Top 20 Trending Stories 2020

COVID-19 dominated 2020’s headlines but advances in medicine, patient care were “must” reading for dermatologists and their teams.

MORGAN PETRONELLI | Associate Editor

The year 2020 was a rollercoaster ride from start to finish. From the onset of the COVID-19 pandemic to new safety protocols and a rise in the use of personal protective equipment (PPE), last year tested the will and dedication of healthcare workers to their industry—and most importantly—their patients.

Despite every challenge 2020 brought, the dermatology industry made major strides in advancing treatment options and improving patient care—from groundbreaking US Food and Drug Administration (FDA) approvals to the latest top-line research and creation of revolutionary technology.

While COVID-19 may have been top-of-mind since early last year, it wasn’t the only topic on the minds of dermatologists, dermatologic surgeons, their teams and other healthcare providers working in the specialty. Based on analytics, here’s what Dermatology Times™ readers see as 2020’s hottest trends.

COVID-19-related telehealth broadens patient population

CHERYL GUTTMAN KRADER, BS PHARM | Staff Correspondent

The shift to telehealth visits during the height of the first wave of the COVID-19 pandemic effected noteworthy changes in the sociodemographic and clinical characteristics of patients presenting for care at a tertiary referral center, according to a recently published study.¹

The findings provide insights for understanding the impact of the pandemic on dermatology and, moving forward, for determining which patient populations may benefit most from access to teledermatology and how to optimize its delivery, says Avery LaChance, MD, MPH, director of COVID-19-RELATED TELEHEALTH CONTINUES ON PAGE 41.

SKIN CANCER

PRAME distinguishes benign, malignant melanocytes in a lesion

ILYA PETROU, MD | Staff Correspondent

PREFERENTIALLY EXPRESSED ANTIGEN IN MELANOMA (PRAME), an immunohistochemical staining technique, may help clinicians differentiate between benign and malignant melanocytic populations in the same lesion. A recent study found this PRAME STAINING CONTINUES ON PAGE 33.
NEW YEAR, NEW OPPORTUNITIES

by MIKE HENNESSY, SR

With COVID-19 vaccinations already being rolled out and hopes for a return to a more connected, social world growing, 2021 holds the promise of becoming a year to remember for all the right reasons.

This issue of Dermatology Times® showcases the therapies, research, treatment approaches and practice management strategies that are likely to create game-changing breakthroughs in controlling—and perhaps, one day, curing—skin diseases. On the horizon are new biologics, oral medications and devices that will increase efficacy without sacrificing safety. New staining techniques could provide valuable insights into differentiating benign and malignant melanocytes within a single lesion. Multiple therapies and novel modalities may represent important strides in acne treatment. Updated guidelines provide direction on the most effective new management approaches to treating rosacea, while psoriasis studies explore expanding associations with the microbiome and the increasing role of comorbidities the disease’s development.

Dermatologists, health care providers and pharmaceutical companies used the challenges of the pandemic to develop fresh solutions for patient care. As our reports on COVID-19-related treatment and management strategies show, some of the changes required during slowdowns of the pandemic to develop fresh solutions for patient care. As our reports on COVID-19-related treatment and management strategies show, some of the changes required during slowdowns of the pandemic to develop fresh solutions for patient care. As our reports on COVID-19-related treatment and management strategies show, some of the changes required during slowdowns of the pandemic to develop fresh solutions for patient care. As our reports on COVID-19-related treatment and management strategies show, some of the changes required during slowdowns of the pandemic to develop fresh solutions for patient care.
An IL-23 inhibitor for adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

**NOTHING IS EVERYTHING**

Nothing less than the opportunity for durable skin clearance. For your patients, that’s everything.

- **DURABLE**: Most patients achieved PASI 90 at Week 16 and maintained it at Week 52. Co-primary endpoints of PASI 90 and sPGA 0/1 at Week 16, including response 4 weeks after first dose. The majority of patients achieved PASI 100 at Week 52. Reliable 3-month dosing after 2 initiation doses at Weeks 0 and 4 (150 mg per dose).

**SAFETY CONSIDERATIONS**

SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Avoid use of live vaccines in SKYRIZI patients.

Please see additional Important Safety Information on the inside spread.

Please see the Brief Summary of the full Prescribing Information on the last page of this ad.
AN IL-23 INHIBITOR FOR ADULTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

ACHIEVEMENTS AT WEEK 16 IN ULTIMMA-1 & ULTIMMA-2 (NRI)\(^2\)

<table>
<thead>
<tr>
<th>Co-primary endpoint (P&lt;0.0001)</th>
<th>PASI 90 at Week 16</th>
<th>sPGA 0/1 at Week 16</th>
<th>PASI 100 at Week 16</th>
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<tr>
<td><strong>SKYRIZI</strong></td>
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<td>8%</td>
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<td>(5/102)</td>
<td>(2/102)</td>
<td>(8/102)</td>
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<td><strong>ULTIMMA-2</strong></td>
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<td>(5/29)</td>
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NRI=Non-Responder Imputation.

Study Design: UltIMMa-1 (N=506) and ultIMMa-2 (N=491) were replicate phase 3, randomized, double-blind, placebo- and active-controlled studies to evaluate the efficacy and safety of SKYRIZI (150 mg) vs placebo over 16 weeks and biologic active control over 52 weeks in adult patients with moderate to severe plaque psoriasis. SKYRIZI (150 mg) was given as 2 subcutaneous injections at Weeks 0, 4, and every 12 weeks thereafter.\(^2\)

CONSISTENT PASI 90/100 RATES AT 2.5 YEARS IN OPEN-LABEL EXTENSION\(^4\)

INTEGRATED RESULTS FROM ULTIMMA-1 AND 2—ALL DATA ARE AS OBSERVED

Participants received treatment at Week 0, Week 4, and every 12 weeks thereafter.

INDICATION\(^1\)
SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION\(^1\)

Infection
- SKYRIZI\(^\text{®} \text{a)}\) (risankizumab-rzaa) may increase the risk of infection. Do not initiate treatment with SKYRIZI in patients with a clinically important active infection until it resolves or is adequately treated.

- In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing SKYRIZI. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, closely monitor and discontinue SKYRIZI until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis (TB)
- Prior to initiating treatment with SKYRIZI, evaluate for TB infection and consider treatment in patients with latent or active TB for whom an adequate course of

EXPLORE LONG-TERM DATA AT VIEWTHEDATA.COM
SKYRIZI® (risankizumab-rzaa) may increase the risk of severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

Prior to initiating treatment with SKYRIZI, evaluate for infection. Do not initiate treatment with SKYRIZI in patients with a chronic infection or a history of latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

In patients with a chronic infection or a history of latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

Immunizations

• Prior to initiating SKYRIZI, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with SKYRIZI.

Adverse Reactions

• Most common (≥1%) adverse reactions associated with SKYRIZI include upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

AT WEEK 52

In the randomized controlled trials, among patients who achieved PASI 90 or PASI 100 at Week 16, level of response was maintained at Week 52 by 88% (n=398/450) and 80% (n=206/258), respectively.¹

AT WEEK 136

In an observed analysis,* among patients who achieved PASI 90 or PASI 100 at Week 52 and had available data at Week 136 in the open-label extension, level of response was maintained at Week 136 by 94% (n=375/398) and 82% (n=232/282), respectively.⁴

*Analysis conducted 8/6/2019.


Please see the Brief Summary of the full Prescribing Information on the following page.
Adverse drug reactions that occurred in >1% but ≤ 10% of subjects are shown in Table 3. These reactions are generally considered to be probably related to SKYRIZI because they were present on initiation of therapy or became more frequent or severe during SKYRIZI treatment. No new adverse reactions were identified and the rates of adverse reactions were similar to those observed during the first 16 weeks of treatment. During this period, serious infections that led to study discontinuation were identified and the rate of seriously adverse reactions that led to study discontinuation was 0.7%.

Table 3. Adverse Drug Reactions Occurring in >1% of Subjects on SKYRIZI Through Week 16

<table>
<thead>
<tr>
<th>Adverse Drug Reaction</th>
<th>SKYRIZI Group (%)</th>
<th>Placebo (%)</th>
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<tbody>
<tr>
<td>Upper respiratory infection</td>
<td>40.0 (36)</td>
<td>20.0 (24)</td>
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<tr>
<td>Headache</td>
<td>40.0 (36)</td>
<td>30.0 (36)</td>
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<tr>
<td>Injection site reaction</td>
<td>30.0 (36)</td>
<td>10.0 (12)</td>
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<tr>
<td>Sinusitis</td>
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<tr>
<td>Onychomycosis</td>
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<td>Dermatitis</td>
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<td>Pneumonia</td>
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<tr>
<td>Urinary tract infection</td>
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<tr>
<td>Otitis</td>
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<td>Malaria</td>
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<td>Epistaxis</td>
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<td>Hemorrhage</td>
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<td>Itch</td>
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<td>Breast tenderness</td>
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<td>Toe ulcer</td>
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<tr>
<td>Vomiting</td>
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<tr>
<td>Diarrhea</td>
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<tr>
<td>Abdominal pain</td>
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<tr>
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<td>Nausea, vomiting</td>
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CLINICAL INSIGHTS
COVID-related telehealth expands patient base
Management strategies reach new populations.  CONTINUES ON PG. 41

SKIN CANCER
PRAME distinguishes benign, malignant melanocytes
Stain may help differentiate identify suspicious cells in a single lesion.  CONTINUES ON PG. 32
Can doctors be expert witnesses against non-physicians?

by DAVID J. GOLDBERG, M.D., J.D.

Dr. Goldberg is director of Skin Laser and Surgery Specialists of New York and New Jersey, past director of Mohs and Laser Research, Icahn School of Medicine at Mt. Sinai; and, adjunct professor of law, Fordham Law School in New York City.

Dr. Expert is a well-respected dermatologist who practices in a jurisdiction where it is perfectly legal for non-physicians to perform cosmetic laser procedures with essentially no physician supervision. Because of these permissive legal rules, many spas in the major metropolitan area where Dr. Expert practices provide energy-based device treatments. Some spas require direct onsite physician supervision of procedures; others do not.

At one such poorly supervised spa, a state-licensed esthetician performed laser hair removal on a Black woman with a laser that, ideally, was being used to treat lighter skinned individuals. Unfortunately, the woman suffered both permanent scarring and pigmentary changes. Dr. Expert has been asked to serve as an expert witness for the suing plaintiff. But he is uncomfortable in this role and has never served as a plaintiff’s expert. However, he has become disgusted with the lack of strict guidelines as to who can perform laser treatments and what supervision he believes should be required.

It is not that he has difficulty with non-physicians performing cosmetic laser treatments. He is a strong advocate of this practice as long as there is direct onsite physician supervision. In fact, both physician assistants (PAs) and nurse practitioners (NPs) perform these treatments in his practice. He accepts his role as plaintiff’s expert witness because he is certain the case will be straightforward. It is not!

Upon finding out that Dr. Expert will testify, the defendant esthetician’s legal counsel files a motion to exclude his testimony. The defendant’s attorney is fully cognizant that his esthetician client will be held to the same standard as a dermatologist performing laser hair removal.

The motion attempting to bar Dr. Expert’s testimony is based on the premise that he is not a state-licensed esthetician and therefore should not be allowed to testify against an esthetician—even if both the physician and esthetician are ultimately held to the same standard. The defendant’s attorney assumes that it will be hard for the aggrieved plaintiff to get an expert opinion from an anesthesiologist. The court disagreed based on Texas’s expert witness statute which requires that the expert 1) practice health care in a field of practice that involves the same type of care or treatment as that provided by the defendant health care provider; 2) has knowledge of accepted standards of care for providers for the diagnosis, care, or treatment of the illness, injury or condition involved in the claim; and 3) is qualified on the basis of training or experience to offer an expert opinion regarding those accepted standards of health care.

Even though the anesthesiologist was not a chiropractor, he fulfilled these requirements and his expert views were accepted.

Similarly, even though he is not a licensed esthetician, Dr. Expert uses similar methods to the defendant esthetician, his specialty overlaps and intertwines with that of an esthetician, and he is qualified to perform the same functions as estheticians. His expert testimony will be accepted.

"Similar methods, specialty overlap & qualifications are key tests."

defendant chiropractor. Mark Vicento, the injured plaintiff, alleged that Group, who was his chiropractor, was negligent in failing to comply with the standard of care. Vicento filed an expert opinion from an anesthesiologist.

Group then filed a motion to exclude the expert report. He contended that a physician was not qualified to testify as to the chiropractic standard of care because he was not a chiropractor.

The court disagreed based on Texas’s expert witness statute which requires that the expert 1) practice health care in a field of practice that involves the same type of care or treatment as that provided by the defendant health care provider; 2) has knowledge of accepted standards of care for providers for the diagnosis, care, or treatment of the illness, injury or condition involved in the claim; and 3) is qualified on the basis of training or experience to offer an expert opinion regarding those accepted standards of health care.

Even though the anesthesiologist was not a chiropractor, he fulfilled these requirements and his expert views were accepted.

Similarly, even though he is not a licensed esthetician, Dr. Expert uses similar methods to the defendant esthetician, his specialty overlaps and intertwines with that of an esthetician, and he is qualified to perform the same functions as estheticians. His expert testimony will be accepted. ◄
COVID-19 Induced Skin Challenges

by ZOE DIANA DRAELOS, M.D.
Dr. Draelos is a consulting professor of dermatology, Duke University School of Medicine, Durham, N.C.

What can be done for extremely dry hands from frequent washing? Hand washing prior to touching your nose and mouth is essential during the pandemic. However, frequent washing will remove the intercellular lipids resulting in damage to the hand skin barrier and xerosis, eventually causing cracking and bleeding of the skin. A healthy skin barrier prevents infection so dermatologists must take excellent care of their hands. It may be difficult to wear a hand cream during the day, but bedtime application is necessary. The best nighttime hand creams are high in glycerin, an excellent humectant that holds water and creates an optimal environment for overnight skin healing. They should also contain an occlusive ingredient to decrease transepidermal water loss (TEWL). This ingredient could be petrolatum, dimethicone or mineral oil. Neutrogena Norwegian Formula Hand Cream is inexpensive and widely available. Apply it to the hands and around the nails to prevent fissuring and bleeding.

It may to wise to wash hands with lukewarm instead of hot water to minimize intercellular lipid removal.

Why am I getting chin acne under my mask? The increase in chin acne from mask wearing is known as “maskne.” It is a form of acne mechanica induced by rubbing of the mask over the chin when speaking. Masks may be made of cloth, paper, textured hydroentangled fibers or a combination of materials. They are designed to fit tightly over the nose and mouth to prevent the expectoration and inhalation of airborne COVID-19. Tighter fitting masks allow less air to enter and escape around the edges, offering superior protection, but they also will rub with facial movement over the chin. “Maskne” occurs when the terminal and vellus hairs on the chin are rubbed preferentially because the hair sits above the skin. This rubbing results in mechanical irritation and the onset of acne mechanica, just like acne tends to occur on the back of susceptible individuals who wear back packs. The solution for “maskne” is to keep the chin clean and bacteria-free. This is best accomplished by wiping the chin with rubbing alcohol each morning prior to donning the mask. Also, try to select a mask that provides protection, but is long enough to allow for some chin movement independent of the mask. Test your mask by putting it on and opening and closing your mouth. If this can be accomplished without the mask rubbing your chin, then “maskne” can be reduced to the greatest degree possible.

Why are my lips always chapped under my mask and what should I do to ameliorate the problem? Many people who wear a mask now mouth breathe to move more air through the mask. This means more air is moving through the mouth than normal resulting in drying of the lips. The best solution is to wear a lip balm, but this can mess up a good mask by making it sticky inside. Lip balm is best applied at night when the lips are at rest. This allows the lips to heal by night and dry out by day. Waxes and cocoa butter are some of the best ingredients for lip balms. An inexpensive lip balm is Palmer’s Cocoa Butter Formula Swivel Stick. The stick can be rubbed over the lips at bedtime when the mask is not worn. It is also important not to lick the lips during the day or wear a mask that constantly rubs the lips. Be sure the mask is big enough to allow easy speech. Chapped lips can be minimized by proper mask selection.
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When the COVID-19 pandemic started to sweep through the United States, primary care physicians saw the number of office visits either dramatically drop or cease all together. Between lockdowns that encouraged people to stay home and fearful patients who didn’t want to risk potentially exposing themselves to the virus, many doctors saw their livelihoods threatened as appointment cancellations piled up.

As a result, the Centers for Medicare & Medicaid Services (CMS) changed Medicare payment policies to reimburse telehealth visits for a wider range of care, and some Health Insurance Portability and Accountability Act (HIPAA) restrictions were temporarily loosened to make it easier for doctors to communicate with their patients through whatever devices they chose. Prior to the pandemic, telehealth would only be reimbursed by Medicare for limited circumstances, such as patients living in rural areas with little access to care. The communication changes removed requirements for patients to only use often clunky HIPAA-compliant platforms, opening up the ability to use smartphones and increasing consumer convenience. Most private payers also followed Medicare’s lead and changed their reimbursement policies.

“The fear from patients and the change in payment policies really drove and facilitated an incredibly high spike in demand for telehealth,” says Anders Gilberg, senior vice president, government affairs, for Medical Group Management Association (MGMA).

Practices with telehealth capabilities quickly ramped up their capacity, while others installed the technology needed to conduct remote visits. According to the Medical Economics® 2020 Telehealth-EHR survey, more than 77% of doctors surveyed used telehealth for the first time because of COVID-19.

“It was a lifeline [for] medical practices,” Gilberg says. Patients and doctors alike embraced the technology and the convenience, and practices began to collect income again.

Gabe Charbonneau, MD, a family physician in Stevensville, Montana, saw the number of in-office visits plummet early in the pandemic. “We really quickly ramped up doing telemedicine, and about half of our visits were on Zoom,” he says. “Because it was such a financial hit, there was a lot of pressure for us to figure out how to get people back in for visits.”

The pandemic quickly proved that telehealth could be a lifeline for practices.

“If there’s a silver lining to this pandemic, it’s the advances made in telehealth,” says Thomas Ely, DO, president of the American Osteopathic Association.

But as the intensity of the pandemic wanes and people are becoming more comfortable returning for office visits, the future of telehealth is in question. “We had practices at one point that were almost doing 100% telehealth visits, but that has come down considerably, even though the payment policies from Medicare are still in place,” Gilberg says.

Charbonneau saw his practice’s telehealth visits drop as patients shifted back to in-office visits. “Some days, we might have two or three telehealth visits, if that,” he says.

When the public health emergency ends, so will the changes that have made telehealth viable, Gilberg says. “In order to make telehealth permanent, it needs to have a viable reimbursement structure behind it, and it’s only going to be permanent if Congress steps in at the federal level.”

While there is interest from both Democrats and Republicans in making such changes, there are unanswered questions about telehealth in the long term.
IS CONGRESS REALLY COMMITTED TO TELEHEALTH?
Despite telehealth being a great solution to some challenges the pandemic created early on, there are still questions that Congress will want answered before making any permanent changes to reimbursement for telehealth.

“I think Congress may not necessarily be looking at full, permanent telehealth coverage, but perhaps an effort to cover it beyond the public health emergency, and then [Congress can] study what its impact is on utilization, cost and quality,” Gilberg says. “It still remains to be seen whether you can provide the same quality of service without a hands-on approach with the patient.”

In some areas, such as behavioral health, where a physical examination may not be needed and a patient might be more comfortable not being in a doctor’s office, it might be an easier sell to Congress to allow for more telehealth. The same goes for chronic care management, where a simple check-in may be all that’s required.

But will telehealth still have the same appeal if it’s more difficult to use once the public health emergency is over?

“It’s likely to be limited to HIPAA-compliant platforms, so no more just dialing up your physician on FaceTime or Zoom or something like that,” Gilberg says. “Consumers today, they demand a certain degree of convenience, so there’s that aspect. Then there’s also, especially among the Medicare population, I think they trust that when they go to the doctor they prefer a hands-on examination,” he says.

Congressional leaders, who have already expressed concerns about rising health care costs, also have to wrestle with the idea that a more convenient telehealth service might be unaffordable.

“One of the reasons that telehealth expansion in Medicare hasn’t really become a reality yet is because there has been a concern that if you have broad coverage, that it would increase volume and potentially increase unnecessary care, because it’s just too convenient,” Gilberg says. “The Congressional Budget Office believes it would increase Medicare volume on the physician side and therefore potentially drive up costs of the program to the government. The other side of that is, if you can do some of the preventive things more conveniently and keep patients out of the hospital, that will, in the long run, save money from expensive in-patient types of utilization.”

Even if Congress makes telehealth policy changes permanent, reimbursement rates would likely be lower for virtual visits than they are now. “CMS determined that physicians would largely [have lower] overhead costs and fewer practice expenses when they utilize telehealth, even though I don’t think most medical practices would agree with that,” says Gilberg, who added that the reimplemention of all HIPAA requirements would necessitate using a compliant platform, which entails vendor costs to the practice. “And prior to the pandemic, telehealth visits were reimbursed less than in-person visits, at least in Medicare.”

WHAT PRIVATE PAYERS THINK ABOUT TELEHEALTH
Most private payers tend to follow whatever Medicare does when it comes to reimbursement, so when Medicare boosted telehealth, most of them did the same. While private insurers remain interested in tele-
In order to make telehealth permanent, it needs to have a viable reimbursement structure behind it, and it’s only going to be permanent if Congress steps in at the federal level.”

Anders Gilberg, senior vice president for governmental affairs, MGMA
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Future of Acne Treatment

Immunity induction therapy with antibodies, wound-healing therapies show potential.

CONTINUED

CHERYL GUTTMAN KRADER, BS PHARM | Staff Correspondent

Continuing research on the pathogenesis of acne has yielded a new understanding of underlying molecular and cellular pathways, suggesting new targets for therapeutic intervention, says Ichiro Kurokawa, MD, director, Department of Dermatology, Meiwa Hospital, and clinical educational professor, Hyogo College of Medicine, Nishinomiya, Hyogo, Japan, in collaboration with Keisuke Nakase, PhD, assistant professor, Department of Microbiology, Tokyo University of Pharmacy and Life Sciences, Tokyo, Japan.

The information on these advances is summarized in a recent article written by Kurokawa and Nakase. The authors review recent findings on the pathogenesis of acne, discuss novel treatments, and propose future therapeutic strategies. With the need for additional treatments for severe acne, Kurokawa tells Dermtology Times® that findings from immunological studies are of interest as they suggest the potential to use immunity induction therapy with antibodies.

“The future treatment for severe acne will involve biologic therapies targeting interleukin (IL)-1α, IL-1β, IL-6, tumor necrosis factor (TNF)-α, and transforming growth factor (TGF)-β,” he says. In particular, these pro-inflammatory cytokines are involved in the development of scar formation, which is the most refractory complication of severe acne. In addition, TNF-α promotes lipogenesis in human sebocytes,” says Kurokawa.

Potential Novel Acne Treatments

- Melanocortin receptor antagonists
- Insulin-like growth factor-1 (IGF-1) inhibitors
- Peroxisome proliferation-activated receptor (PPAR) modulators
- Acetylcholine inhibitors
- Topical retinoic metabolism-blocking agents
- Antimicrobial peptides
- Antioxidants
- Phosphodiesterase inhibitors
- Vitamin D analogues

CHART DATA PROVIDED BY ICHIRO KUROKAWA, MD
“Treatments that enable wound healing are also of interest as a therapeutic intervention to prevent permanent scarring in patients who suffer from severe acne,” he adds.

The discussion of recent findings on acne pathogenesis is divided into sections reviewing research pertaining to sebaceous gland biology, sebum, genetics, keratinization, hair cycles, immunology, bacteriology, and wound healing. Findings from these studies suggest numerous novel potential treatments.

Kurokawa explains that insulin growth factor (IGF)-1 is involved in acne pathogenesis through stimulation of lipid formation. In addition, research investigating genetic associations with acne development implicates the involvement of genes in the IGF family as well as in the melanocortin receptor and peroxisome proliferator-activated receptor (PPAR) families among others.

Kurokawa and Nakase note that while existing antimicrobial agents used for treating acne are believed to have benefits for both their effects on Cutibacterium acnes (C. acnes) and anti-inflammatory activity, the search for alternatives continues due to concern over the emergence of bacterial resistance with antibiotic overuse. Vaccination strategies for eradicating C. acnes and preventing its overgrowth show promise.

“C. acnes induces production of pro-inflammatory cytokines. Complete suppression of acne inflammation would likely mean combining these vaccinations with monoclonal antibody agents able to block the pro-inflammatory cytokines,” Kurokawa says.

Although there has been limited study of hair cycles in acne and a lack of research into keratin expression in the hair cycle in acne lesions, available evidence shows a shift in the hair cycle from anagen to telogen or catagen phases, according to the authors.

Kurokawa and Nakase speculate that progenitor cells in the junctional zone might differentiate towards the infundibulum and sebaceous duct cells rather than towards the lower portion of the hair follicles.

“The sebaceous gland with hypercornification in the sebaceous duct is usually atrophic without the outer root sheath below the opening of orifice of sebaceous gland,” Kurokawa says.

ALTERNATIVE THERAPY

The authors also review novel acne therapies being used in Japan this show encouraging results for the treating both nodulocystic acne and perifolliculitis capitis abscedens et suffodiens, a related treatment-refractory disorder.

Kampo is a traditional Japanese herbal medicine using Saireito. While it is used in combination with topical benzoyl peroxide, oral antimicrobial agents, and local steroid injections, there is biological plausibility for benefit of Saireito, according to the article’s authors.

“Basic research studies are needed to determine the mechanisms by which Saireito modulates acne pathogenesis, but there is evidence that its activities include effects on endogenous corticosteroids, inflammation, reactive oxygen species, coagulation, macrophages, neutrophils, and endothelial cells,” Kurokawa says.

Other treatments used for severe acne in Japan include Jyumihaidokuto and Keigairengyoto. Jyumihaidokuto contains Bokusoku, an extract from Quercus cortex that has been shown to inhibit testosterone-induced sebum synthesis. Keigairengyoto has both an antibacterial effect on C. acnes and inhibits reactive oxygen species.

Disclosure:

Kurokawa, MD and Nakase, PhD report no relevant disclosures.

Reference:


“"The future treatment for severe acne will involve biologic therapies targeting IL-1α, IL-1β, IL-6, TNF-α, and TGF-β."”

Ichiro Kurokawa, MD, director, Department of Dermatology, Meiwa Hospital, and clinical educational professor, Hyogo College of Medicine, Nishinomiya, Hyogo, Japan.
New data on the action of demodex folliculorum and the composition of the symbiotic microbiota in the skin of patients with rosacea may provide valuable insights into the pathogenesis and pathophysiology of this widespread skin disease, said Elena Araviiskaia, MD, PhD, professor, Department of Dermatology, First Pavlov Medical State University of Petersburg, St. Petersburg, Russia, in her presentation1 at the European Academy of Dermatology and Venereology 2020 Virtual Congress October 28–November 1.

Various factors have been implicated in the development of rosacea including genetics, the innate immune system, vascular hypersensitivity, ultraviolet radiation, skin barrier dysfunctions as well as the patient’s skin and gastrointestinal (GI) microbiome status. The composition of the skin’s microbiome is crucial for normal skin immune functions. The imbalance of the skin’s microbiota and/or perturbation of its microbial populations have long been thought to play a key role in rosacea, she adds. Continued research has shed some light on the role of the microbiome in rosacea, in particular the impact of demodex folliculorum. In patients with rosacea, some potentially pathogenic bacteria include Bacillus oleronius, Bartonella quintana, and Chlamydia pneumoniae, which are sometimes found within the demodex mite itself, and Helicobacter pylori (H. pylori), she adds.

Recent studies also implicate imbalances in the gastrointestinal flora in the development of rosacea symptoms. It has become clearer that rosacea is associated with systemic inflammation and with a number of GI comorbidities including celiac disease, ulcerative colitis, Crohn’s disease, irritable bowel syndrome, gastroesophageal reflux disease, and H. pylori colonization, according to Araviiskaia. Other comorbidities linking rosacea to systemic inflammation include cardiovascular comorbidities, myocardial infarction, diabetes mellitus, and hyperlipidemia.

“Of the comorbidities seen in patients with rosacea, most are associated with GI diseases,” says Araviiskaia. “Whether these are due to the breaks of the barrier of the gut or indirect via innate immunity still needs to be clarified.” She recommends that future research and studies in rosacea focus on symbiotic microbiota and the potentially pathogenic bacteria, as well as the still incompletely known impact of Staphylococcus epidermidis in the development of the disease.

“Some potentially pathogenic bacteria are now suspected of playing a larger role in the development of rosacea.”

Elena Araviiskaia, MD, PhD, professor, Department of Dermatology, First Pavlov Medical State University of St. Petersburg, St. Petersburg, Russia

References:

Disclosures:
Dr. Araviiskaia reports no relevant disclosures.

For a complete list of references, visit dermatologytimes.com

“Continued research will offer new medications and open the door for novel therapeutics including probiotics and dermocosmetics, both of which have shown good efficacy in modulating the microbiome and improving the symptoms of rosacea,” says Araviiskaia.
Combination rosacea therapy improves outcomes

Subtyping patients by lesions and signs yields better results.

SANDRA FYFE | Staff Correspondent

Combination therapy could emerge as a focus for treating rosacea in 2021. That’s according to Julie C. Harper, MD, who says the use of multiple therapies to address each sign or symptom is “the best and most comprehensive method for bringing relief to patients.”

Harper, clinical associate professor of dermatology at the University of Alabama at Birmingham, Birmingham, Ala., and one of the founding directors and current president, American Acne and Rosacea Society, outlined the benefits of and treatment regimens involving combination therapy in her presentation at the ODAC Dermatology, Aesthetic and Surgical Conference 2021 Pre-Conference Sneak Peek Inflammatory Diseases Virtual Symposium in December.

She discourages treatment solely by categorizing patients with rosacea by type (erythematotelangiectatic, papulopustular, phymatous, and ocular) because symptoms may overlap. Since patients often fit into more than one category, they require more comprehensive methods to effectively treat their symptoms, she adds.

STRATEGIES FOR COMBINATION THERAPY

To optimize combination therapy, Harper says practitioners should subtype patients by lesions and signs of rosacea rather than type. She recommends treating all manifestations of visible symptoms.

“Different lesions and signs of versation will require multiple modes of treatment,” Harper notes.

1. U.S. Food and Drug Administration (FDA)-approved therapies for treating the inflammatory papules of rosacea, the papules and pustules, including ivermectin (IVM), metronidazole, azelaic acid and sodium sulfacetamide, and sulfur and modified release doxycycline.

2. Alpha agonist brimonidine (BR) and oxymetazolinede, which are indicated for persistent facial erythema or background erythema.

3. Device-based treatments such as pulsed dye laser, intense pulsed light (IPL) or electrotherapy.

Harper stresses that the goal is not just partial improvement; it is completely clear skin. Combination therapy treatment can help patients with rosacea achieve that goal faster than single treatments and maximize remission periods while minimizing disease burden for patients, she adds.

Harper highlights evidence-based studies that support combination therapy. The first, a randomized, double-blind, placebo-controlled 2007 study conducted over 16 weeks showed inflammatory lesion counts were significantly reduced after 12 weeks with the use of both anti-inflammatory doses of modified release doxycycline and topical 1% metronidazole gel. Some patients receiving the combination therapy reported improvement as early as week 4. This reduction, seen up to week 12, was significant compared to 1% metronidazole gel used with placebo.

In 2017, researchers examined the safety and efficacy of topical IVM 1% cream and BR 0.33% in a multi-center, randomized, vehicle-controlled study. Patients had moderate-to-severe rosacea with both persistent diffuse erythema and inflammatory papules and pustules.

“Concomitant administration of IVM cream with BR gel demonstrated good efficacy and safety, endorsing the comprehensive approach to this complex disease. Early introduction of BR, along with a complete daily skin care regimen may accelerate treatment success without impairing tolerability,” study authors concluded.

However, reduction of papules and pustules and a reduction of erythema is not complete treatment, according to Harper. “Targeting inflammation in the papules and the pustules does not translate to less background erythema,” she says. “Combination therapies could target those two things.”

For ocular rosacea, she emphasizes lid care and suggests the standards from the International Workshop on Meibomian Gland Dysfunction (MGD), which recommends warm compresses, lid massage, artificial tears, topical azithromycin, topical emollient lubricant or liposomal spray, and oral doxycycline. The guidelines also include use of topical cyclopentolate and topical steroid while monitoring intraocular pressure.

“All inflammation is not the same,” she says. She emphasizes documenting every symptom that is part of the patient’s rosacea and treating it with this multi-pronged approach.

Disclosures:

Dr. Harper has reported disclosures related to Almirall, Casispolo, Cutera, El Paso, Galderma, and Cassiopeia.

References:

INDICATIONS AND USAGE
ZILXI (minocycline) topical foam, 15% is a tetracycline-class drug indicated for the treatment of inflammatory lesions of rosacea in adults.

Limitations of Use: This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, ZILXI should be used only as indicated.

IMPORTANT SAFETY INFORMATION
Contraindications
Persons who have shown hypersensitivity to any of the tetracyclines or any other ingredient in ZILXI.

Warnings and Precautions
Flammability: The propellant in ZILXI is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application.

ZILXI is a topical foam. While systemic absorption of ZILXI is low, and serious adverse reactions were not seen in clinical studies, the following adverse reactions associated with oral minocycline should be considered:

IMPORTANT SAFETY INFORMATION, CONTINUED
- Teratogenic effects, inhibition of bone growth & permanent tooth discoloration: Use during the second and third trimesters of pregnancy, infancy and childhood up to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown) and reversible inhibition of bone growth.
- Clostridioides difficile associated diarrhea (CDAD): If CDAD occurs, discontinue ZILXI.
- Hepatotoxicity & metabolic effects: If renal impairment exists or if liver injury suspected, discontinue ZILXI.
- Central nervous system effects: Patients experiencing light-headedness, dizziness or vertigo should be cautioned about driving vehicles or operating heavy machinery.
- Intracranial hypertension: Clinical manifestations include headache, blurred vision, diplopia, and vision loss. Discontinue ZILXI immediately if symptoms occur.
- Autoimmune syndromes: Symptoms may be manifested by fever, rash, arthralgia, and malaise. Discontinue ZILXI immediately if symptoms occur.
The first time minocycline has been approved for rosacea

Zilxi is the first and only topical minocycline proven effective in adult patients with inflammatory lesions of rosacea

- Evaluated in 2 large, 12-week phase 3 trials (N=1522)
- Significantly reduced inflammatory lesion count by Week 12
- Demonstrated improvement in IGA treatment success by Week 12

Proven safe and well-tolerated on already-sensitive skin

- The most commonly reported adverse reaction was diarrhea (1%)
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Delivered in a gentle, proprietary foam vehicle

- Leverages Molecule Stabilizing Technology (MST) for stable topical delivery
- Contains naturally moisturizing ingredients, is surfactant-free, and does not contain drying agents, such as ethyl alcohol

IMPORTANT SAFETY INFORMATION, CONTINUED

Photosensitivity: Patients should minimize or avoid exposure to natural or artificial sunlight while using ZILXI. Advise patients to discontinue treatment with ZILXI at the first evidence of sunburn.

Hypersensitivity reactions: Discontinue ZILXI immediately if symptoms of anaphylaxis, serious skin reactions, erythema multiforme, and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome occur.

Tissue hyperpigmentation: Discoloration of organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (teeth, mucosa, alveolar bone), sclerae and heart valves.

Superinfection: Overgrowth of non-susceptible organisms, including fungi if superinfection occurs, discontinue ZILXI and institute appropriate therapy.

Adverse Reactions

The most common adverse reaction reported during clinical trials of ZILXI was diarrhea.

IGA—Investigator's Global Assessment. *Co-primary endpoints at Week 12 were: absolute change from baseline in inflammatory lesion count and IGA treatment success. IGA treatment success was defined as an IGA score of 0 or 1 (clear or almost clear) and at least a 2-grade improvement (decrease) from baseline. Patients were included if they had 15–75 facial lesions (papules and pustules), no more than 2 facial nodules, and an IGA score of moderate or severe (grade 3 or 4) (N=1522).†

†Zilxi 1.5% topical foam contains the following inactive ingredients: soybean oil, coconut oil, light mineral oil, cyclomethicone, cetostearyl alcohol, stearic acid, myristyl alcohol, hydrogenated castor oil, white wax (beeswax), stearyl alcohol, docosanol, and propellants (butane + isobutane + propane).†


Please see Brief Summary of Prescribing Information for ZILXI on the following pages.

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INDICATION 
ZILXI is indicated for the treatment of inflammatory lesions of rosacea in adults. 

Limitations of Use: This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, ZILXI should be used only as indicated. 

CONTRAINDICATIONS 
This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines or any other ingredients within ZILXI. 

WARNINGS AND PRECAUTIONS 
• Flammability: The propellant in ZILXI is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application. Do not puncture or incinerate the containers. Do not expose containers to heat or store at temperatures above 120°F (49°C). 

• Teratogenic Effects: Minocycline, like other tetracycline-class drugs, may inhibit bone growth when administered orally during pregnancy. Based on animal data, when administered orally, tetracyclines cross the placenta, are found in fetal tissues, and can cause skeletal malformation and retardation of skeletal development on the developing fetus. 

• Tooth Discoloration: The use of tetracycline class drugs orally during tooth development (second and third trimesters of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term oral use of the tetracycline but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported with oral tetracycline drugs. Use of tetracycline drugs is not recommended during tooth development. 

• Inhibition of Bone Growth: All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued. Results of animal studies indicate that oral tetracyclines cross the placenta, are found in fetal tissues, and can cause retardation of skeletal development on the developing fetus. Evidence of embryotoxicity has been noted in animals treated orally early in pregnancy. 

• Clostridioides difficile Associated Diarrhea: Clostridioides difficile associated diarrhea (CDAD) has been reported with nearly all antibacterial agents, including oral minocycline, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated. 

• Hepatotoxicity: Post-marketing cases of serious liver injury, including irreversible drug-induced hepatitis and fulminant hepatic failure (sometimes fatal) have been reported with oral minocycline use. 

• Metabolic Effects: The anti-anabolic action of the tetracyclines may cause an increase in blood urea nitrogen (BUN). In patients with significantly impaired function, higher serum levels of tetracycline-class drugs may lead to azotemia, hyperphosphatemia, and acidosis. If renal impairment exists, recommended oral or parenteral doses may lead to excessive systemic accumulations of the drug and possible liver toxicity. Under such conditions, adjust the dose downward, and if therapy is prolonged, serum level determinations of the drug may be advisable. 

• Central Nervous System Effects: Central nervous system side effects including light-headedness, dizziness or vertigo have been reported with oral minocycline therapy. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery while on minocycline therapy. These symptoms may disappear during therapy and may disappear when the drug is discontinued. 

• Intracranial Hypertension: Intracranial hypertension has been associated with the use of tetracycline-class drugs. Clinical manifestations of intracranial hypertension include headache, blurred vision, diplopia and vision loss; papilledema can be found on fundoscopy. Women of childbearing age who are overweight or have a history of IH are at a greater risk for developing intracranial hypertension. Patients should be questioned for visual disturbances prior to initiation of treatment with tetracyclines. Concomitant use of isotretinoin and tetracycline should be avoided because isotretinoin, a systemic retinoid, is also known to cause intracranial hypertension. Although intracranial hypertension typically resolves after discontinuation of treatment, the possibility for permanent visual loss exists. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Because intracranial pressure can remain elevated for weeks after drug cessation, patients should be monitored until they stabilize. 

• Autoimmune Syndromes: Tetracyclines have been associated with the development of autoimmune syndromes. The long-term use of oral minocycline has been associated with drug-induced lupus-like syndrome, autoimmune hepatitis and vasculitides. Sporadic cases of serum sickness have presented shortly after oral minocycline use. Symptoms may be manifested by fever, rash, arthralgia, and malaise. In symptomatic patients, immediately discontinue the use of all tetracycline-class drugs, including ZILXI. 

• Photosensitivity: Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking oral tetracyclines; this reaction has been reported less frequently with minocycline. Although ZILXI did not induce phototoxicity or photoallergic responses in human dermal safety studies, patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVAB treatment) while using minocycline. If patients need to be outdoors while using ZILXI, they should wear loose-fitting clothes that protect skin from sun exposure and discuss other sun protection measures with their physician. Advise patients to discontinue treatment with ZILXI at the first evidence of sunburn. 

• Serious Skin/Hypersensitivity Reaction: Cases of anaphylaxis, serious skin reactions (e.g. Stevens Johnson syndrome, erythema multiforme, and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome have been reported postmarketing with oral minocycline use. DRESS syndrome consists of cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, and one or more of the following visceral complications such as: hepatitis, pneumonitis, nephritis, myocarditis, and pericarditis. Fever and lymphaedenopathy may be present. In some cases, death has been reported with oral minocycline use. If this syndrome is recognized, discontinue ZILXI immediately. 

• Metabolic Effects: In patients with significantly impaired renal function, higher serum levels of tetracycline-class drugs may lead to azotemia, hyperphosphatemia, and hypercalcemia. If renal impairment exists, recommended oral or parenteral doses may lead to excessive systemic accumulations of the drug and possible liver toxicity. Under such conditions, adjust the dose downward, and if therapy is prolonged, serum level determinations of the drug may be advisable. 

• Tissue Hyperpigmentation: Oral tetracyclines are known to cause hyperpigmentation. Tetracycline therapy may induce hyperpigmentation in many organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity, (teeth, mucosa, alveolar bone), sclerae and heart valves. Skin and oral pigmentation has been reported to occur independently of time or amount of drug administration, whereas other tissue pigmentation has been reported to occur upon prolonged administration. Skin pigmentation includes diffuse pigmentation as well as pigmentation over sites of scars or injury. 

• Development of Drug-Resistant Bacteria: ZILXI has not been evaluated in the treatment of infections. Bacterial resistance to the tetracyclines may develop in patients using ZILXI, therefore, the susceptibility of bacteria associated with infection should be considered in selecting antimicrobial therapy. Because of the potential for drug-resistant bacteria to develop during the use of ZILXI, it should be used only as indicated. 

• Superinfection/Potential for Microbial Overgrowth: Use of ZILXI may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue ZILXI and institute appropriate therapy. 

ADVERSE REACTIONS 

• Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In three (two Phase 3 and one Phase 2) multicenter, randomized, double-blind, vehicle-controlled trials, adult subjects applied ZILXI or vehicle once daily for 12 weeks. A total of 1,087 subjects were treated with ZILXI and 591 with vehicle. The majority of subjects were White (97%) and female (70%). Approximately 67% were non-Hispanic/Latino. The mean age was 50.0 years and ages ranged from 18 to 86 years. 

• The most common adverse reaction reported by ≥1% of subjects treated with ZILXI and more frequently than in subjects treated with vehicle was diarrhea (1% vs. 0%), respectively. 

For more information, including the FDA-approved Prescribing Information, go to www.zilxi.com
• During the two Phase 3 trials, local tolerability evaluations were conducted at each study visit by assessment of erythema, telangiectasia, burning/stinging, flushing/blushing, dryness, itching, peeling and hyper-pigmentation. Subjects treated with ZILXI had improved local tolerability signs and symptoms at Week 12 when compared with corresponding baseline values. These occurred at a similar frequency and severity as subjects treated with the vehicle component of ZILXI. The local tolerance assessments in ZILXI patients (N = 1,008, of which 897 had local tolerability assessments at week 12) by incidence rate (%) and severity grade were as follows (mild, moderate, severe): erythema (36.2%, 18.3%, 0.7%), Telangiectasia (61.0%, 18.8%, 0%), burning/stinging (13.3%, 2.8%, 0%), flushing/blushing (39.0%, 9.6%, 0.9%), dryness (23.9%, 4.0%, 0.1%), itching (20.0%, 3.3%, 0.1%), skin peeling (16.1%, 1.9%, 0.1%), and hyperpigmentation (22.5%, 2.8%, 0%). Hyperpigmentation was most frequently assessed as characteristic of inflammatory and post-inflammatory changes associated with inflammatory lesions of rosacea. In a 40-week open-label extension safety study (for a total of up to 52 weeks of treatment) [NCT03276936], frequency and severity of local tolerability signs and symptoms at Week 52 were comparable to those reported at Week 12.

DRUG INTERACTIONS
• Anticoagulants: Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.
• Penicillin: Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline-class drugs in conjunction with penicillin.
• Drug/Laboratory Test Interactions: False elevations of urinary catecholamine levels may occur due to interference with the fluorescence test.

USE IN SPECIFIC POPULATIONS
• Pregnancy: Risk Summary: Available data with ZILXI use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Systemic absorption of ZILXI in humans is low following once daily topical administration of ZILXI under maximal clinical use conditions. Because of low systemic exposure, it is not expected that maternal use of ZILXI will result in significant fetal exposure to the drug. Tetracycline-class drugs may cause permanent discoloration of teeth and reversible inhibition of bone growth when administered orally during pregnancy. Animal reproduction studies were not conducted with ZILXI. In animal reproduction studies, oral administration of minocycline administered to pregnant rats and rabbits during organogenesis induced skeletal malformations in fetuses at systemic exposures of 2,000 and 1,300 times, respectively, the maximum recommended human dose (MRHD based on AUC comparison) of ZILXI (see Data). The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.
• Data: Animal Data: Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can cause retardation of skeletal development of the developing fetus. Minocycline induced skeletal malformations (bent limb bones) in fetuses when orally administered to pregnant rats and rabbits during the period of organogenesis at doses of 30 mg/kg/day and 100 mg/kg/day, respectively, (2,000 and 1,300 times, respectively, the systemic exposure at the MRHD based on AUC comparison). Reduced mean fetal body weight was observed when minocycline was orally administered to pregnant rats during the period of organogenesis at a dose of 10 mg/kg/day (680 times the systemic exposure at the MRHD based on AUC comparison).
• Minocycline was assessed for effects on peri- and post-natal development of rats in a study that involved oral administration to pregnant rats during the period of organogenesis through lactation, at doses of 5, 10, or 50 mg/kg/day. In this study, body weight gain was significantly reduced in pregnant females that received 50 mg/kg/day (1,700 times the systemic exposure at the MRHD based on AUC comparison). No effects of treatment on the duration of the gestation period or the number of live pups born per litter were observed. Gross external anomalies observed in F1 pups (offspring of animals that received oral minocycline) included reduced body size, improperly rotated forelimbs, and reduced size of extremities. No effects were observed on the physical development, behavior, learning ability, or reproduction of F1 pups, and there was no effect on gross appearance of F2 pups (offspring of F1 animals).

NONCLINICAL TOXICOLOGY
• Carcinogenesis, Mutagenesis, Impairment of Fertility: In a carcinogenicity study in which minocycline hydrochloride was orally administered to male and female rats once daily for up to 104 weeks at dosages up to 200 mg/kg/day, minocycline hydrochloride was associated in both sexes with follicular cell tumors of the thyroid gland, including increased incidences of adenomas, carcinomas and the combined incidence of adenomas and carcinomas in males, and adenomas and the combined incidence of adenomas and carcinomas in females. In a carcinogenicity study in which minocycline hydrochloride was orally administered to male and female mice once daily for up to 104 weeks at dosages up to 150 mg/kg/day, exposure to minocycline hydrochloride did not result in a significantly increased incidence of neoplasms in either males or females. Minocycline was not mutagenic in vitro in a bacterial reverse mutation assay (Ames test) or CHO/HGPRT mammalian cell assay in the presence or absence of metabolic activation. Minocycline was not clastogenic in vitro using human peripheral blood lymphocytes or in vivo in a mouse micronucleus test.
• Male and female reproductive performance in rats was unaffected by oral doses of minocycline of up to 300 mg/kg/day (27,500 times the systemic exposure at the MRHD based on AUC comparison). However, oral administration of 100 or 300 mg/kg/day of minocycline to male rats (10,000 or 27,500 times, respectively, the systemic exposure at the MRHD based on AUC comparison), adversely affected spermatogenesis. Effects observed at 300 mg/kg/day of oral minocycline included a reduced number of sperm cells per gram of epididymis, an apparent reduction in the percentage of sperm that were motile, and (at 100 and 300 mg/kg/day) increased numbers of morphologically abnormal sperm cells. Morphological abnormalities observed in sperm samples included absent heads, misshappen heads, and abnormal flagella.

HANDLING: Allow the can to warm to room temperature before first use. Shake well before use.

WARNING: Flammable. Avoid fire, flame, or smoking during and immediately following application. Contents under pressure. Do not puncture or incinerate. Do not expose to heat or temperatures above 49°C (120°F).

For more information, including the FDA-approved Prescribing Information, go to www.ZILXI.com or call 1-844-375-3673.

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Aquaphilus Dolomiae demonstrates skin soothing properties

Researchers have found that Aquaphilus Dolomiae, a flagellated bacterium contained in Avène Thermal Spring Water, facilitates soothing and calming of the skin.
Skin microbiota takes part in the control of cutaneous inflammation. In skin diseases such as atopic dermatitis (AD), cutaneous dysbiosis and the emergence of Staphylococcus aureus contribute to the pathophysiology of the disease,” researchers wrote in a study published November 2016 in *Pharmaceutical Biology*. New therapeutic approaches consist of topical application of natural products able to counteract *S. aureus* effects through activation of resident immune cells producing anti-inflammatory cytokines such as IL-10.

They studied the possible immunosuppressive properties of Aquaphilus Dolomiae, previously unrecognized bacteria that only survive in the deepest, pure, crystalline waters of Avène, France and was first identified by Avène in 2001. Key substances of Aquaphilus Dolomiae are biotechnologically extracted through single centrifugation to create a novel ingredient counteracting the *S. aureus* secretome in the skin of children with atopic dermatitis. The researchers concluded Aquaphilus Dolomiae extract could ease atopic dermatitis severity.

Bacteria play a major role in wound repair, secreting molecules that can activate cell multiplication and stimulate skin repair. The biofilm helps to protect that wound from invasion and helps to keep that balance between symbiotic and pathogenic bacteria, according to Ted Lain, M.D., M.B.A., dermatologist and chief medical officer of Sanova Dermatology, with practices throughout Texas and Louisiana.

“This is a gram-negative highly flagellated bacteria, which is rich in molecules that support cell differentiation and keratinocyte migration for fibroblast proliferation,” Dr. Lain said. Research published in 2011 in the Journal of the European Academy of Dermatology and Venereology touted Avène Thermal Spring Water’s key component and specific properties. The clinical efficacy of the Water was demonstrated at the Hydrotherapy Center in chronic and disabling diseases such as atopic dermatitis but also in various settings in medical and post-dermatology procedures such as photodynamic therapy or photothermolysis. Avène Thermal Spring Water is a key component.”

Continued research has led to the development of a second key ingredient, Aquaphilus Dolomiae Ferment Filtrate, by completing two centrifugations. Researchers assessing the efficacy of keratinocyte migration conducted an in vitro study incubating human keratinocytes in two environments. One was exposed to Aquaphilus Dolomiae Ferment Filtrate, the other was in an untreated environment. They found keratinocyte migration and skin repair was 2.5 times faster in the Aquaphilus Dolomiae environment, according to the “Wound Healing: Inspiration from the Intestine and a New Postbiotic Active Ingredient” white paper including 2019 data on file at Pierre Fabre Research Institute. Authors of the same white paper cited an in vitro study looking at measuring antimicrobial peptide human beta-defensin 2 (hBD-2) expression in an environment with 3ug/mL Aquaphilus Dolomiae Ferment Filtrate exposure versus an untreated environment. They found hBD-2 increased by 2,121.3% compared to skin exposed to the untreated environment, which showed no significant antimicrobial peptide expression.

“Dermatologists can easily incorporate this Water as a spray to be applied after gentle cleansing, advising patients to allow the water to evaporate before moving on to the next steps in their treatment plan. Alternatively, the spray could be applied directly to inflamed or affected skin to soothe and calm the skin,” Dr. Lain said. “Avène Thermal Spring Water should be used as adjunctive care alongside your normal skin routine. Its soothing and softening effects are beneficial and can help care for all skin types including sensitive, hypersensitive and irritated skin.”

**REFERENCES**


“**This is a gram-negative highly flagellated bacteria, which is rich in molecules that support cell differentiation and keratinocyte migration for fibroblast proliferation.**”

Ted Lain, M.D., M.B.A., Sanova Dermatology, Texas and Louisiana

Human beta-defensin 2 (hBD-2) increased by **2,121.3%** with 3ug/mL Aquaphilus Dolomiae Ferment Filtrate exposure vs untreated environment.
Recent phase 3 studies\(^1\)\(^2\) investigating oral selective janus kinase 1 (JAK1) inhibitor abrocitinib (Pfizer) for the treatment of moderate-to-severe atopic dermatitis (AD) in patients ages ≥12 years met their primary efficacy endpoints. The U.S. Food and Drug Administration (FDA) granted abrocitinib a Priority Review designation and is currently reviewing the medication’s New Drug Application. Their decision is expected April 2021.

Emma Guttman-Yassky, MD, PhD, Sol and Clara Kest Professor of Dermatology and Immunology and system chair, Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, N.Y, says there is an unmet need for additional treatments. “Because of its selectivity for JAK1, abrocitinib would be expected to be associated with fewer side effects than JAK inhibitors affecting multiple isoforms of the enzyme,” adds Mark Lebwohl, MD, Dean for clinical therapeutics and chair emeritus, Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY.

**PHASE 3 PROGRAM**

Known as JADE (JAK1 Atopic Dermatitis Efficacy and Safety), the phase 3 study program investigating abrocitinib for the treatment of moderate-to-severe AD in individuals ≥12 years consists of four prospective, multinational, randomized, controlled trials. JADE MONO-1 and JADE MONO-2 randomized a total of nearly 800 patients ages ≥12 years 2:2:1 to abrocitinib 100 mg, abrocitinib 200 mg, or placebo. JADE TEEN included 287 adolescent patients ages 12 to <18 years who were randomized 2:2:1 to the abrocitinib 100 mg, abrocitinib 200 mg, or placebo. JADE COMPARE enrolled 838 adults aged ≥18 years. It compared the same dosages and placebo but included dupilumab in an active control arm.

Eligibility criteria for all studies in the JADE program required that participants have an Investigator’s Global Assessment (IGA) rating ≥3, Eczema Area and Severity Index (EASI) score ≥16, ≥10% body surface area involvement, and Peak Pruritus Numerical Rating Scale score ≥4. JADE MONO-1 and MONO-2 trials enrolled patients who had an inadequate response to treatment with medicated topical therapy or required systemic therapy. Patients in JADE COMPARE and JADE TEEN were on standardized background topical therapy, which other participants were not.

The primary outcome visit in all of the JADE studies was at 12 weeks and assessed co-primary endpoints of 1) proportion of patients achieving an IGA of clear (0) or almost clear (1) and a 2-point or greater reduction from baseline, and 2) proportion of patients achieving a ≥75% change from their baseline EASI score. Data from all studies showed abrocitinib to be associated with rapid reduction of itch, with some patients seeing improvement within 24 to 48 hours. In addition, the percentage of patients achieving a clinically significant reduction in itch by week 2 in the JADE COMPARE study was significantly higher among patients treated with abrocitinib 200 mg than for those receiving dupilumab.

**NO SERIOUS SAFETY SIGNALS**

In the JADE MONO studies, the most frequently reported treatment-emergent adverse events (AEs) that appeared dose-related and occurred more often in the abrocitinib 100 mg and 200 mg groups compared with placebo were nausea and headache. Rates of serious AEs were similar in the abrocitinib and placebo groups. Abrocitinib-treated groups had low rates of AE-related study discontinuations and infections.

Treatment with abrocitinib with some early dose-related decreases in median platelet counts that returned toward baseline with continued treatment. One patient in JADE MONO-2 discontinued treatment with abrocitinib 200 mg because of thrombocytopenia, but the platelet count returned to normal and treatment was restarted without a recurrence.

Results from the JADE MONO-1 and JADE MONO-2 have been published in peer-reviewed literature.\(^1\)\(^2\)

**Disclosures:**

Drs. Guttman-Yassky and Lebwohl are consultants and investigators for Pfizer and other companies that market or are developing treatments for atopic dermatitis.

**References:**

For a list of references see dermnetologytimes.com.
A new generation of therapeutics nearing approval and groundbreaking research exploring factors ranging from genetics to comorbidity associations could move the focus of plaque psoriasis treatment from control to cure within 5 to 10 years, according to a panel of experts speaking on the Dermatology Times® Viewpoints video program.

The anticipated launches of new biologics and an oral therapy in the next several years point to ongoing opportunities to treat this skin disease more effectively while maintaining safety standards, they say.

Panelists April W. Armstrong, associate dean of clinical research, Keck School of Medicine at the University of Southern California, Los Angeles, Calif., Andrew Blauvelt, MD, MBA, president of the Oregon Medical Research Center, Portland, Ore., and Erin E. Boh, MD, PhD, FAAD, professor and chairman, Joseph Chastain Endowed Chair of Clinical Dermatology, Tulane University School of Medicine, New Orleans, La., joined moderator Andrew F. Alexis, MD, MPH, chair of the Department of Dermatology, Mount Sinai Morningside and Mount Sinai West, New York City, N.Y., in presenting a strategic look at the opportunities and challenges ahead in a series of videos developed for dermatologytimes.com on “The Changing Treatment Landscape of Plaque Psoriasis.”

**CURRENT STANDARDS OF CARE**

“The old paradigm for treating patients with psoriasis involving more extensive body surface area (BSA) was going from phototherapy to oral systemic therapy to biologics. In the last 3 to 5 years, that shifted to thinking about biologics, oral therapies, and phototherapies concurrently,” says Armstrong. “Now, a key recommendation is to consider biologics as one of the first-line treatments for most patients with moderate-to-severe plaque psoriasis.”

Systemic therapies have an added role in treatment regimens for patients with psoriasis and psoriatic arthritis (PsA). “If a patient has psoriasis but also PsA, then we really want to think about systemic treatments that can target both,” says Armstrong.

- Tumor necrosis factor (TNF) inhibitors etanercept, adalimumab, certolizumab, and infliximab, all of which are U.S. Food and Drug Administration (FDA)-approved for both psoriasis and PsA.
- Interleukin (IL)-17 inhibitors secukinumab and ixekizumab, both FDA-approved for psoriasis and PsA, and brodalumab, approved for psoriasis in the United States but also for PsA in other parts of the world.
- Interleukin (IL)-23 inhibitors guselkumab, tildrakizumab, and risankizumab. Guselkumab, recently gained approval for PsA.

**BSA AND BEYOND**

“I’m not stuck on BSA,” says Blauvelt. “I’m looking at a little bit broader use of biologics compared to just the BSA criteria. I find that I can get a drug for most of my patients that meets one of these criteria: failure of a topical, BSA greater than 10%, or special area involved. That fits with some new recommendations that the International Psoriasis Council has put forth on treating patients.”
We’re looking at strategies to knock down this disease permanently.”

Andrew Blauvelt, MD, MBA, president of the Oregon Medical Research Center, Portland, Ore.

Comorbidities “absolutely influence my choice,” he adds. PsA tops that list. Blauvelt estimates 40% to 50% of patients in his practice have PsA, significantly higher than the 25% to 33% typically reported. “My class of choice is actually IL-17 blockers,” he says. “I consider TNF blockers as the second line for my patients with PsA because the data are comparable in joint data with TNFs and IL-17s. We also see the skin data and safety profile being better for IL-17s.” The other major comorbidity is heart disease. “It’s common with more severe psoriasis and less common with more mild disease. Any patient with psoriasis with over 10% BSA is at risk for heart disease, according to Blauvelt.

“I don’t necessarily go with class. I try to think about clearing psoriasis to zero,” says Blauvelt. “It’s pretty rare for me to use a TNF blocker. I favor IL-17 blockers if the patients have PsA and IL-23 inhibitors if they don’t,” he adds.

WHAT’S NEXT?
Looking to the future, Armstrong predicts further development of agents with a higher efficacy not only in the skin but also in the joint. “We have a long way to go in treating psoriatic arthritis,” she says. “We still use ACR20 as our bar. That aspect of psoriatic disease will need to be addressed better with newer therapies,” she adds. “We will also see newer agents in different classes of topical and oral therapies that work very differently from traditional therapies. These medications would address the needs of patients who prefer oral therapies and those who have limited psoriasis and want safe, effective topical therapies.”

Additional IL-17 and IL-23 inhibitors will likely be approved in 2021 or shortly thereafter, forecasts Blauvelt. A new oral therapy that blocks the molecule TYK2 also may launch soon. “It’s not going to be close to the best biologic therapy, but for those looking for oral therapies, it’s going to go to the head of the class, ahead of apremilast, methotrexate, cyclosporin, and acitretin,” he says.

However, as effective as these new therapies are, they all require continued use, he adds. “That’s starting to change. ‘We’re going to be using the C[cure]-word more in the next 5 to 10 years,’” says Blauvelt, who serves on the National Psoriasis Foundation’s Scientific Advisory Committee and is involved with its Milestones to a Cure initiative.

SAFETY PROFILES AND STRATEGIES

Biologics as a group have a good safety profile, which has proven consistent as patients use these medications over the long term. But practitioners need to weigh various risk factors.

Tumor necrosis factor (TNF) inhibitor medications. “They aren’t for everyone,” says Erin E. Boh, MD. Special consideration may be needed for patients with severe congestive heart failure, those with morbid obesity; those with first-degree relatives who have multiple sclerosis (MS) since this medication can induce or unmask MS and, as a group, can deregulate, and those at risk for reactivation of tuberculosis and hepatitis B. Less common adverse events (AEs) include increasing or inducing elevations in liver tests and “a very slight increased risk” of malignancy, particularly squamous cell carcinoma. Boh recommends additional blood work and more vigilant monitoring than that required for third-generation biologics for patients at risk.

Ustekinumab or the interleukin (IL)-12/23 inhibitors. Both have a very good safety profile, Boh says. Key concerns could include the patient’s ability to commit to the entire 12-week program for ustekinumab and also whether the patient has psoriatic arthritis. “Ustekinumab is not as good for joints as TNFs, which are first line for prominent PsA,” Boh points out.

The IL-17 inhibitors. “They’re even safer and have fewer AEs compared with the TNFs,” Boh says. However, brodalumab has a black box warning regarding increased risk of depression. Patients with psoriasis “generally are more depressed” than the general population, notes Boh, but in her experience, brodalumab does not significantly worsen the condition. However, she recommends that all patients with psoriasis be screened for depression.

Though the risk is low, IL-17 blockers could unmask or induce inflammatory bowel disease. Taking a careful history and screening would help mitigate that, she adds. These biologics may slightly increase the risk of yeast infections and candida infections, including oral candidiasis.

All classes: Hypersensitivity is a consideration across all biologics, says April W Armstrong, MD. Other potential AEs include injection site reactions, nasal pharyngitis, and upper respiratory tract infections, seen with the biologics in some patients with an increased risk compared to the placebo.

CHALLENGES REMAIN

Despite advances in psoriasis treatment, there are still a number of issues for multiple patient populations relating to medication access and affordability, as well as patient and dermatologist education. For Boh, Medicare patients are a major population with unmet needs. “The only drugs we can get are infliximab or the tilakizumab if you go through the Medicare major medical,” she says. Boh and Armstrong stress the importance of not backing down from fighting insurance companies to obtain superior treatment methods for Medicare patients.

Boh adds that pediatric patients are benefitting from a number of new treatments entering this population. But, says Armstrong, more research is needed, not on safety alone, but on long term effects. “Are we doing any disease modification in this patient population by treating them earlier?” she asks.

Doctor and patient education is another area for improvement in treating psoriasis. “Just put the patient first, just think about that human being in front of you. If it was your brother or your mother, would you want them to go on methotrexate?” says Blauvelt. “It’s a woefully low percentage of patients who need biologics are on them in this country.”
Quick Takes

New AAD-NPF psoriasis guidelines mark changes

SANDRA FYFE | Staff Correspondent

The first update in more than a decade, the most recent version of the American Academy of Dermatology (AAD)-National Psoriasis Foundation (NPF) guidelines identify some substantive changes in the management and treatment of psoriasis.

The newly released guidelines cover six topics: biologics, topical therapy, systemic non-biological therapies, management of pediatric patients, use of phototherapy, and comorbidities. Abby S. Van Voorhees, MD, highlighted these updates at the ODAC 2021 Pre-Conference Sneak Peek Inflammatory Diseases Virtual Symposium held in December.

One key change is the timeline for treatment success or failure. She used a case study of a 42-year-old male patient with psoriasis and inflammatory bowel disease who experienced a worsening flare of psoriasis despite being on adalimumab for 32 weeks to illustrate the failure in treatment caused by the biologic not working.

“A primary failure of a biologic medication is when a disease doesn’t respond to the initial course of treatment within the expected timeline,” she says. A secondary failure is when the disease responds initially, but skin clearance is lost over time. Practitioners need to understand how long to give a treatment to work and how to define what’s too short or too long, according to Van Voorhees, professor and chair of dermatology at Eastern Virginia Medical School, Norfolk, Va.

Medications vary for peak efficacy. For example, she says adalimumab has a peak efficacy at week 16. While the patient in the case study did well initially, the drug lost its efficacy and experienced secondary biologic failure. Practitioners should be aware of each drug’s efficacy timelines. For tumor necrosis factor (TNF) inhibitors, peak efficacy for etanercept is week 12; for infliximab week 10, and for adalimumab week 16. For interleukin (IL)-12/23 usteukinumab, peak efficacy is week 12; for IL-23 guselkumab it is week 16; for tildrakizumab and risakizumab week 12. Lastly for IL-17, peak efficacy is week 12.

Van Voorhees notes that psoriasis is connected to many co-morbidities, including metabolic syndromes such as obesity, hypertension, dyslipidemia, and diabetes. The risk of sleep apnea is increased, she adds. There is also an increased risk of uveitis, depression, chronic obstructive pulmonary disease (COPD), kidney disease, cardiovascular disease, sexual dysfunction, as well as cigarette smoking and alcohol abuse. Van Voorhees emphasizes the importance of screening psoriasis patients for comorbidities so patients can receive proper treatment.

Disclosures:
The author reports disclosures related to Celgene, AbbVie, Lilly, Novartis, and Janssen.

Reference:
COVID-19 studies assess effects on psoriasis

KRISTEN COPPOCK, MA | Editor, Contemporary Clinic

Recent studies have analyzed how individuals with autoimmune conditions prescribed specialty medications may be affected by the COVID-19 pandemic. Results of several studies were presented during a session of the National Association of Specialty Pharmacy 2020 Annual Meeting & Expo Virtual Experience, along with provider guidelines for managing these chronic conditions and medications with the virus.1

During the session “State of Care: Autoimmune Disorders,” presenter Kate Jelline, PharmD, CSP, MSCS, director of pharmacy operations at Ardon Health, says her health care system has had experiences in helping patients with autoimmune disorders manage their chronic conditions and medications during the COVID-19 pandemic. Some common patient questions included:

- Am I at extra risk for COVID-19 because I am taking an immune-suppressing medication?
- Are there going to be supply issues?
- What extra steps should I take to protect myself?
- Should I stop taking my medication?
- If the medication I am taking is being used in COVID-19 studies, does this mean I am protected?

Jelline says patients became interested in potential COVID-19 benefits through their current medications when the news reported that some of these drugs were being studied for possible treatment of the virus. Although all the answers are not yet known, Jelline says, she shared data from nonrandomized trials relevant to patients with autoimmune conditions.

NYU LANGONE HEALTH CASE SERIES2

In presenting the data, Jelline noted that New York is “an area that was hit very hard by the pandemic early on.” This study analyzed 86 patients with immune-mediated inflammatory disease, of whom 69% had confirmed cases of COVID-19 and 31% were highly expected to have had the virus. Overall, 72% of the 86 patients were receiving biologics or JAK inhibitors. The study results showed a hospitalization rate of approximately 11%, which the authors concluded was similar to the rate of hospitalization in the general population in New York, according to Jelline.

However, the overall incidence of hospitalization for all 86 patients was 16%. According to Jelline, the results published in the New England Journal of Medicine showed the rate of hospitalization rose above that of the general population for those patients with immune-mediated inflammatory disease who were using oral glucocorticoids, hydroxychloroquine or methotrexate.

GLOBAL RHEUMATOLOGY ALLIANCE REGISTRY CASE SERIES3

This study examined 600 cases of COVID-19 in patients with rheumatic disease, 46% of whom were hospitalized for treatment of the virus. Nine percent of the patients died.

“The authors looked at the impact of various medications and found that prednisone doses greater than or equal to 10 mg/day were associated with higher risks of hospitalization,” says Jelline.

Conversely, the use of tumor necrosis factor inhibitors (TNFi) was associated with a reduced risk of hospitalization (odds ratio [OR], 0.40; 95% CI, 0.19-0.81). However, investigators found that conventional synthetic disease-modifying antirheumatic drugs alone or in combination with biologics or JAK inhibitors were not associated with a higher risk of hospitalization (OR, 1.23; 95% CI, 0.70-2.17; and OR, 0.74; 95% CI, 0.37-1.46), respectively.

LOMBARCY, ITALY, CASE CONTROL4

This study found that patients with psoriasis who were being treated with biologics had a higher risk of testing positive for COVID-19 (OR, 3.43; 95% CI, 2.25-5.73), needing to self-quarantine at home (OR, 9.05; 95% CI, 5.61-14.61), and needing hospitalization (OR, 3.59; 95% CI, 1.49-8.63) compared with the general population.

This controlled study examined 1193 patients with plaque psoriasis, most of whom were treated with biologics. They included patients treated with IL-17 inhibitors (45.0%), TNFi (22.0%), IL-12/23 inhibitors (20.0%), PDE4 inhibitors (6.5%), and IL-23 inhibitors (5.0%).

According to the investigators, only 17 patients with PsO and confirmed cases of COVID-19 were quarantined at home, and 5 were hospitalized; no patients with PsO and COVID-19 were admitted to the intensive care unit or died. Investigators recommended that patients with PsO who are taking biologics be monitored at home through telemedicine.

CONCLUSIONS

Jelline says a better understanding of the virus and more trial data will provide clearer information for this population. For a full list of references, see dermatologytimes.com
Although there are many safe, effective treatments for actinic keratosis (AK) and skin cancers, beneficiary costs for the same procedures and provider availability differ significantly among U.S. states, reports a recent study.1

In designing the study, lead author Abdullah Aleisa, MD, Mohs Micrographic Surgery (MMS) and Dermatologic Oncology fellow at Memorial Sloan Kettering Cancer Center, New York, N.Y., and his fellow researchers set out to analyze interstate variability in Medicare spending and access to care for these treatments. Aleisa presented results at the American Society for Dermatologic Surgery 2020 Annual Virtual Meeting.1

The research team extracted information on spending on the treatments of interest and the number of Medicare providers and beneficiaries from the 2013-2014 Medicare provider Utilization and Payment Data for 13 states, encompassing 15 U.S. cities with populations over 400,000.

Data showed the average state-wide Medicare spending on AK treatment and skin cancer removal was $26.37 million and $28.18 million, respectively. Spending on skin cancer removal was highest with MMS at 79.62%, followed by destruction and excision at 11% and 8.84%, respectively. AK treatment spending was led by cryotherapy at 64.4%, followed by topical treatment and photodynamic therapy (PDT) at 31% and 4.6%, respectively.

“We found that there was a real, significant variation in the healthcare and procedure costs for actinic keratosis among the states, especially when you also account for the per-beneficiary spending not just the total Medicare spending,” says Aleisa. “We consistently found more expensive practice per beneficiary for almost all treatments.”

The study results confirmed dramatic differences in payments for topical AK treatment among states. It accounted for 18.47% of spending in Georgia but up to 56.67% in New York; for cryotherapy, from 40.76% in New York to 77.93% in the District of Columbia; and, for PDT, from 2.44% in Minnesota to 9.28% in Georgia. Similar fluctuations in pricing from state to state were also seen for skin cancer treatments.

Per-beneficiary spending for AK and skin cancer treatment demonstrated even greater variability. Here, data showed that the per-beneficiary spending for cryotherapy of AK ranged from $5.84 in Minnesota to $25.23 in Florida; for PDT, from $0.37 in Pennsylvania to $1.60 in Florida; for MMS, from $7.33 in Michigan to $29.72 in Florida; and for destruction of skin cancer, from $0.40 in Minnesota to $6.04 in Florida.

“Patient populations are definitely different in Florida and [there are] increased volumes of patients with AKs and skin cancers treated every year compared to other more northern states,” says Aleisa. “Nevertheless, that doesn’t explain why treatments should be more expensive than other states.”

Some theories suggest that differences in patient populations, environmental exposure, and patient preference be analyzed since all may account for some of the variability and play a role in the final calculus. For insurance coverages, market managers and supply chains may come into play.

VARIANCE IN ACCESS TO SPECIALISTS

Results of the study revealed that dermatologists comprised the majority of providers that billed Medicare for cryotherapy (54.68%), PDT (82.42%), excisions (74.08%), destruction (86.03%), and MMS (97.89%). Data also confirmed that dermatologists were not as available as other healthcare providers for specific therapies, highlighting the paucity of specialists for specific treatment options.

The significant variabilities regarding healthcare costs and availability of dermatologists for specialized treatments taps into a broader issue that likely can only be resolved by legislators, notes Aleisa. He recommends that future studies aim to clarify variations in Medicare spending among the states and in rural versus urban areas.

Disclosures:
Dr. Aleisa had no relevant disclosures.

Reference:
PRAME staining novel technique holds promise in distinguishing melanocyte populations of melanoma arising within nevi.

This encoded protein is now utilized in gene expression profiling tests, but the diagnostic potential is still unfolding. "PRAME is a very technically difficult stain to do. Its role is not to replace hematoxylin and eosin (H&E) staining," says Mary E. Lohman, MD, resident dermatologist, Department of Dermatology, University of San Francisco (USFC), San Francisco, Calif. "Similar to other melanocytic histological staining techniques, it is a diagnostic tool that can help differentiate between benign and malignant melanocytic cell populations and may push the needle towards or away from a diagnosis of melanoma."

Lohman, head author, presented the research at the 2020 American Society for Dermatologic Surgery (ASDS) Virtual Annual Meeting in October. She and her colleagues conducted the study to evaluate PRAME expression in nevus-associated melanoma lesions. They used the USFC database to identify all cases of melanoma and melanoma in-situ arising within a nevus over the past five years.

Each case was submitted for PRAME staining. As in prior studies, PRAME expression was graded 0–4 based on the percentage of labeled cells for each population of melanocytes, both benign and malignant. No labeling was graded 0, 1% to 25% labeling was 1+, 26% to 50% was 2+, 51% to 75% was 3+, and >76% was 4+. No staining or grade 0 was indicated as “negative,” with grade 1+ to 3+ as “intermediate,” and grade 4+ as “positive.”

Researchers evaluated 36 melanomas from the database. Results showed that 67% (24/36) of the melanomas were PRAME positive (4+), consistent with previously reported data, while no (0/36) nevi showed 4+ positivity. In addition, 81% (29/36) of nevi were completely PRAME negative compared to 17% (6/36) of melanomas. In 69% of cases (25/36), PRAME differentiated between benign and malignant melanocyte populations.

The authors observed a high rate of differential PRAME staining in adjacent benign and malignant melanocyte populations, while only two cases demonstrated identical intermediate PRAME staining for both benign and malignant populations. In PRAME-positive melanomas alone, PRAME staining differentiated all benign and malignant melanocyte populations.

“The differential density of staining in the malignant and benign components of a single lesion suggests that whatever is driving PRAME overexpression in malignant melanocytes is likely a late-stage development in the degenerative process," says Aaron Steen, MD, Department of Dermatology, Mayo Clinic, Rochester, Minn., co-author of the study. "When the burden of mutations reaches a tipping point, and a benign melanocyte starts behaving like a malignant melanocyte, this is when we see melanocytes start to overexpress PRAME."

In addition to having potential future utility in the assessment of margins following wide local excision, Steen says that PRAME might also prove useful in the assessment of frozen sections such as during micrographic surgery of melanomas on chronically sun-damaged skin.

“It is important to exercise caution when utilizing a new stain,” he says. "We know there are other benign lesions such as Spitz nevi and actinic keratoses that overexpress PRAME. Clinicians should not rely on this stain alone in the diagnostic workup of suspicious lesions. However, it is an additional tool in the toolbox for the diagnostic workup of suspicious lesions, helping to differentiate between benign and malignant melanocytic neoplasms."

Disclosures: Dr. Lohman and Dr. Steen report no relevant disclosures.


Quick TAKES

PRAME distinguished between benign and malignant melanocyte populations in 67% of melanoma cases evaluated in a recent study.
This novel staining technique may have potential for assessing margins after wide local excisions.
PRAME may be a useful adjunctive diagnostic tool alongside other modalities that differentiate among lesions at the point of becoming malignant.

I don’t think PRAME is going to be the ultimate arbiter of truth between benign and malignant lesions…however, it is an additional tool in the toolbox for the diagnostic workup of suspicious lesions.”

Aaron Steen, MD, Department of Dermatology, Mayo Clinic, Rochester, Minn.

BY THE NUMBERS

81% ➔ Percentage of nevi that were completely PRAME negative.
17% ➔ Percentage of melanomas that were completely PRAME negative.

DermatologyTimes.com JANUARY 2021
A refrigerated topical cosmetic formulation shows 90-day stability for platelet-rich plasma (PRP) and provides statistically significant improvement in facial appearance at 16 weeks, reports a new study.

Although PRP has gained popularity in aesthetic medicine as an injectable, difficulties with stability and shelf-life slowed development of an effective topical vehicle. “Degranulation of PRP must be inhibited until the topical preparation is applied to the skin,” the authors wrote.

Their research evaluated the role of platelet homeostasis in a novel PRP formulation. It also examined whether this topical vehicle could maintain platelet granule stability while delivering an effective PRP-containing anti-aging formulation.

A multi-site in vitro assessment tested platelet stability and morphology over 90 days. Researchers studied four samples: cosmetic base, PRP, cosmetic base+PRP, and cosmetic base+PRP+hydrochloric acid (HCl) activator. They stored some samples at room temperature, others at 4°C refrigeration for 90 days and tested them at set times.

Analyte concentration analysis using enzyme-linked immunosorbent assay (ELISA) demonstrated that the PRP is substantially more inactive than control conditions as evaluated by analyte concentration curves (PDGF-AB, EGF, and P-selectin).

Platelet morphology analysis using scanning electron microscopy (SEM) and light microscopy (LM) showed the PRP has less aggregation/activation over time within the cosmetic base. It also verified that refrigeration is superior to room-temperature storage.

Though well-tolerated, the vehicle must be refrigerated at all times and removed from the refrigerator only at the time of application. That resulted in a higher quality and quantity of preserved platelets compared to the control conditions at 30, 60, and 90 days and demonstrated topical clinical PRP facial benefits, conclude the authors.

A double-blind split face in vivo study (n=20) followed. This single-site study evaluated the effect of 5-7x and 2-3x baseline platelet count PRP on facial photaging.

After subjects underwent a phlebotomy, 3 mL of PRP obtained from two different harvesting methods (one to obtain 60 mL of anti-coagulated blood, a second to obtain 20 mL) was added to the vehicle.

Subjects were randomized to determine which side of the face would receive the 60-mL PRP-containing cosmetic and which would receive the 20-mL formulation. Each cosmetic used in this double-blind study had a total of 3mL of PRP or 10% PRP in the cosmetic base (BioLyte complex in SoME, Aesthetics Biomedical, Phoenix, Ariz.).

Researchers applied one bottle to the randomized right face, the other to the randomized left face twice daily. Subjects returned to the center for identical study activities at week 8 and week 16, which marked completion. Eight volunteers underwent a 2-mm punch biopsy from the randomized left or right preauricular area at baseline—2 at week 8 and 6 at week 16.

The dermatologist investigator and subjects assessed each side of the face separately for efficacy. Data showed that both preparations produced statistically significant results at week 16. Both investigator assessment and histology established parity between the 20-mL and 60-mL PRP preparations.

Disclosures:
Wooten and Rheins work for Aesthetics Biomedical, Inc, Phoenix, Ariz.
Draelos and Keller served as researchers for Aesthetics Biomedical, Inc.
Aesthetics Biomedical, Inc, funded the study.

References:

For a full list of references, visit dermatologytimes.com
Quick Takes

Finasteride may be associated with psychological adverse events (AEs), especially in male patients with alopecia under the age of 45.

Study cites reports of suicidal ideation, but found no signals for attempted or completed suicide.

There may be overreporting of AEs due to publicity in 2012 around finasteride’s side effects.

Study examines finasteride risks for younger males

JOHN JESITUS | Staff Correspondent

A recent study1 showing an association between finasteride use and psychological adverse events (AEs) including suicidality suggests that dermatologists should weigh benefits and risks carefully when considering finasteride for certain patients with hair loss, according to one expert.

Based on the study, the characteristics of finasteride may precipitate or potentiate psychological morbidities including suicidality specifically in patients with alopecia who are less than 45 years of age, says Roger S. Ho, MD, MS, MPH. He is director of resident education and associate professor in the Ronald O. Perelman Department of Dermatology at New York University Grossman School of Medicine, New York, N.Y. Ho was not involved with the study but wrote an accompanying editorial on the topic.2

“While a definitive causal association has not yet been established, dermatologists should take into consideration this potential signal and conduct a detailed, personalized risk-benefit assessment with the patient before each prescription of finasteride for our younger alopecia population,” says Ho.

Study1 authors Nguyen et al. used disproportionality analysis (specifically, case-noncase design) to detect signals of adverse finasteride reactions of interest reported in the World Health Organization’s global VigiBase database as of June 2019. Researchers identified 3282 adverse events (AEs) of interest, including 2926 reports of psychological AEs and 356 reports of suicidality. Nearly all cases involved male patients, and 70.9% of involved patients with age data available were 18 to 44 years old.

Researchers identified significant disproportionality signals for both psychological AEs (reporting odds ratio [ROR] 4.33; 95% confidence interval [CI] 4.17-4.49, and suicidality [ROR, 1.63; 95% CI 1.47-1.81] in finasteride users. Investigators found no signals for attempted or completed suicide.

In sensitivity analyses stratified by indication and age, patients younger than 45 years (ROR 3.47; 95% CI 2.90-4.15) and those with alopecia (ROR 2.06; 95% CI 1.81-2.34) had significant disproportionality signals for suicide compared to patients in the database using other alopecia drugs such as minoxidil. No suicidality signals appeared among older men who presumably took finasteride for benign prostate hyperplasia.

According to Nguyen et al., the findings raise concern that younger men with alopecia may be especially at risk for suicidality compared with the general population. “Taken together,” they wrote, “our findings suggest that the disproportional reporting of suicidality and psychological AEs in association with finasteride use could potentially be attributed to unique characteristics of the drug in young patients with alopecia.”

For example, psychological AEs could stem from the possibility that the persistent sexual dysfunction (after discontinuation of treatment) that has been associated with finasteride takes a greater toll on younger patients who had used the drug to treat a non-urological condition.

The disproportionality signals for psychological AEs and suicide among finasteride users also may stem partly from reporting bias. Sensitivity analyses showed disproportional reporting of finasteride-associated suicidality after 2012, a year that drew significant attention to a possible link between finasteride and these AEs.

Ho points out the signals for suicidality and psychological AEs identified by Nguyen et al. for finasteride only serve to stimulate further large-scale prospective pharmacoepidemiologic studies designed specifically to further evaluate these potential AEs in young patients using the drug for androgenetic alopecia. “They should not be mistaken as proof that there is a causal association between the two, as the study had some inherent biases, in particular a reporting bias due to stimulated reporting in the database,” he says.3

Disclosures:
Dr Ho reports no relevant financial interests.

References:
HUMIRA is the only FDA-approved treatment for your HS patients 

Results Your HS Patients Can See

MODERATE/STAGE II
Actual HUMIRA-treated patient achieving HiSCR

Before

After

HiSCR is at least a 50% reduction in total abscess and inflammatory nodule count, with no increase in abscesses and draining fistulas relative to baseline

Indication
Hidradenitis Suppurativa: HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

Safety Considerations
Serious Infections: Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. These infections include active tuberculosis (TB), reactivation of latent TB, invasive fungal infections, and bacterial, viral, and other infections due to opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Malignancies: Lymphoma, including a rare type of T-cell lymphoma, and other malignancies, some fatal, have been reported in patients treated with TNF blockers, including HUMIRA.
Clinically Meaningful Improvement (HiSCR) at Week 12

- In the PIONEER clinical trials, 42% (PIONEER I) and 59% (PIONEER II) of HUMIRA-treated adult patients achieved HiSCR at Week 12 (primary endpoint), vs 26% and 28% on placebo, respectively.

HUMIRA also has flare data available for HS

OCCURRENCE OF FLARE THROUGH 3 MONTHS
Pre-specified Other Secondary Endpoint in Period A

- 88% of patients on HUMIRA experienced no flares.
- 65% of control patients experienced no flares.

PIONEER I (N=307) and II (N=326) were 36-week, randomized, double-blind, placebo-controlled clinical trials in adult patients with moderate to severe HS on HUMIRA 40-mg weekly (after initial doses).

- 22% (of 100) patients who were withdrawn from HUMIRA after 12 weeks experienced flare.

Integrated analysis of PIONEER I and PIONEER II through 12 weeks

Flare: ≥25% increase in AN count and an absolute increase of ≥2 relative to baseline.

DATA LIMITATIONS

- Since PIONEER I did not reach statistical significance at the first key secondary endpoint, all endpoints in this integrated analysis cannot be regarded as statistically significant.

Safety Considerations

Other Serious Adverse Reactions: Patients treated with HUMIRA also may be at risk for other serious adverse reactions, including anaphylaxis, hepatitis B virus reactivation, demyelinating disease, cytopenias, pancytopenia, heart failure, and a lupus-like syndrome.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on the third page of this advertisement.

Please see Brief Summary of full Prescribing Information on the pages following this advertisement.

To learn more, please go to ResultsforHS.com
IMPORTANT SAFETY INFORMATION for HUMIRA® (adalimumab)

SERIOUS INFECTIONS
Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue HUMIRA if a patient develops a serious infection or sepsis. Reported infections include:
- Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before HUMIRA use and during therapy. Initiate treatment for latent TB prior to HUMIRA use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

Carefully consider the risks and benefits of treatment with HUMIRA prior to initiating therapy in patients: 1. with chronic or recurrent infection, 2. who have been exposed to TB, 3. with a history of opportunistic infection, 4. who resided in or traveled in regions where mycoses are endemic, 5. with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HUMIRA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start HUMIRA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated with rituximab who have received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of HUMIRA with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions.

MALIGNANCY
Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including HUMIRA. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including HUMIRA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn’s disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of HUMIRA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among HUMIRA-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for HUMIRA-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy, for the presence of NMSC prior to and during treatment with HUMIRA.

- In HUMIRA clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressants, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.

Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSensitivity
Anaphylaxis and angioedema have been reported following HUMIRA administration. If a severe allergic reaction occurs, stop HUMIRA and institute appropriate therapy.

HEPATitis B Virus Reactivation
Use of HUMIRA, including HUMIRA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.
- Exercise caution in patients who are carriers of HBV and monitor them during and after HUMIRA treatment.
- Discontinue HUMIRA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming HUMIRA after HBV treatment.

NEUROlogic Reactions
- TNF blockers, including HUMIRA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome.
- Exercise caution when considering HUMIRA for patients with these disorders. Discontinuation of HUMIRA should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

HEMATOlOGic Reactions
- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medicaly significant cytopenia has been infrequently reported with HUMIRA.
- Consider stopping HUMIRA if significant hematologic abnormalities occur.

CONGESTIVE Heart Failure
Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have been observed with HUMIRA; exercise caution and monitor carefully.

AUTOImmunity
- Treatment with HUMIRA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNizations
- Patients on HUMIRA should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating HUMIRA therapy.
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the infant exposed in utero. The safety of administering live or live-attenuated vaccines in infants exposed to HUMIRA in utero is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE Reactions
- The most common adverse reactions in HUMIRA clinical trials (>10%) were infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

Please see Brief Summary of full Prescribing Information on the following pages.

References:


1053x189
In clinical trials, more cases of malignancies were observed among HUMIRA users after treatment with HUMIRA, including the possible development of TB in chronic exposure to immunosuppressant therapies, may be at higher risk of developing malignancies. Consider and monitor patients closely for TB infection. Evaluate patients at risk for TB infection for prior evidence of TB infection before initiating therapy. If a patient has a positive test for latent TB infection, receive appropriate treatment before initiation of therapy with HUMIRA. In the controlled studies of all TNF blockers, the rate of active TB cases among TNF blocker-treated patients was 0.01 cases per 100 patient-years (PYs) (range 0.00 to 0.14 cases per 100 PYs). One active TB case has been reported in a clinical study of HUMIRA users.

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The safety and efficacy of HUMIRA has been established in pediatric patients 2 years of age and older. The course of HS is sufficiently similar in adult and pediatric patients to suggest the potential for similar efficacy in pediatric patients. The recommended dose in pediatric patients 12 years of age or older is based on weight. The use of HUMIRA has not been established in pediatric patients less than 12 years of age.

Geriatric Use

Adolescent Drug Use

In adult patients with ankylosing spondylitis, anti-adalimumab antibodies were identified in 4.8% (12/249) of patients treated with adalimumab. However, due to the limitation of the assay conditions, antibodies to adalimumab may be cross-reactive with antibodies to adalimumab in these patients. However, patients were not specifically studied for the incidence of severe infections and malignancies.

Use in Specific Populations

Juvenile Idiopathic Arthritis

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Quick TAKES

**Inflammatory dermatoses top primary telehealth diagnosis**

A retrospective study shows significant differences in the characteristics of patients seen by telehealth during the COVID-19 pandemic versus those seen during in-office visits 1 year earlier.

The telehealth cohort was significantly younger, more diverse racially, ethnically, and linguistically, and included a higher proportion of Medicaid recipients and fewer Medicare patients.

Telehealth patients were more likely to present for evaluation of inflammatory and hair disorders and less likely to have a neoplastic disease primary diagnosis than the in-office cohort.

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Health Policy and Advocacy, Brigham and Women's Hospital Department of Dermatology, and instructor in Dermatology, Harvard Medical School, Boston, Mass.

“It is essential that we study how the rapid expansion of telehealth throughout the pandemic impacted our patients and the practice of medicine,” says LaChance. “As a medical community, we should seek to learn as much as possible about how we can optimize telemedicine to improve patient access to dermatologic care.”

To evaluate the impact of the transition to telehealth on the practice of dermatology, LaChance and colleagues at the University of Massachusetts Department of Dermatology conducted a retrospective chart review comparing the characteristics of patients seen for in-person visits in April 2019 versus by telehealth in April 2020. The in-person cohort included 1,565 patients while 767 patients were seen via telehealth during the period.

“In April, Massachusetts was recommending that all non-emergent health care be provided by telehealth,” [increased access to in-person care opened up in late May/early June.] Focusing on the month of April gave us an opportunity to investigate which patient populations were seeking out and accessing telehealth during this unique time period,” says LaChance.

She adds, “We felt that only patients who believed they would truly derive benefit from telehealth, such as those who felt their care could not wait, their condition could be adequately managed by telehealth, or who found this mode of care to be an acceptable alternative to an in-person visit, would have transitioned to virtual care during this period of time.”

Statistically significant differences identified in the two patient populations show that patients seen by telehealth during the COVID-19 pandemic versus those seen during in-office visits 1 year earlier.

In-person cohort patients were more likely to be older, more diverse racially, ethnically, and linguistically, and included a higher proportion of Medicare recipients but a lower proportion of Medicare patients than the in-office cohort.

**INVESTIGATOR INSIGHTS**

Virtual visits for inflammatory dermatoses and hair disorders accounted for higher percentages of the primary diagnoses in the teledermatology cohort. However, skin cancer and other neoplastic disorders were most common among study group patients seen in-office. (Figure 1).

Commenting on the findings, LaChance says that the proportional increase in patients presenting for hair disorders is interesting considering a study reporting that dermatologists believe examinations for alopecia are less amenable to teledermatology.

“Hair loss is a very emotionally charged disease. Affected patients may have felt very strongly about keeping their appointment during the pandemic,” she says. “Another factor may be that certain hair loss disorders, such as telogen effluvium, which is a type of stress-induced hair loss, have increased throughout the pandemic, possibly contributing to this finding.”

LaChance says she and her colleagues “were happy to see” the uptake of telehealth by Medicaid patients. The investigators credit the broad insurance coverage of telehealth during the pandemic across multiple modalities and different types of technologies in facilitating telehealth access for patients across all backgrounds. Additionally, she notes that patients with Medicaid or in a low income bracket often face social pressures that may limit their access to in-person visits.

“The flexibility and convenience afforded by telehealth may offset the influence of a potential ‘digital divide’ and help explain the increased percentage of Medicaid patients seen by telehealth,” she says. “This is echoed by our findings in another study showing decreased no-show rates for teledermatology versus in-person visits with the most dramatic difference seen among minority patients.”

“We need to do the heavy lifting and conduct more research to understand how patients in all demographic and socioeconomic groups interface with technology and what can be done to ensure equitable access to telehealth now and moving forward,” says LaChance.

**CURRENT AND FUTURE PERSPECTIVES**

As in-person care has opened up, LaChance says that the characteristics of the patient she is seeing virtually match those of the study’s teledermatology cohort. The telehealth clinic patients are generally younger, face numerous social stressors, and have inflammatory diseases (versus concerning lesions).

“Patients and doctors together are considering multiple factors to select the mode of care for all patients.”

---

**FIGURE 1**

**PRIMARY VISIT DIAGNOSES (%) AMONG PATIENTS SEEN IN-OFFICE APRIL 2019 AND VIA TELEHEALTH APRIL 2020**

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<th>Diagnosis</th>
<th>April 2019 (%)</th>
<th>April 2020 (%)</th>
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<tr>
<td>Inflammatory</td>
<td>28%</td>
<td>49%</td>
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<tr>
<td>Infections, infestations, bites</td>
<td>6.1%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Neoplastic disease</td>
<td>36%</td>
<td>21%</td>
</tr>
<tr>
<td>Hair disorders</td>
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<td>4.8%</td>
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<tr>
<td>Other</td>
<td>7.9%</td>
<td>6.7%</td>
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Avery LaChance, MD, MPH, director of Health Policy and Advocacy, Brigham and Women's Hospital Department of Dermatology, and instructor in Dermatology, Harvard Medical School, Boston, Mass.
Tips for navigating practice challenges during COVID-19

MORGAN PETRONELLI | Assistant Editor

When the COVID-19 pandemic initially hit and restrictions were subsequently imposed, physicians had to think on their feet as to how to best protect their patients, as well as themselves and their staff. From increased use of masks to sanitizing stations and the implementation of telemedicine, the pandemic has turned the world of dermatology on its head.

Some physicians, such as George Martin, MD, dermatologist, Kihei, Hawaii, have used the pandemic’s challenges to develop innovative protocols for seeing patients in-office and virtually while keeping everyone safe and healthy.

Martin, who is also program director of the 2021 Maui Derm Live and Maui Derm Connect annual conferences being held January 25-29 in Maui, Hawaii, shares his checklist of essential advice for optimizing practice management during COVID-19:

- **Adaptability**: responding creatively to the environment presented to you.
- **Flexibility**: being nimble in your thinking and finding new solutions.
- **Innovation**: creating new protocols or adapting existing ones.

Team involvement: listening to employees for their different perspectives and ideas.

Though adaptability, flexibility and innovation are critical to creating opportunities and limiting downside, tapping into the team is also essential to success, he says. “There’s no I in team. You hire talented people. Sit down with them and listen. Your employees are exceptionally bright creative. They can offer a fresh point of view.”

**NAVIGATING COVID-19**

Martin says that his office followed Center of Disease Control and Prevention (CDC) guidelines, screened patients outside of the office, took temperatures, socially distanced and wore N95 masks in order to keep the practice running safely and efficiently during the pandemic.

The office also allotted 15 minutes for every patient instead of the typical 10 minutes to allow for extra time for room sterilization. The extra time also meant that no one would feel rushed and patient contact in the corridors with staff and other patients could be minimized.

Martin says because of this due diligence, his practice had no staff shortages due to the pandemic and both team members and patients remained healthy and safe.

**ONGOING CHALLENGES**

While COVID-19 remains a concern in Maui, Hawaii, where he practices, Martin says the virus is not as prevalent in Hawaii as it is in states such as New York and South Dakota.

Despite this, he reports a 10% to 15% decrease in patient volume when the practice only saw life-threatening emergencies. Soon after, his practice implemented telemedicine as a modality to see patients, but that came with its own learning curve, according to Martin.

“COVID-19 slowed us down initially for about 6-8 weeks,” says Martin. “Coming out of that, we realized that telemedicine for dermatology was really just a screening tool for us, like triage. But it allowed patients to connect so that they didn’t feel like they were left out there stranded,” says Martin.

He adds that most of his telemedicine appointments ended with patients having to come into the office for in-person exams. Most follow-ups were conducted via phone rather than telemedicine.

**COVID-19 telehealth CONTINUES FROM PAGE 41**

of care that is best for each patient individually. We are improving access to care and the patient experience,” she says.

Ongoing research is focusing on defining the current digital divide in the dermatology patient population, evaluating patient satisfaction between telehealth and in-person visits for different conditions, and understanding how telehealth has improved access to care for different patient populations. Recognizing that patient populations differ depending on practice characteristics, LaChance is hopeful that others practicing in different settings and geographic locations will conduct similar research to gain a more comprehensive picture of which patient populations and disease states would benefit from continued access to teledermatology.

She and her colleagues are using their findings to advocate for legislation to ensure broad telehealth coverage in Massachusetts.

“To date, a lot of expanded coverage for telehealth is afforded by emergency legislation and executive orders at the state and federal levels,” she adds. “Legislation is needed to ensure patients continue to have broad access to telehealth coverage now and in the future.

**Physicians must advocate for our patients to influence the next wave of telehealth legislation so we can maintain equitable access to this mode of care for all patients.”**

**Disclosures:**

There are no relevant disclosures.

**References:**


FDA Expands Toxic Hand Sanitizer List
The FDA has reported a sharp uptick in hand sanitizers containing methanol and urges the public to be vigilant of the ingredients in their hand sanitizers.

The agency initially issued a warning at the beginning of July, listing hand sanitizer manufacturers whose products had been tested by the FDA and found to contain the toxic substance. Cath O’Neill, chief scientific officer at SkinBioTherapeutics and professor of translational dermatology at the University of Manchester, discusses her latest research with Dermatology Times and explains how probiotics might be a new viable therapy for other inflammatory skin disease besides psoriasis.

Skin Symptoms Observed in COVID-19 Patients
The list of COVID-19 symptoms continues to grow. The virus can reportedly affect not only the lungs, but other internal organs as well as the senses. Now, dermatologists are observing skin reactions in patients with the disease. These reactions include “dengue fever-like rash,” a “hives-like rash,” livedo reticularis, a “measles-like rash” and pernio located on the extremities (also known as “COVID toes”).

New Picosecond Laser Treats Pigmentary Disorders in Darker Skin Types
A case report published in The American Society for Laser Medicine and Surgery shows the new 730-nm picosecond laser to have strong efficacy and safety in treating endogenous pigmentary disorders on darker skin types. The study examines two Korean patients with III-IV Fitzpatrick skin types, as well as melasma, freckles and lentigines, who were treated with 730-nm Ti:Sapphire picosecond laser (PicoWay, Syneron Candela Corp) with a pulse duration of 240 picoseconds. Researchers saw significant pigmentary reduction within one treatment session, which was well-tolerated without topical anesthesia in both patients. In the 6-week follow-up, there was no observed post-inflammatory hyperpigmentation/regression in either patient.

Probiotics for Psoriasis?
With new and emerging biologic therapies for psoriasis seemingly popping up daily, one research team is seeking a new route for treatment with the development of a probiotic specifically tailored for this inflammatory skin disease.

Cath O’Neill, chief scientific officer at SkinBioTherapeutics and professor of translational dermatology at the University of Manchester, discusses her latest research with Dermatology Times and explains how probiotics might be a new viable therapy for other inflammatory skin disease besides psoriasis.

Silicone Pads Aim to Reduce Mouth Lines
While mouth lines can be pesky and appear prematurely due to everyday activities such as drinking out of a straw or bottle, one company is aiming to combat these wrinkles and fine lines by introducing a product specifically tailored for the mouth area.

Multi-Area Pads from SilcSkin, are made of medical grade silicone and designed to promote cell growth and stimulate collagen and blood flow to help reduce fine lines and wrinkles in the mouth area.

Similar to the benefits of using silicone to treat scars, the product hydrates wrinkles, refines collagen structure and flattens out lines through prolonged use, according to the company.

Antihistamines Effective in Alopecia Areata Study
A study published in the Journal of the American Academy of Dermatology (JAAD) evaluated the efficacy of a combination consisting of antihistamines, topical corticosteroids (TCs) and superficial cryotherapy (SC) for the treatment of alopecia areata.

The study found that after seven months of treatment, 100% of patients taking antihistamines achieved major hair regrowth compared to 79.3% of patients who were treated only with TCs and SC. Also, the study’s authors report no adverse effects resulting from treatment.

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2. Silicone Pads Aim to Reduce Mouth Lines
3. FDA Expands Toxic Hand Sanitizer List
4. Antihistamines Effective in Alopecia Areata Study
5. Skin Symptoms Observed in COVID-19 Patients
6. New Picosecond Laser Treats Pigmentary Disorders in Darker Skin Types
Top 20 Trending Stories 2020

1. Alembic Launches Adapalene Gel for Acne Vulgaris

Adapalene Gel USP 0.3% (Alembic Pharmaceuticals), a bioequivalent and therapeutically equivalent to Galderma’s Differin Gel 0.3% (adapalene), has launched in the United States, according to manufacturer Alembic Pharmaceuticals.

Adapalene Gel USP 0.3% is indicated for the treatment of acne in patients ages 12 years and older. The topical treatment will be available in a 45mg gel tube, as well as a 45mg gel pump, the company states.

2. Can Botulinum Toxin Benefit Rosacea Patients?

Botulinum toxin may help address erythema and flushing in patients with refractory rosacea, according to data presented at the American Academy of Dermatology (AAD) 2020 Virtual Meeting Experience (VMX) in June 2020.

Hema Sundaram, MA, MD, FAAD, explains how botulinum toxin can be used to address erythema and flushing caused by rosacea and details other considerations providers will want to keep in mind when using this treatment in their patients.

3. How Safe Are Cosmetics?

In this Q&A, Zoe Diana Draelos, MD, explains the role of preservatives in skincare products and the general safety and efficacy of products when it comes to protecting the skin against environmental factors.

4. Topical Androgen Receptor Inhibitor Approved by FDA for Acne

Clascoterone cream 1% (Winlevi, Cassiopeia) has been approved by the FDA for the treatment of acne vulgaris in patients 12 years and older, the company announced.

The topical, a first-in-class androgen receptor inhibitor, restricts sebum production and inflammation caused by androgen hormones. The approval is backed by positive data from clinical studies investigating the topical, in which clascoterone cream 1% reduced the number of acne lesions and was well-tolerated. The most commonly reported local skin reaction reported was mild erythema.

5. First Injectable for Cellulite Approved by FDA

The FDA has approved collagenase clostridium histolyticum-aas (Qwo, Endo International) for the treatment of moderate-to-severe cellulite in the buttocks in adult women, making it the first FDA-approved injectable cellulite treatment.

The injectable combines two collagens, AUX-1 and AUX-2, which are purified enzymes produced naturally by the clostridium histolyticum bacterium. Together, the enzymes degrade types 1 and 3 collagen by releasing the fibrous septae, which leads to an improvement in appearance and texture of the skin, according to the company.

The company expects the injectable to be available to aesthetic healthcare providers in the United States beginning in Spring 2021.

6. The Promise of Laser-Assisted Drug Delivery

Hema Sundaram, MA, MD, FAAD, highlights important safety considerations to keep in mind regarding laser-assisted drug delivery.

This includes using products that are suited for intradermal injections and ensuring they are sterile. She also suggests treating localized body surface areas with laser-assisted drug delivery and considering the indications of the drug that will be delivered.

She initially presented her findings in her presentation, What’s New in Aesthetic Therapeutics, at AAD 2020 VMX in June.

7. Injection Technique Aims to Optimize Outcomes

A recent study highlighted the advantages of a novel facial rejuvenation protocol that gives special attention to the line of ligaments for optimal and more efficient lifting and volumizing in clinical outcomes.

When re-volumizing the midface, the technique allows the clinician to reposition the facial structures while injecting only a small amount of filler product. After repositioning the fat pads, the clinician can re-volumize and contour the mid-cheek and face according to treatment goals.

The technique can be used to correct the tear troughs, nasolabial folds, nasojugal grooves, and enhancing mid-face volume, according to Gabriela Casabona, MD, director of clinical research at the Ocean Clinic Marbella, Spain.

8. Medical Innovation Expands Hair Loss Treatment

A variety of topical and injectable therapies show potential for addressing hair loss in both men and women, says Matt Leavitt, DO.

Some of the therapies mentioned include clascoterone (cortexolone 17-alpha propionate; Breezula, Cassiopeia), an androgen receptor inhibitor being developed as a treatment for both male and female androgenetic alopecia (AGA), topical and oral finasteride, minoxidil, ketoconazole shampoo, platelet-rich plasma (PRP), and exosomes.

9. How to Optimize Outcomes

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Diversity Initiative
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Skinbetter Allergan, stand the aesthetic needs of all patients.

The Spectrum of Dermato-aim is to publish to address bias when it occurs. Another settings while also demonstrating how implicit bias in clinical and academic lum designed to assist with identification of ethnic diversity, equity, understanding, inclusion and respect within the plastic surgery and dermatology fields.

The initiative plans to create curriculum designed to assist with identification of implicit bias in clinical and academic settings while also demonstrating how to address bias when it occurs. Another aim is to publish The Spectrum of Dermatologic Disease, a photo atlas textbook showing the characteristics of skin conditions across racial and ethnic skin types. Also, the initiative will organize Forces of Beauty Summits to recognize diverse beauty standards amongst various ethnic and racial groups to help aesthetic providers, companies and the media understand the aesthetic needs of all patients.

FDA Accepts BLA for Tralokinumab for Atopic Dermatitis
The FDA has accepted the Biologics License Application (BLA) for tralokinumab (Leo Pharma) for treatment of moderate-to-severe atopic dermatitis (AD) in adults. The BLA acceptance follows published positive results from three phase 3 clinical studies (ECZTRA 1, 2 and 3) that investigated efficacy and safety. Tralokinumab, a fully human monoclonal antibody, works by offsetting the interleukin-13 (IL-13) cytokine, which is believed to be one of the main contributors of inflammation in AD. Results showed all primary and secondary endpoints were met across all three trials, including an Investigator Global Assessment (IQA) score of clear (0) or almost clear (1) at week 16 and a minimum change from the baseline of 75% or greater at week 16. The secondary endpoints include a change from the baseline in week 16 in SCORing of AD (SCORAD), Pruritis Numeric Rating Scale (NRS) of 4 and Dermatology Life Quality Index (DLQI). The FDA will make a decision on tralokinumab in the second quarter of 2021.

Sunscreen Controversies Confuse Consumers
Media reports about sunscreen use, including its potential harms, can lead consumers to wonder whether they should be using sunscreens for photoprotection and which product to choose. Adam Friedman, MD, says dermatologists need to be knowledgeable about the controversies and be prepared to answer patients’ questions with information that will reinforce the importance of sunscreen use.

Reference:

AbbVie Launches Hidradenitis Suppurative Education Center for Physicians
AbbVie is working to spread awareness of hidradenitis suppurativa (HS) with the launch of their new educational website tailored for physicians. By gathering feedback from various advocacy and professional organizations, the company has created a website to provide physicians with the best resources to better identify, diagnose, manage, and treat HS. The website provides a variety of HS resources that physicians can use, including patient case studies, links to organizations advancing HS education, treatment and management information, links to HS support, a differential diagnosis quiz, and an overview of causes of HS and disease progression.

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