with them—be they lengthy credentialing, a high denial rate, and/or low fees—their issues. These are the issues that must be addressed to your satisfaction if you are to remain in their networks.

Arbitrary Downcoding
Some payers have been sneaky in automatically or arbitrarily downcoding E/M services. Level 5 services are downcoded and paid at level 4 prices, and level 4 services get the level 3 treatment. Think about it this way: Level 4 office visits (new and established) generally pay 45-55 percent more than their level 3 counterparts. I don’t see this often, but when I do, I call the payer right away. I consider such behavior egregious and would be willing to terminate an agreement over unwarranted downcoding.

Credentialing Issues
There are opposing incentives when it comes to credentialing new providers. The sooner a practice gets a provider credentialed, the sooner it can bill and get paid. Conversely, the longer it takes a payer to credential a provider, the more money they save since the practice may not bill for services delivered by un-credentialed providers. If your state does not have credentialing timelines, your practice could lose thousands of dollars due to credentialing delays. My recommendation is to make it an issue with your payers. Share your expectations in advance of bringing in a new provider and let your provider representative know their performance will be part of your next renegotiations.

Authorization
It costs the practice more to do business with a payer who needs an authorization for seemingly everything. Unless a payer can prove that my practice has much higher utilization of a procedure or test than our peers, I fight to make the authorization go away since the authorization process’s only result is costing us more money.

Excessive Denials/Higher Accounts Receivable
Some payers deny more claims than others. Ask your staff to show you the first pass denial rate for your payers—that is, what percent of initial claims submitted to each payer are denied. Ceteris paribus, a payer who denies more claims is cutting into your bottom line since a denied claim requires additional work by your billing department.

While looking at denial rates, take the extra step to look at why claims are being denied. You may find patterns—incomplete/incorrect registration, for example—that can be improved internally.

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