The cost of skin cancer treatments continue to increase in the United States where a large proportion of expenditures stem from the cost of systemic agents for melanoma, shows a 2013 analysis of Medicare patients.

“We also found that the cost of treating actinic keratoses (AK) in the office, which excludes prescription coverage, was roughly equivalent to treatment costs for squamous cell carcinoma (SCC),” says Dr. Ruiz, M.D., of Brigham and Women’s Hospital in Boston, who presented findings at the Atlantic Dermatology Conference in May.

A total of $2.5 billion was spent on professional fees for skin cancer-related diagnoses.

Nearly half (49%) of total spending was for basal cell carcinoma (BCC) and SCC combined, translating into $715 million and $525 million, respectively. “This is not surprising, as they account for approximately three-quarters of all skin malignancies,” Dr. Ruiz tells Dermatology Times.

Dr. Ruiz says the overall treatment cost for AKs is striking. “It actually approaches what we are spending to treat BCCs when accounting for field therapeutics, which has been estimated in a different study by Dr. Mostaghimi from Brigham and Women’s Hospital in Boston,” Dr. Ruiz says.

In this issue, we feature a case study and quiz by Kaivon Sobhani, B.S., and, Eve Lowenstein, M.D., Ph.D., FAAD, who address Dermatofibrosarcoma protuberans (DFSP). The article begins on page 60.

(Photo courtesy of Mr. Sobhani and Dr. Lowenstein.)
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Individual results may vary.
What can be done about high drug prices?

by DR. NORMAN LEVINE, M.D.

Dr. Levine is a private practitioner in Tucson, Ariz.

We are all well aware of the disastrous turn of events over the past five years with regard to the rising cost of medications. What was once a $4 special at Walmart, now amounts to a $50 cost, if not more. Patients with significant and imminently treatable skin disorders go without therapy for financial reasons alone. Limited third-party payer formulations, high deductibles and co-pays drive many to cheap home remedies or weird nostrums advertised in late night infomercials.

Some physicians have acquiesced to what they see as the reality of modern healthcare and have stopped caring for patients who require expensive medication. One young dermatologist related that some of his former co-residents have decided to stop writing prescriptions altogether. I suspect that they are avoiding the hassle of fighting with insurance companies to get prior authorization for necessary medications and answering phone calls from irate patients complainting about unaffordable therapies.

This is a sad state of affairs for me. What we do as dermatologists is largely predicated on using myriad topical and systemic medications to relieve or cure skin diseases. Yes, we are also surgeons, dermatopathologists and cosmetic dermatologists, but we were trained to relieve suffering with medications. If that practice stops, dermatology will have little reason to exist.

In a 2015 Dermatology Times editorial, I touched on general principles of reducing costs for patients. In the following, I will update this discussion about what we can do to provide effective and reasonably affordable medical care.

Prices of generic drugs have skyrocketed over the past three to five years, but they remain a bargain compared to name-brand medications. If there is a generic equivalent, there is no reason to prescribe the branded drug, with very few exceptions. There is virtually no published data to support the notion that generic drugs do not work as well as branded medications.

Discount coupons are sometimes available for otherwise overpriced name-brand drugs. With these coupons, patients with commercial insurance may have little or no co-pays. I have several objections to these coupons:

- Many of my patients who try to use them are denied the discount for whatever reason.
- They cannot be used for patients with government insurance, such as Medicare and Medicaid.
- They are often time-limited. I still feel guilty 15 years after continuing some study patients on Enbrel who were provided the drug free of charge for three months after the study was completed...but then what?
- Someone winds up paying for these expensive drugs, usually the third-party payer. This is not a free ride and is one reason why everyone’s insurance premiums keep rising.

The costs of medications in the same class can vary widely. By choosing the least expensive alternative, the savings can be substantial. An example is class one corticosteroids, which are roughly equivalent in potency. A 60-gram tube of clobetasol cream costs approximately $130 while a 50-gram tube of betamethasone dipropionate augmented cream sells for about $54. A 60-gram tube of cindamycin 1% cream costs about $60, while a 60-ml bottle of cindamycin solution is priced at about $33. The combination product containing cindamycin and benzoyl peroxide costs $137-$160. Using each ingredient separately drops the price to about $40.

PRICE SHOPPING

Price shopping can be an effective way of finding the lowest cost for medications. There are several ways to do this online. I am familiar with two such services, both of which can save a lot of money. The most familiar to most of us is GoodRX. Anyone is eligible to participate, but using GoodRX should be limited to patients without an insurance-backed prescription plan or when co-pays or deductibles are extremely high.

After the physician writes the prescription, the patient searches GoodRX for the least expensive pharmacy price in the community, then prints a coupon for the selected drug store and is guaranteed a certain price.

For those with a high deductible drug plan, with an expensive co-pay or with no health insurance coverage, another excellent alternative is Blink Health. After enrolling online, the patient chooses the medication and the service quotes a price that is often well below retail. If the price is acceptable, the patient pays online and then fills the prescription at any one of 40,000 pharmacies nationwide.

We are all annoyed when third-party payors dictate the algorithm that must be followed in treating some ailments. My most recent frustration came when an insurance carrier insisted that a patient with severe psoriasis who had failed Humira, must first try and fail Enbrel before she could move on to a different class of biologic agent. There are good reasons, however, to use a step-wise approach in many dermatoses. In many cases the first step is safer, cheaper and might work well.

Most insurance plans require that a patient with psoriasis try and fail a first line systemic medication such as methotrexate before approving a biologic agent or Otezla. Many practitioners try to game the system by claiming that methotrexate is too toxic to use over biologic agents. If I were a benefits manager, I would respond that the drug wasn’t too toxic when biologics were not yet available. Methotrexate is a pretty effective and fairly safe medication in those with moderate-to-severe psoriasis, and is up to 95% less costly than the average biologic agent.

Our patients are being victimized by the high cost of drug therapy. We can help them by prescribing less expensive drugs and by guiding them to the least expensive places to purchase them.
For more than 15 million Americans, hyperhidrosis is more than just an inconvenience.\textsuperscript{1,2}

Primary axillary hyperhidrosis impacts a patient’s emotional and social well-being. Despite the embarrassment and low self-confidence sufferers feel, about 70% remain undiagnosed and untreated.\textsuperscript{1,3}

\textbf{85\% EXPERIENCE EMBARRASSMENT}\textsuperscript{1}
\textbf{70\% REPORT IMPACT TO DAILY ACTIVITIES AND LACK OF TOLERABILITY}\textsuperscript{1}
\textbf{63\% SAY IT LIMITS THEM AT WORK}\textsuperscript{2}

It is hard for your patients to talk about sweat.\textsuperscript{1}
Visit CheckTheirSweat.com for resources to manage hyperhidrosis.

References:

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I use social media and now I might lose my license?

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. Jam is a successful medical and cosmetic dermatologist with 25 years of experience. He has three millennial children who convinced him that it’s time to “get with the times” and use social media advertising to let the public know about his practice.

Within six months Dr. Jam has learned how to optimize various social media sources. As he thought about the strengths of his practice, he tried to focus on his outgoing personality, his love of music and the great work environment he has created for his staff.

He has always enjoyed singing—and sometimes even dancing—to calm his patients’ fears and anxiety. His staff often joins him in singing and dancing while he performs surgery. Dr. Jam has videotaped a series of these musical/dance surgery episodes and uploaded them onto multiple social media sites. All patients signed the requisite release for such use.

Some of his patients found this cute, other weren’t so certain. Unfortunately for Dr. Jam, several unhappy patients have come together in a chat room and decided to file various medical malpractice complaints against him for post-surgical infection and scarring that they claimed resulted from his interest in the music rather than in their own care.

They have also filed a complaint against him with the local state board of medical examiners alleging gross negligence. They are providing the videos uploaded to his social media sites as evidence of Dr. Jam’s poor care. They also cite five previous medical malpractice lawsuits against him.

Is Dr. Jam in trouble? Does a similar case exist? Will he lose his license?

CNN recently reported on an attorney representing three women in a case against an Atlanta-area dermatologist known for singing and dancing while performing surgery.

The attorney said that nearly 100 other women contacted her office to claim they, too, had suffered under the doctor’s care.

In the Atlanta case, on videos posted to YouTube, the dermatologist can be seen singing as she cuts into a patient or rapping and dancing with surgical instruments in hand during surgical procedures. At times, assistants in scrubs sashayed alongside her.

The attorney representing three of these women claimed they suffered from serious post-surgical complications due to infections. The lawsuits alleged the dancing doctor was negligent in performing treatments in such a manner. In this case, many of the women were motivated, they said, to come forward due to the dermatologist’s apparent lack of care and concern for her patients—as evidenced by a staff member’s focus on filming. At least two former patients said they identified themselves in the doctor’s video.

Since the filing of the Atlanta case, the videos have since been removed from the dermatologist’s YouTube channel. However, what has been established is that more than 20 videos were once posted to YouTube, apparently for promotional purposes.

The attorney in this Atlanta case suggested that one of the most important things a patient should do before surgery, second to checking the physician’s credentials, is research the facility where procedures will be performed.

A local Georgia plastic surgeon noted that such cases should not be tried in the press. He suggested that one does not want to rush to judgment and end up making an error that could be professionally harmful.

So, is Dr. Jam in trouble? His patients will need to prove that his singing and dancing was 1) a breach in the standard of care and 2) that breach directly led to infection and bleeding.

Although his approach to calming anxiety may not be typical, it is in itself not likely to cause him to lose a medical malpractice case or, more importantly, lose his license to practice medicine.

However, even if he has no liability, Dr. Jam has learned the obvious: that social media has both strengths and weaknesses.
FROM DRY, CRACKED SKIN TO MINOR WOUND CARE, WE’VE GOT IT COVERED.¹

Aquaphor Healing Ointment repairs the barrier and helps protect compromised skin.¹

Reference: ¹ Data on file, Beiersdorf, Inc.
Skincare for sensitive and diseased skin

by ZOE DIANA DRAELOS, M.D.
Dr. Draelos is a clinical and research dermatologist with Dermatology Consulting Services, High Point, N.C. and a consulting professor of dermatology, Duke University School of Medicine, Durham, N.C.

The skincare industry promotes products designed for sensitive skin, yet dermatologists are concerned about the use of skincare products for skin disease. Are sensitive skin products suitable for persons with skin disease? The answer is yes. Sensitive skin products that are dermatologist tested are evaluated in a panel of subjects that demonstrate sensitive skin attributes. These attributes include a defective skin barrier, enhanced immune reactivity, and increased neurosensory awareness. Since skincare products are about beauty, individual skin diseases are typically not mentioned, but a current trend in the crowded product offering arena is to single out products designed for diabetes or eczema or psoriasis patients. This is a huge step forward as this creates more awareness of these conditions.

A defective skin barrier, enhanced immune reactivity, and an increased neurosensory awareness translate into diseases that the dermatologist regularly treats. For example, eczema and atopic dermatitis are both characterized by a defective skin barrier. In addition, atopic dermatitis combines the barrier issues with enhanced immune reactivity. Rosacea is the classic disease where patients experience increased neurosensory awareness manifesting as stinging, burning, and itching. Sensitive skin panels are composed of persons with these diseases, which is why dermatologists can feel confident when recommending sensitive skin care products to subjects with skin disease.

**WHAT CLEANSERS ARE GOOD FOR ATOPICS?**
Since atopics have a defective skin barrier with staph aureus colonization, cleansing is particularly important. The special cleanser formulations most appropriate for these skin needs are the nonfoaming cleansers (CeraVe Cleanser, L’Oreal; Cetaphil Gentle Cleanser, Galderma). Nonfoaming cleansers as the name implies do not foam and do not alkalinize the skin. In atopic dermatitis, the acid mantle is felt to be especially important in infection prevention and some moisturizers for atopics are formulated at a slightly acidic pH. Normal skin will regain its acid mantle even after exposure to an alkaline cleanser within 15-30 minutes, but it can take longer in atopic skin. Nonfoaming cleansers also include mild surfactants with reduced ability to disrupt the intercellular lipids. This in turn reduces unwanted cleanser penetration from stratum corneum protein swelling. These cleansers can be used without water and simply wiped from the skin or water rinsed away. One new trend in cleansers for atopic dermatitis is the introduction of acidic low pH cleansers to decrease unwanted microbial growth. Another trend is the introduction of ceramides, triglycerides, cholesterol and free fatty acids, which are the constituents of the intercellular lipids, into cleanser formulations. While this might be beneficial, the cleanser contact time with the skin is short and must be thoroughly removed to prevent skin irritation.

**WHAT FACIAL CLEANSERS MINIMIZE ROSACEA REDNESS?**
Facial cleansers for rosacea are aimed at reducing noxious sensory stimuli, such as stinging, burning, and itching, associated with barrier damage and heightened neurosensory awareness. Avoiding skin irritation is key to prevent rosacea flares and minimize facial erythema.

Nonfoaming cleansers also include mild surfactants with reduced ability to disrupt the intercellular lipids. This in turn reduces unwanted cleanser penetration from stratum corneum protein swelling. These cleansers can be used without water and simply wiped from the skin or water rinsed away. One new trend in cleansers for atopic dermatitis is the introduction of acidic low pH cleansers to decrease unwanted microbial growth. Another trend is the introduction of ceramides, triglycerides, cholesterol and free fatty acids, which are the constituents of the intercellular lipids, into cleanser formulations. While this might be beneficial, the cleanser contact time with the skin is short and must be thoroughly removed to prevent skin irritation.

"Since atopics have a defective skin barrier with staph aureus colonization, cleansing is particularly important."
A BRIGHT IDEA

The Only FDA Approved
Clobetasol Propionate 0.025%

IMPOYZ™ (clobetasol propionate) Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions
Topical corticosteroids, including IMPOYZ Cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. This may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose to HPA axis suppression include, use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. If HPA axis suppression occurs, gradually withdraw the drug, reduce frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of withdrawal occur, systemic corticosteroids may be required. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Although rare, systemic effects of topical corticosteroids may manifest as Cushing’s syndrome, hyperglycemia, and glucosuria. Pediatric patients may be more susceptible to systemic toxicity because of their larger skin surface to body mass ratios. Local Adverse Reactions with Topical Corticosteroids - Local adverse reactions from topical corticosteroids may be more likely to occur with occlusion, prolonged use, or use of higher potency corticosteroids. Some local adverse reactions may be irreversible. Concomitant Skin Infections - Use an appropriate antimicrobial agent if a skin infection is present or develops. If appropriate, discontinue use of IMPOYZ Cream. Allergic Contact Dermatitis - Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Adverse Events - The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in < 1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia and rash.

Please see Brief Summary of Prescribing Information on the following page.
INDICATIONS AND USAGE
IMPOYZ Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.

DOSAGE AND ADMINISTRATION
Apply a thin layer of IMPOYZ Cream to the affected skin areas twice daily and rub in gently and completely. Use IMPOYZ Cream for up to 2 consecutive weeks of treatment. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis [see Warnings and Precautions (5.1)]. Discontinue IMPOYZ Cream when control is achieved. Do not use if atrophy is present at the treatment site. Do not bandage, cover, or wrap the treated skin area unless directed by a physician. Avoid use on the face, scalp, axilla, groin, or other intertriginous areas. IMPOYZ Cream is for topical use only. It is not for oral, ophthalmic, or intravaginal use. Wash hands after each application.

DOSAGE FORMS AND STRENGTHS
Cream, 0.025%: each gram contains 0.25 mg of clobetasol propionate in a white to off-white cream base.

CONTRAINDICATIONS
None

WARNINGS AND PRECAUTIONS
Effects on the Endocrine System: IMPOYZ Cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Because of the potential for systemic absorption, use of topical corticosteroids, including IMPOYZ Cream, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient to HPA axis suppression include the use of potent topical steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Evaluation for HPA axis suppression should be performed by assessing the response to a 24-hour dynamic ACTH stimulation test. In general, the lack of a responsive ACTH stimulation test is strongly suggestive of primary adrenal insufficiency. A basal 24-hour urinary free cortisol level may be measured on another day and, if abnormal, should be followed by a 24-hour urinary free cortisol collection after 2 days of corticotropin (ACTH) stimulation. If HPA axis suppression is noted, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of steroid withdrawal occur, supplemental systemic corticosteroids may be required. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Systemic effects of topical corticosteroids may also manifest as Cushing's syndrome, hyperglycemia, and glucocorticoid withdrawal symptoms. These complications are rare and generally occur after prolonged use or exposure to larger than recommended doses, particularly with high-potency topical corticosteroids. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids. Minimize the unwanted risks from endocrine effects by mitigating risk factors favoring increased systemic bioavailability and by using the product as recommended [see Dosage and Administration (2)]. Pediatric patients may be more susceptible to systemic toxicity because of their larger skin surface to body mass ratios [see Use in Specific Populations (8.4)].

Local Adverse Reactions with Topical Corticosteroids: Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hyperpigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including IMPOYZ Cream. These local adverse reactions may be irreversible. Concomitant Skin Infections: Use an appropriate antimicrobial agent if a skin infection is present or develops. If a favorable response does not occur promptly, discontinue use of IMPOYZ Cream until the infection has been adequately treated. Allergic Contact Dermatitis: Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Such an observation should be corroborated with appropriate patch testing. If irritation develops, discontinue the topical corticosteroid 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. IMPOYZ Cream was evaluated in two randomized, multicenter, prospective, vehicle-controlled clinical trials in subjects with moderate to severe plaque psoriasis. Subjects applied IMPOYZ Cream or vehicle cream twice daily for 14 days. A total of 354 subjects applied IMPOYZ Cream and 178 subjects applied vehicle. The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in <1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia, and rash.

Postmarketing Experience
The following adverse reactions have been identified during post-approval use of clobetasol propionate: striae, irritation, dryness, acneiform eruptions, hyperpigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, hypertrichosis, and miliaria. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

USE IN SPECIFIC POPULATIONS
Pregnancy: Risk Summary
There are no available data on IMPOYZ Cream in pregnant women to inform a drug associated risk for adverse developmental outcomes. Published data report a significantly increased risk of low birthweight with the use of greater than 300 grams of potent or very potent topical corticosteroid during a pregnancy. Advise pregnant women of the potential risk to a fetus and to use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible (see Data). In animal reproduction studies, increased malformations, such as cleft palate and skeletal abnormalities, were observed after subcutaneous administration of clobetasol propionate to pregnant mice and rabbits. No comparisons of animal exposure with human exposure are provided due to minimal systemic exposure noted after topical administration of IMPOYZ Cream [see Clinical Pharmacology (12.3)].

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% to 4% and 15% to 20%, respectively.

Data
Human Data
Multiple observational studies have not shown associations between the use of potent and/or potent topical corticosteroids and congenital malformations, prematurity, delivery, or fetal mortality. However, when the dispensed amount of potent or very potent topical corticosteroid exceeded 300 g during the entire pregnancy, use was associated with an increase in low birth weight infants (adjusted RR, 7.74 [95% CI, 1.49–40.11]). In addition, a small, additional, a small cohort study, in which 28 sub-Saharan women using potent topical corticosteroids (27/28 used clobetasol propionate 0.05%) for skin lightening during pregnancy, noted a higher incidence of low birth weight infants in the exposed group. The majority of subjects treated large areas of skin (a mean quantity of 60 g/month [range, 12–170 g]) over long periods of time.

Animal Data
In an embryo fetal development study in mice, subcutaneous administration of clobetasol propionate resulted in fetotoxicity at the highest dose tested (1 mg/kg) and malformations at the lowest dose tested (0.03 mg/kg). Malformations were included cleft palate and skeletal abnormalities. In an embryofetal development study in rabbits, subcutaneous administration of clobetasol propionate resulted in malformations at doses of 0.003 and 0.001 mg/kg. Malformations included cleft palate, craniorachischisis, and other skeletal abnormalities.

Lactation: Risk Summary
There is no information regarding the presence of clobetasol propionate in breast milk or its effects on the breastfed infant or milk production. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of clobetasol propionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for IMPOYZ Cream and any potential adverse effects on the breastfed infant from IMPOYZ Cream or from the underlying maternal condition. Clinical Considerations: To minimize potential exposure to the breastfed infant via breast milk, use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply IMPOYZ Cream directly to the nipple and areola to avoid direct infant exposure.

Pediatric Use: The safety and effectiveness of IMPOYZ Cream in patients younger than 18 years of age have not been established; therefore, use in children younger than 18 years is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of systemic toxicity, including HPA axis suppression, when treated with topical drugs [see Warnings and Precautions (5.1)]. Rare systemic toxicities such as Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients, especially those with prolonged exposure to large doses of high potency topical corticosteroids. Local adverse reactions involving skin and atrophic changes have also been reported in use of topical corticosteroids in pediatric patients. Avoid use of IMPOYZ Cream in the treatment of diaper dermatitis.

Geriatric Use: Clinical studies of IMPOYZ Cream did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. Other reported clinical experience with topical corticosteroids in this indication does not identify differences in responses between the elderly and younger adults. No clinically significant differences in safety and effectiveness were observed between older and younger adults.

Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate cream. In a 13-week repeat dose toxicity study in rats, topically administered clobetasol propionate cream, 0.001, 0.005 and 0.025% at corresponding doses of 0.004, 0.02 and 0.01 mg/kg/day resulted in corticosteroid class-related systemic effects such as reductions in body weight gain, reductions in total leukocytes and individual white cells, decrease in weight of adrenals, thymus, spleen, liver and lung. Histologically, there were decreased hematopoiesis in the bone marrow, thymic atrophy and cell infiltration of the mesenteric lymph nodes. All these effects were indicative of severe immune suppression consistent with long-term exposure to corticosteroids. No observable adverse effect level (NOAEL) was determined to be clobetasol propionate cream, 0.001% (0.034 mg/kg/day) in male rats while a NOAEL of 0.02% (0.17 mg/kg/day) was determined in female rats. The clinical relevance of the findings in animals to humans is not clear, but sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk of carcinogenesis. Clobetasol propionate was not mutagenic in three different test systems: the Ames test, the Saccharomyces cervisiae gene conversion assay, and the E. coli B WP2 fluctuation test. Fertility studies conducted in the rat following subcutaneous administration of clobetasol at dosage levels up to 0.05 mg/kg/day revealed that females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

Manufactured by DPT Laboratories Ltd. San Antonio, TX 78215 For Encore Dermatology, Inc. Scottsdale, AZ 85254 © 2018 Encore Dermatology, Inc., Malvern, PA 19355 IMPOYZ is a trademark of Encore Dermatology, Inc.
FDA GRANTS PEDIATRIC DISEASE DESIGNATION TO DIACEREIN FOR EB

THE FOOD AND DRUG ADMINISTRATION (FDA) has approved rare pediatric disease designation for diacerein 1 percent ointment (CCP-020, Castle Creek Pharmaceuticals) for the treatment of epidermolysis bullosa (EB).

The designation means the FDA could give Castle Creek a priority review voucher if diacerein is approved for the rare pediatric indication. Diacerein contains anti-inflammatory properties and contains an active metabolite, rheiin, that has demonstrated inhibition of in vitro and in vivo production and activity of interleukin-1 beta and other inflammatory cytokines. CCP-020 was formulated to block an inflammatory signaling pathway associated with EBS, which helps to heal blisters and strengthen epidermal tissue, according to a news release.

CCP-020’s safety and efficacy are being assessed in the DELIVERS study for patients with epidermolysis bullosa simplex (EBS). A separate, phase 2 clinical trial that has completed involved 17 patients with EBS. Of the study participants, 60 percent demonstrated a 40 percent reduction in blistering after four weeks of treatment with diacerein ointment, compared to 18 percent on vehicle. Notable adverse events included increases in blistering, pruritus and skin infections. None of the adverse events were related to treatment or involving the treatment areas.

Receiving this important rare pediatric disease designation is a significant recognition of CCP-020 and its potential as an important therapy for people living with EBS,” Castle Creek co-founder and CEO Michael Derby said.

FDA APPROVES RESTYLANE LIFT FOR VOLUME LOSS IN HANDS

RESTYLANE LIFT (hyaluronic acid, Galderma) has been approved by the Food and Drug Administration (FDA) for use in the back of the hands to correct age-related volume loss in patients age 21 and older.

This approval marks the first time a hyaluronic acid filler has been cleared by the FDA for use in any area other than the face, according to a company news release.

The approval followed results of a multicenter, randomized, evaluator-blinded, split-hand study of Restylane Lift in the backs of the hands of 89 patients ages 22 and older. The study met its primary endpoint, demonstrating clinically meaningful improvement in correcting volume deficits in the treated hands for up to six months.

"Many of my patients start to notice their youthful-looking faces aren't matching their aging hands, and ask me what they can do about it," said Ellen Marmur, M.D., a New York City-based dermatologist who served as clinical investigator for the Restylane Lift study. "I am now pleased to be able to offer them Restylane Lift, an injectable HA treatment that many are familiar with since it has been on the market for over 10 years for facial wrinkles."

ANTIMICROBIAL POST-THERAPY GEL EARNED 510(K) CLEARANCE

AN ANTIMICROBIAL POST-THERAPY GEL developed by Sonoma Pharmaceuticals has earned 510(k) clearance from the Food and Drug Administration (FDA), according to a news release.

The gel is intended for use following nonablative laser treatments, microdermabrasion therapy and chemical peels. It could also serve as a pain reliever and to address itch from minor skin irritations, abrasions, lacerations and minor burns, according to the company.

With cosmetic procedures on the rise, this antimicrobial product is designed to reduce the pain and itch associated with healing after certain dermatologic treatments, while also providing protection against potential secondary infections.

"In our clinical testing to date, we have seen dramatically improved outcomes with quicker healing times and less patient discomfort when this advanced technology is added to our procedure management protocol," Michael Gold, M.D., founder of Gold Skin Center and the Tennessee Clinical Research Center, Nashville, said in a statement.
FDA CLEARS SUBCUTANEOUS FORMULATION OF ACTEMRA FOR PJIA

THE SUBCUTANEOUS FORMULATION of Actemra (tocilizumab, Genentech) has been approved by the Food and Drug Administration (FDA) for the treatment of polyarticular juvenile idiopathic arthritis (PJIA) in patients ages 2 years and older, according to a recent news release.

“With this approval, we are pleased Actemra offers an alternative delivery option to physicians and parents of children ages 2 or older to treat this debilitating disease,” Sandra Horning, M.D., chief medical officer and head of Global Product Development, Genentech, said in the news release.

For patients with PJIA, physicians can prescribe the subcutaneous formulation of Actemra alone or in conjunction with methotrexate. An intravenous formulation of Actemra was approved by the FDA in 2013 for patients with PJIA ages 2 years and up.

FDA APPROVES CIMZIA LABEL EXTENSION FOR PSORIASIS PATIENTS

BELGIAN PHARMACEUTICAL firm UCB has entered the immunodermatology field in the U.S. market. The Food and Drug Administration (FDA) recently approved extending the label for Cimzia (certolizumab pegol) for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy, according to a news release.

With this approval, Cimzia is the first Fc-free, PEGylated anti-tumor necrosis factor (anti-TNF) therapy for this indication. The FDA’s consent follows a phase 3 clinical development program that included more than 1,000 patients in CIMPASI-1, CIMPASI-2 and CIMPACT.

In CIMPASI-1 and CIMPASI-2, patients achieved at least 75 percent or greater disease improvement from baseline within 16 weeks. In CIMPACT, patients achieved 75 percent or greater disease improvement within 12 weeks.

“It’s a great day when new psoriasis treatments come to market, as both dermatologists and patients are given hope that this could be the treatment that will work for them,” Michael Siegel, Ph.D., senior vice president of Research and Clinical Affairs, National Psoriasis Foundation, said in the news release.

Additionally, a recent label update for Cimzia by the FDA includes information for use in pregnant and breastfeeding patients.

“The approval of Cimiza for psoriasis and the recent Cimzia label update regarding pregnancy and breastfeeding in women with chronic inflammatory diseases are important treatment advances,” said Emmanuel Caeymaex, executive vice president of Immunology Patient Value Unit and head of Immunology at UCB. “UCB is committed to improving care for psoriasis patients and is also investigating bimekizumab, a therapy with significant potential for psoriasis patients.”

INTERLEUKIN-25 FUELS SKIN INFLAMMATION

A STUDY OF the role of interleukin-25 (IL-25) in psoriasis demonstrated the cytokine is involved in propelling skin inflammation in psoriasis, according to a recent analysis.

In the Editor’s Choice of the May 4 issue of Science Immunology, authors Lokesh Kalekar and Michael Rosenblum, Department of Dermatology, University of California, San Francisco, examined a recent study by Xu M, Lu H, Lee Y, et al. that was published in Immunity.

Using a topical application of imiquimod in skin lesions of a mouse model of psoriasis, IL-25 expression was observed. Additionally, administering recombinant IL-25 intradermally fueled psoriasis-like disease in the mice.

“Expression of this cytokine is regulated by IL-17A, because IL-17A knockout mice have lower IL-25 expression in the imiquimod model,” Kalekar and Rosenblum wrote. “Imiquimod-induced disease was also substantially diminished in global IL-25 knockout mice.”

In mice with keratinocyte-selective deletion of the IL-25 gene, the pathology was weakened. A feedback loop of IL-17 receptor B with IL-25 resulted in keratinocyte proliferation and inflammatory gene expression in a STAT3-dependent manner. Further, treatment with anti-IL-25 improved disease expression.

“If these findings are validated in humans, inhibition of IL-25 may prove to be a novel therapeutic target in the treatment of psoriasis and associated diseases,” the authors wrote in the editorial.

The original study was published in the April 17 issue of Immunity.
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INDICATION

RETIN-A MICRO (tretinoin gel) microsphere is indicated for topical application in the treatment of acne vulgaris.

IMPORTANT SAFETY INFORMATION

- The skin of certain individuals may become excessively dry, red, swollen or blistered during the use of RETIN-A MICRO.
- Tretinoin has been reported to cause severe irritation on eczematous skin and should be used with utmost caution in patients with this condition.
- If warranted, patients should temporarily reduce the amount or frequency of application, or discontinue use temporarily or altogether. If a reaction suggesting sensitivity occurs, use should be discontinued.
- Unprotected exposure to sunlight, including sunlamps, should be minimized during the use of RETIN-A MICRO, and patients with sunburn should be advised not to use the product until fully recovered because of heightened susceptibility to sunlight with the use of tretinoin.
- Patients should be encouraged to use a sunscreen with a SPF of 15 or higher and protective clothing over treated areas when exposure cannot be avoided.
- Weather extremes, such as wind or cold, also may be irritating to patients under treatment with tretinoin.
- The most common adverse events are mild to moderate irritation (erythema, peeling, dryness, burning/stinging, or itching of the skin).
- RETIN-A MICRO should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus, and caution should be exercised in prescribing for nursing mothers. Safety and efficacy in patients under 12 have not been established.

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


Ortho Dermatologics

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GERMAN-BASED biopharmaceutical firm InflaRx has opened a research facility in Ann Arbor, Mich., which will serve to expand its complement-based therapeutics, according to a company news release.

InflaRx’s flagship candidate is IFX-1, a monoclonal anticomplement factor C5 antibody that has completed three clinical phase 2 studies of more than 150 patients. It demonstrated an ability to block C5a as a key amplifier driving inflammatory response. IFX-1 is designed to treat HS and ANCA-associated vasculitis.

ESKATA AVAILABLE IN U.S. FOR SEBORRHEIC KERATOSIS TREATMENT

A TOPICAL TREATMENT for raised seborrheic keratoses (SKs), Eskata (Aclaris Therapeutics), is now available in the United States for purchase by dermatologists.

Eskata is a high-concentration stabilized hydrogen peroxide formulation that provides targeted treatments; physicians use a pen-like applicator to apply the solution directly onto the raised SKs, according to a company news release. Treatments usually require two in-office sessions, three weeks apart, administered by a healthcare professional.

“Though not life-threatening, raised SKs can make patients feel self-conscious, yet the majority of these lesions go untreated. Now, with the introduction of Eskata, my colleagues and I finally have a topical treatment option,” Marina Peredo, M.D., F.A.A.D., associate clinical professor of dermatology, Mount Sinai Hospital, New York, said in the news release.

The solution is the first and only topical treatment approved by the Food and Drug Administration for this indication. Eskata was approved by the FDA in December 2017 and will be offered to physicians as a self-pay treatment for patients.

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GERMAN BIOPHARMACEUTICAL COMPANY OPENS MICHIGAN FACILITY

GERMAN-BASED biopharmaceutical firm InflaRx has opened a research facility in Ann Arbor, Mich., which will serve to expand its complement-based therapeutics, according to a company news release.

The Michigan facility will be part of InflaRx Pharmaceuticals. It develops innovative treatments for inflammatory diseases such as hidradenitis suppurativa (HS) by targeting the complement system, which is crucial in the innate immune system.

“The company’s return to its scientific origins in Ann Arbor [where the cofounders met and conducted studies on the complement system] by opening this research facility is a significant milestone for InflaRx that will afford us significant advantages as we focus on our mission of discovering and developing superior treatments for inflammatory conditions,” InflaRx’s Chief Scientific Officer Renfeng Guo, M.D., said in the news release.

InflaRx’s flagship candidate is IFX-1, a monoclonal anticomplement factor C5 antibody that has completed three clinical phase 2 studies of more than 150 patients. It demonstrated an ability to block C5a as a key amplifier driving inflammatory response. IFX-1 is designed to treat HS and ANCA-associated vasculitis.
Pityrosporum folliculitis?
This common bacterial infection is often mistaken for acne

LISETTE HILTON | Staff Correspondent

Pityrosporum folliculitis is often mistaken by physicians as acne vulgaris, which can be a dire mistake leading to a worsening condition, shows a review published in the Journal of the American Academy of Dermatology.

“The reason it’s important to distinguish Pityrosporum folliculitis is that antibiotics used for acne actually make this worse. And azole antifungals make it better. So, the treatment is different,” says study author Brea Prindaville, M.D., a pediatric dermatologist and assistant professor, Warren Alpert Medical School of Brown University.

Acne and Pityrosporum folliculitis can occur together, given that acne patients often have increased sebum production and follicular hyperkeratinization resulting in occlusion, and acne is often treated with antibiotics. But while Pityrosporum folliculitis, which is caused by naturally-occurring yeast, appears similar in presentation to acne, there are important differences.

“Pityrosporum folliculitis usually presents as monomorphic keratosis pilaris-like fine papules and pustules. And it’s often pruritic. It’s often located on the upper forehead, extending into the hairline and the upper back,” Dr. Prindaville said.

Acne, on the other hand, isn’t usually pruritic. It typically presents as polymorphic lesions with open and closed comedones, inflammatory papules and pustules, as well as nodules and cysts, the authors write. Acne might appear in similar areas as Pityrosporum folliculitis, including on the forehead leading up to the hairline and occurring on the upper back.

WHAT THE REVIEW REVEALED
Dr. Prindaville and colleagues did a retrospective chart review of 110 Pityrosporum folliculitis patients (up to 21 years of age) who were seen in the dermatology department at the University of Massachusetts. More than 75% had acne that was treated with antibiotics and of those, 65% reported pruritus.

“Pityrosporum folliculitis was almost always described as numerous 1- to 2-mm monomorphic papules and pustules and often described as keratosis pilaris-like,” they write.

Fewer than one-fifth of patients studied had associated seborrheic dermatitis or tinea versicolor, although the authors write that the Malassezia yeasts that cause Pityrosporum folliculitis are also implicated in folliculitis, seborrheic dermatitis and tinea versicolor.

The forehead, often extending into the hairline, and upper back were the most common areas affected by Pityrosporum folliculitis.

While most of the patients in the study were white females, the authors note Pityrosporum folliculitis likely affects males and females, as well as all races similarly. Dr. Prindaville says the higher incidence of the skin condition among white females in this study could be due to a referral bias, rather than a true association.

“Females tend to be more bothered by their acne,” she says.

Pityrosporum folliculitis was more common after antibiotic use. More than 75% of the patients indicated they...
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Otezla® (apremilast) has a proven efficacy and safety profile, oral dosing, and no label-required lab monitoring—making it a treatment experience patients can respond to.¹

Otezla® (apremilast) significantly increased PASI-75 response (n = 562) at week 16 (primary endpoint) vs placebo (n = 282) (33% vs 5%; P < 0.0001) in ESTEEM 1.²

ESTEEM® Study Design
- Evaluated in 2 multicenter, double-blind, placebo-controlled trials of similar design. Patients with moderate to severe plaque psoriasis (N = 1257) were randomized 2:1 to Otezla 30 mg twice daily or placebo for 16 weeks after a 5-day titration¹
- Selected inclusion criteria: age ≥18 years, BSA ≥10%, sPGA ≥3, PASI ≥12, candidates for phototherapy or systemic therapy¹

INDICATIONS
Otezla® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla® is indicated for the treatment of adult patients with active psoriatic arthritis.

IMPORTANT SAFETY INFORMATION
Contraindications
- Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation

Warnings and Precautions
- Diarrhea, Nausea and Vomiting: Cases of severe diarrhea, nausea, and vomiting have been reported with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting
- Depression: Treatment with Otezla is associated with an increase in depression. During clinical trials 1.3% (12/920) of patients reported depression, compared to 0.4% (2/506) on placebo. Suicidal behavior was observed in 0.1% (1/11308) of patients on Otezla, compared to 0.2% (1/506) on placebo. Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on
Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

- **Weight Decrease**: Body weight loss of 5-10% occurred in 12% (96/784) of patients treated with Otezla and in 5% (19/382) of patients taking placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

- **Drug Interactions**: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

### Adverse Reactions

- Adverse reactions reported in ≥5% of patients were (Otezla%, placebo%): diarrhea (17.6, 6), nausea (17.7, 4), upper respiratory tract infection (9.6, 4), tension headache (8.4, 4), and headache (6, 4).

### Use in Specific Populations

- **Pregnancy and Nursing Mothers**: Otezla is Pregnancy Category C; it has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether apremilast or its metabolites are present in human milk. Caution should be exercised when Otezla is administered to a nursing woman.

- **Renal Impairment**: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

*Following a 5-day titration, the recommended maintenance dosage is 30 mg twice daily.

†To receive a free bridge supply of Otezla, patients must have an on-label diagnosis and be denied or waiting for coverage. Patients in Massachusetts are not eligible to receive bridge.

‡Certain restrictions apply; eligibility not based on income, must be 18 years or older. This offer is not valid for persons eligible for reimbursement of this product, in whole or in part under Medicaid, Medicare, or similar state or federal programs. Offer not valid for cash-paying patients. People who are not eligible can call 1-844-OTEZLA to discuss other financial assistance opportunities.

BSA, body surface area; ESTEEM, Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis; PASI, Psoriasis Area and Severity Index; SPGA, static Physician Global Assessment.


Please turn the page for Brief Summary of Full Prescribing Information.

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OTEZLA® (apremilast) tablets, for oral use

The following is a Brief Summary; refer to Full Prescribing Information for complete product information.

INDICATIONS AND USAGE

OTEZLA® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

CONTRAINDICATIONS

OTEZLA is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation [see Adverse Reactions (6.1)].

WARNINGS AND PRECAUTIONS

Diarrhea, Nausea, and Vomiting: There have been postmarketing reports of severe diarrhea, nausea, and vomiting associated with the use of OTEZLA. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting.

Severe Diarrhea: Severe diarrhea associated with the use of OTEZLA. Most severe diarrhea occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting.

Depression: Treatment with OTEZLA is associated with an increase in adverse reactions of depression. Before using OTEZLA in patients with a history of depression and/or suicidal thoughts or behavior prescribers should carefully weigh the risks and benefits of treatment with OTEZLA in such patients. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and if such changes occur to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment with OTEZLA if such events occur. During the 0 to 16 week placebo-controlled period of the 3 controlled clinical trials, 1.3% (12/920) of patients treated with OTEZLA discontinued treatment due to depression compared with none in placebo-treated patients (0/506). Depression was reported as serious in 0.1% (1/1308) of patients exposed to OTEZLA, compared to none in placebo-treated patients (0/506). Instances of suicidal behavior have been observed in 0.1% (1/1308) of patients while receiving OTEZLA, compared to 0.2% (15/506) in placebo-treated patients. In the clinical trials, one patient treated with OTEZLA attempted suicide while one who received placebo committed suicide.

Weight Decrease: During the controlled period of the trials in psoriasis, weight decrease between 5%-10% of body weight occurred in 12% (96/824) of patients treated with OTEZLA compared to 5% (19/382) treated with placebo. Weight decrease of ≥20% of body weight occurred in 2% (16/784) of patients treated with OTEZLA 30 mg twice daily compared to 1% (3/382) patients treated with placebo. Patients treated with OTEZLA should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated, and discontinuation of OTEZLA should be considered.

Drug Interactions: Co-administration of strong cytochrome P450 enzyme inducer, rifampin, resulted in a reduction of systemic exposure of apremilast, which may result in a loss of efficacy of OTEZLA. Therefore, the use of cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) with OTEZLA is not recommended [see Drug Interactions (7.1) and Clinical Pharmacology (12.3)].

ADVERSE REACTIONS

Clinical Trials Experience in Psoriasis: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. Diarrhea, nausea, and upper respiratory tract infection were the most commonly reported adverse reactions leading to discontinuation for patients taking OTEZLA were diarrhea (1.6%), nausea (1.0%), and upper respiratory tract infection (0.8%). The proportion of patients with psoriasis who discontinued treatment due to any adverse reaction was 6.1% for patients treated with OTEZLA 30 mg twice daily and 4.1% for placebo-treated patients.

Table 3: Adverse Reactions Reported in ≥2% of Patients on OTEZLA and With Greater Frequency Than in Patients on Placebo; up to Day 112 (Week 16)

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Placebo (N=506)</th>
<th>OTEZLA 30 mg BID (N=920)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>32 (6)</td>
<td>160 (17)</td>
</tr>
<tr>
<td>Nausea</td>
<td>35 (7)</td>
<td>155 (17)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>31 (6)</td>
<td>84 (9)</td>
</tr>
<tr>
<td>Tension headache</td>
<td>21 (4)</td>
<td>75 (8)</td>
</tr>
<tr>
<td>Headache</td>
<td>19 (4)</td>
<td>55 (6)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>11 (2)</td>
<td>39 (4)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>8 (2)</td>
<td>35 (4)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>9 (2)</td>
<td>29 (3)</td>
</tr>
<tr>
<td>Decrease appetite</td>
<td>5 (1)</td>
<td>26 (3)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4 (1)</td>
<td>21 (2)</td>
</tr>
<tr>
<td>Back pain</td>
<td>4 (1)</td>
<td>20 (2)</td>
</tr>
<tr>
<td>Migraine</td>
<td>5 (1)</td>
<td>19 (2)</td>
</tr>
<tr>
<td>Frequent bowel movements</td>
<td>1 (0)</td>
<td>17 (2)</td>
</tr>
<tr>
<td>Depression</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Tooth abscess</td>
<td>0 (0)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
<tr>
<td>Sinus headache</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
</tbody>
</table>

*Two subjects treated with OTEZLA experienced serious adverse reaction of abdominal pain.

Severe worsening of psoriasis (rebound) occurred in 0.3% (4/1184) patients following discontinuation of treatment with OTEZLA (apremilast).

DRUG INTERACTIONS

Strong CYP 450 Inducers: Apremilast exposure is decreased when OTEZLA is co-administered with strong CYP450 inducers (such as rifampin) and may result in loss of efficacy [see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)].

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C: OTEZLA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to OTEZLA during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972. Nursing Mothers: It is not known whether OTEZLA or its metabolites are present in human milk. Because many drugs are present in human milk, caution should be exercised when OTEZLA is administered to a nursing woman.

Pediatric use:

Adolescence: Apremilast exposure is increased in adolescent patients compared to younger adult patients <65 years of age in the clinical trials. Due to the limited experience in this patient population, OTEZLA is not recommended for use in patients who are less than 16 years of age [see Clinical Pharmacology (12.7)].

Adults: Apremilast pharmacokinetics were characterized in patients with severe plaque psoriasis who were candidates for phototherapy or systemic therapy. Apremilast exposure is decreased when OTEZLA is co-administered with strong CYP450 inducers (such as rifampin) and may result in loss of efficacy [see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)].

OVERDOSAGE

In case of overdose, patients should seek immediate medical help. Patients should be managed by symptomatic and supportive care should there be an overdose.

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Pat. http://www.celgene.com/therapies

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Based on APRPI.006 OTZ_FrO_HCP_Bsv.006_08_2017
were treated with antibiotics for persistent acne, with more than half of those being prescribed oral antibiotics.

Only three of the Pityrosporum folliculitis patients studied had never had acne vulgaris, according to the authors.

And they found Pityrosporum folliculitis was quite common. Almost 5% of the 2,368 acne patient charts they reviewed indicated patients had Pityrosporum folliculitis at some point during their acne course, Dr. Prindaville said.

**TREATING PITYROSPORUM FOLLICULITIS**

Dr. Prindaville and her colleagues have had a good success treating Pityrosporum folliculitis with topical ketoconazole shampoo 2%, which is applied or 5-10 minutes every other day.

“Sometimes if it’s severe, you need to combine that with oral [azole antifungal therapy]. But most people respond to the topical,” she says.

Three-quarters of the patients studied were treated with topical ketoconazole shampoo, which improved or resolved the condition for most. Patients with more severe disease benefited from either oral fluconazole and ketoconazole. Doctors prescribed from 100 mg daily for one week to 200 mg daily for three weeks of fluconazole. Dermatologists instructed patients to use ketoconazole 2% wash after oral therapy to prevent recurrence. In some cases, they used the wash alone at least until the follow up visit in two to three months.

About half of patients were free of Pityrosporum folliculitis within one to two follow-up visits. In fact, 100% of patients treated with each of these regimens improved: oral fluconazole, ketoconazole 2% shampoo used as a wash, ketoconazole 2% cream, ketoconazole 2% shampoo and sulfur wash. But nine of the 12 patients treated with oral ketoconazole did not improve. The authors note oral ketoconazole hasn’t been an appropriate option for these patients since 2013, when the FDA strongly cautioned against using oral ketoconazole for superficial fungal infections because of risk of liver or adrenal injury.

While studies have suggested patients with Pityrosporum folliculitis need oral therapy, this paper shows that’s not necessarily the case, and most patients improve or clear with topical options.

**References**

**Considerations for diagnosing eosinophilic fasciitis**

_**INGRID TORJESEN | Staff Correspondent**_

**Quick Takes**
- Eosinophilic fasciitis is diagnosed for patients who meet key criteria.
- Key criteria include symmetrical plate-like sclerotic lesions on the limbs.
- Biopsies should reach the fascia.

**Major Criterion in Eosinophilic Fasciitis**
- Symmetrical plate-like sclerotic lesions on the limbs.
- It presents without Raynaud’s phenomenon.
- Systemic sclerosis can be excluded.
- The diagnosis must include at least one of two minor criteria: Histology of a skin biopsy that incorporates the fascia shows fibrosis of the subcutaneous connective tissue, with thickening of the fascia and cellular infiltration of eosinophils and monocytes; and/or thickening of the fascia is seen using imaging tests such as magnetic resonance imaging.

Eosinophilic fasciitis is a rare condition for which there are no established diagnostic criteria or clinical guidelines for its management. The condition has an unclear etiology and pathophysiology meaning it is difficult to diagnose as patients present with variable symptoms. Dermatologists in Japan reviewed the latest available evidence to draft a set of diagnostic criteria and severity classification for the condition and a clinical guideline for its management. They also highlight specific problems and issues dermatologists treating the condition should be aware of:

Whitney High, M.D., director, Dermatology Clinic and Dermatopathology, University of Colorado, Denver, says that around 30 years ago there were a spate of cases of eosinophilic fasciitis linked to a contaminated batch of tryptophan supplements manufactured in Japan, which may have been why the Japanese group decided to develop a guideline on the rare condition.

The guideline says that a definitive diagnosis of eosinophilic fasciitis can be made if the patient has the major criterion — a symmetrical plate-like sclerotic lesions present on the limbs, the condition lacks Raynaud’s phenomenon and systemic sclerosis can be excluded — plus at least one of two minor criteria. The minor criteria are: histology of a skin biopsy that incorporates the fascia shows fibrosis of the subcutaneous connective tissue, with thickening of the fascia and cellular infiltration of eosinophils and monocytes; and/or thickening of the fascia is seen using imaging tests such as magnetic resonance imaging.

It also points out that peripheral eosinophilia is present in approximately 63–86% of cases, serum immunoglobulin G levels are elevated in approximately 3–72%, accelerated erythrocyte sedimentation rate is seen in approximately 29–80%, and elevated serum aldolase levels in approximately 60% of cases. Furthermore the guideline adds that on skin biopsy, eosinophil infiltration is seen in 65–80% of cases, epidermal atrophy in 16%, increase of thickened collagen bundles in 40–70%, thickening of fat septum in more than half and fascia thickening in almost all. And it says that when the biopsy is taken it should include the fascia.

“It’s very important that the biopsy is a big excisional biopsy right down to the fascia, which is just above the muscle surface. It can’t be a little tiny punch or shave biopsy,” he says.

Without a clear etiology and pathology, eosinophilic fasciitis can be a difficult diagnosis as patients present with variable symptoms. “It’s very important that the biopsy is a big excisional biopsy right down to the fascia, which is just above the muscle surface. It can’t be a little tiny punch or shave biopsy.”

Whitney High, M.D., director, Dermatology Clinic and Dermatopathology, University of Colorado, Denver
Complications low with chemical peels in darker skin

INGRID TORJESEN | Staff Correspondent

Superficial chemical peels have a relatively low complication rate in patients with darker skin types when performed appropriately, a study published in *Journal of the American Academy of Dermatology* has found.

While chemical peels have been shown to be effective for treating acne, photaging and pigmentary dyschromias, few studies have evaluated the occurrence of side effects, particularly in patients with darker skin. Researchers in Boston undertook a retrospective analysis to determine the frequency and range of side effects following the use of a range of chemical peels for different conditions in this patient group.

They reviewed consecutive adult patients with skin types III to VI who received a chemical peel of the face, upper extremities, hands, axillae, back, abdomen, buttocks or lower extremities for skin and reduce any burning sensation. A portable fan was used to help cool the skin and reduce any burning sensation.

For all single agent peels with glycolic acid (n=199, 42.1%), lactic acid (n=7, n=1.5%) or mandelic acid (n=42, 8.9%), and all combination peels with glycolic acid, lactic acid or mandelic acid (n=175, 37.0%), sodium bicarbonate was applied to the affected area after two to twelve minutes to neutralize the acid. The time varied according to the patient’s tolerance of the chemical peel; if patients developed intolerable burning at any point during the procedure, the acid was immediately neutralized and/or removed.

Repeat peels were performed no sooner than two weeks later, and the strength of the acid used and/or the contact time was increased in patients who had tolerated the chemical agent with no side effects during the initial peel and had shown some improvement in their condition.

Iced cotton gauze was used to remove all peeling agents, and this was left on the treated area for several minutes and then triamcinolone .025% cream or ointment was applied to reduce inflammation; the cream was used for patient who had acneiform lesions in the treated area, and the ointment for all other patients.

Patients were provided with Neutrogena Ultra Gentle cleanser and instructed to use it daily on the treated area. They were told to avoid harsh skin treatments and avoid sunlight for 48 hours after the peel, and after that to apply a sunscreen with sun protection factor (SPF) 30+ before any sun exposure.

In total, 473 chemical peel treatments were performed on 132 patients with skin types ranging from III to VI; of which 198 were given for melasma, 129 for PIH, 10 for acne, 98 for more than one diagnosis, and 37 for other indications. Most of the treatments were performed on women (82%) and to the face (80.1%). The majority of patients had a single agent peel (n=296; 62.6%), and the most common was 35% glycolic acid (n=89, 18.8%).

Three quarters of patients (75.5%) reported that the peel had a positive impact on their skin condition, and only 18 treatments (3.8%) were associated with side effects and these had a median duration of 4.5 weeks.

Lead author Shalini Vemula, M.D., of the University School of Medicine, Boston, said: “Overall, superficial chemical peels have a relatively low complication rate in darker skin types. However, people with darker skin (Fitzpatrick skin type VI) are more likely to experience side effects when exposed to chemical peels. The most common side effects are crusting and hyperpigmentation.”

The study found that the most frequent complications were prolonged crust (2.3%), PIH (1.9%) and erythema (1.9%). Blistering and post-inflamatory hypopigmentation each occurred in one patient (0.2% each), and no treatments resulted in folliculitis or exacerbation of the patients’ existing dermatologic conditions. Patients with skin type VI I had significantly higher odds of side effects (OR, 5.14; 95% confidence interval [CI], 1.21-21.8; P=0.0118).

CHEMICAL PEELS CONTINUES ON PAGE 34
Avoid antibiotics for acne treatment when possible

INGRID TORJESEN | Staff Correspondent

Y
ears ago, antibiotics started to be used to treat acne because it was thought that the condition was an infectious disease, Hilary E. Baldwin, M.D., of Rutgers Robert Wood Johnson Medical School, Newark, New Jersey. However, it is now realized that while Propionibacterium (P) acnes is implicated in the pathophysiology of the condition by producing an inflammatory cascade, acne is not the result of a bacterial infection because all adults have P. acnes in follicles and the severity of acne does not correlate with P. acnes counts.

“Dermatologists make up less than 1% of U.S. physicians, but they write 5% of all scrips for oral antibiotics. "In my experience perhaps less than 50% [of dermatologists] have bought into the concept that they are part of the problem.”

Hilary E. Baldwin, M.D.
Rutgers Robert Wood Johnson Medical School, Newark, New Jersey

And, it’s not that antibiotics don’t work, she concedes. “Sometimes we can’t make people better without them. The point is, we need to try to avoid them whenever possible.”

Rising antimicrobial resistance and a dearth of new antibiotics means that the use of antibiotics need to be avoided whenever possible throughout healthcare and in veterinary practice, but the majority of dermatologists treating acne still embrace the antibiotic stewardship agenda, said Dr. Baldwin who also serves as medical director of The Acne Treatment and Research Center in Morris-town, N.J. She addressed the issue of antibiotic use for acne treatment at the Skin of Color Seminar Series held in May in New York.

Dermatologists make up less than 1% of U.S. physicians, but they write 5% of all scrips for oral antibiotics. “In my experience perhaps less than 50% [of dermatologists] have bought into the concept that they are part of the problem, so it’s...
Making
college dreams come true

As part of its commitment to the dermatology community, Ortho Dermatologics created the Aspire Higher scholarship program. The program sponsors scholarships for new college students, graduate students, and mothers returning to college. Patients who have been treated for skin conditions are eligible to apply.

Dr. Linda Stein Gold began serving as one of several judges for Aspire Higher in 2016. She also performs clinical research and cares for patients at the Henry Ford Health System.

How did you become involved as a judge for the Aspire Higher program?

I was approached by Ortho Dermatologics, and I thought it was a wonderful opportunity. I really liked that they were giving back to the community and that I could help people who want to further their education.

What is your favorite part about being a judge for Aspire Higher?

I really enjoy the whole experience, but two things come to mind: Seeing the impact the scholarships have on the lives of the people who win, and reading their stories.

One of last year’s winners left a voicemail for the judges. I was in the middle of grocery shopping when I heard it, and I started crying because it was so touching. Also, reading about how a problem with a person’s skin impacts each aspect of their life urges us to seek the best possible treatment for our patients even more. I think that what Ortho Dermatologics is doing is exceptionally worthwhile.

It’s so satisfying to see how the Aspire Higher scholarship can change somebody’s life by helping them further their education.

What are your thoughts about Ortho Dermatologics’ commitment to the dermatology community through this scholarship program?

I’m thrilled to be part of it. I’m thrilled to have had the opportunity to hear the patients’ stories, to understand their journey, and to be part of making their educational dreams come true. I think this is a major gift that Ortho Dermatologics gives back to the community, and it’s important to get the word out to our patients that this is available. Ortho Dermatologics really does care about our specialty.

Hear from 2017 winner Robby Ruffolo at aspirehigherscholarships.com
“All side effects occurred in patients that had a chemical peel on their face for an underlying pigmentation disorder, such as melasma or post-inflammatory hyperpigmentation. None of the patients who had a chemical peel with 40% mandelic acid had side effects,” Vemula added.

Adverse events were most frequently reported with lactic acid (14.3%), followed by glycolic acid (14.6%), and salicylic acid 20% (5.17%). Side effects were less likely when peels performed in the winter; by season, side effects were more frequent in the spring (n=8, 6.0%), followed by fall (n=5, 4.6%), then summer (n=4, 3.8%) and winter (n=1, 0.8%).

Asked how dermatologists can minimize the risk of side effects when performing chemical peels in patients with skin of color, senior author Neelam A. Vashi, M.D., of director of the Boston University Center of Ethnic Skin and the Boston University Cosmetic and Laser Center said: “It is important to cleanse the skin thoroughly prior to application of the chemical peel and to apply the same amount of pressure to the entire face while applying the peel. In addition, iced gauze and low to medium potency topical steroids immediately after a chemical peel can be helpful in minimizing the risk of potential side effects.

“Chemical peels get a passable grade for skin of color patients” FROM PAGE 31

still an uphill climb to really convince people that although antibiotics make people better in the long run, they are doing us a harm,” she says.

These dermatologists are not thinking about antimicrobial resistance, or they presume there is another antibiotic just around the corner, she believes, particularly the older generation who were used to a new antibiotic every year when they first started practice. But the truth is, there hasn’t been a new antibiotic for acne since dapтомycin was launched in the late 1980s.

USING ANTIBIOTICS

Topical erythromycin should be avoided completely for the treatment of acne, Dr. Baldwin emphasizes. “Topical erythromycins no longer works in the United States, because P. acnes has become so resistant to it, and when you use topical erythromycins it does not treat acne. All it does is increase the resistance of all the bacteria that happened to be sitting on the skin.”

Topical clindamycin loses effectiveness after about two months unless it is combined with benzoyl peroxide, she explains. “Benzoyl peroxide reduces the development of resistant organisms when used in conjunction with either topical or oral antibiotics, so if you are going to use clindamycin, in my opinion, it ought to be in the tube along with the benzoyl peroxide.”

In fact, every time an oral or topical antibiotic is prescribed, it should be combined with benzoyl peroxide, she says. “Every single time, without fail.”

But as patients don’t like benzoyl peroxide because it bleaches fabric, dermatologists don’t recommend it because they don’t want to be faced with patients annoyed that their sheets and pillowcases have become stained, she says.

“You have to take the extra effort to educate the patients so that they are using this very important product,” she says.

Regardless of what other treatments they are receiving, every acne patient should be using a retinoid, Dr. Baldwin adds. “A lot of non-dermatologists try to treat acne without the topical retinoids and it just doesn’t work. Everybody needs to be treated with a topical retinoid to unclog the follicles and to reduce the pre-pimples.”

The biggest problem with antibiotics, if they work, is that patients are being left on them for years she explains. “Patients don’t want to come off them, so it is our responsibility to insist on it and of course people don’t want to do that because it takes a lot of time, it takes a lot of medication and the patients are not happy, they want to stay on it, because it works so well,” Dr. Baldwin says.

COMING OFF ANTIBIOTICS

When it is necessary to offer antibiotics, dermatologists need to ensure they put an exit strategy in place by informing the patient that they will be on antibiotics only for the short term. Tell them: “You are only going to be on this for two months, at the end of two months I am going to take you off this, period, and the topical medication that I give you is what is going to stop you from relapsing,” Dr. Baldwin states. “Never ever should a patient just be on an oral antibiotic. At the very least they have to have benzoyl peroxide and they have to use a retinoid,” she says.

“There are a lot of patients out there who realize that pills are a lot easier than creams. Then the day comes that I stop the oral antibiotics and it takes a month or two for the topicals to work so they flare. If they’ve been used to topicals all along, they will be able to come off their antibiotics.”

If patients really can’t come off antibiotics, they may be able to be downgraded from an antibiotic to the anti-inflammatory dose of doxycycline (40 mg delayed release doxycycline), she suggests.

OTHER OPTIONS

Dermatologists should utilize everything they can in their medication toolbox to avoid using antibiotics, Dr. Baldwin says.

For women, she suggests trying spironolactone and oral contraceptives. However, spironolactone has antiandrogen effects, so she recommends early use of isotretinoin.

Products in the pipeline that could be used instead of existing antibiotics, include topical minocycline gel and sarecycline, which is an oral antibiotic with a more narrow spectrum that does not kill as many organisms in the gut so may be less of risk in terms of raising antimicrobial resistance.

Two other drugs which had appeared promising – a topical sebum inhibitor and a nitric oxide gel – did not perform well in phase three trials, she says. 

Antibiotics: Devise an exit strategy before prescribing for acne treatment FROM PAGE 32
The atopic march strides toward eosinophilic esophagitis

WAYNE KUZNAR | Staff Correspondent

Eczema, food allergy, and asthma independently and cumulatively increase the risk for eosinophilic esophagitis, show findings presented at the 2018 American Academy of Allergy, Asthma and Immunology and World Allergy Organization Joint Congress in Orlando.

The findings suggest that eosinophilic esophagitis falls into the pattern of atopic march, but much later in the progression. The atopic march describes how patients with early atopic dermatitis eventually progress to IgE-mediated food allergy, asthma, and allergic rhinitis.

Using a case-control design with propensity score matching, researchers at Children’s Hospital of Philadelphia examined the relationship between eosinophilic esophagitis and the atopic march in a cohort of 130,457 children who entered the study before age two.

A total of 139 children developed eosinophilic esophagitis during the observation period, for a prevalence 0.11%. The peak age of developing eosinophilic esophagitis was 2.7 years, compared with 0.4 years for the development of atopic dermatitis, one year for the development of food allergy, and 4.1 years for the development of allergic rhinitis. Risk factors for eosinophilic esophagitis were male gender.

Independently, atopic dermatitis increased the risk of EoE by 2.7-fold, food allergy increased this risk by 8.9 times, and allergic rhinitis more than doubled it. The presence of eosinophilic esophagitis significantly increased the risk of subsequent allergic rhinitis by almost four-fold.

“The cumulative risk of eosinophilic esophagitis also went up with each subsequent atopic, or allergic, disease,” said study co-author author Jonathan M. Spergel, M.D., Ph.D., in a prepared statement. With one atopic condition, the risk of subsequent eosinophilic esophagitis increased by a factor of four; with two conditions, the risk of eosinophilic esophagitis increased by 6.5 times; with three conditions, risk increased by nearly 10-fold, and with four conditions, this risk increased by 12 times.

Other treatment options for eosinophilic fasciitis

SYMPTOMS AND INDICATORS

- Peripheral eosinophilia: 63–86% of cases
- Elevated serum immunoglobulin G levels: 3–72% of cases
- Accelerated erythrocyte sedimentation rate: 29–80% of cases
- Elevated serum aldolase levels: 60% of cases
- Epidermal atrophy: 16% of cases
- Increase of thickened collagen bundles: 40–70% of cases
- Thickening of fat septum in more than half and fascia thickening in almost all.
- Heliotrope rash: 80% of cases
- Presence of orange peel-like appearance: 50% of cases
- Presence of swelling and puckering of affected skin
- Eosinophil infiltration seen in skin biopsy: 65–80% of cases

Eosinophilic fasciitis has engaged in harsh exercise and work or have a history of trauma, including bruising, immediately before the onset. Dr. High says that in adults eosinophilic fasciitis appears more common in those aged under 50 than above, and that the condition can begin suddenly after strenuous exertion, for example after embarking on a new exercise routine or enrolling in the military.

Eosinophilic fasciitis is like dermatomyositis, Dr. High explains, which is difficult to diagnose because there isn’t one reliable thing that is always present. “Even heliotrope rash, which is the red rash above the eyelids, is only present in 80% of patients [with dermatomyositis] so you have to keep an open mind.”

His Denver clinic, which serves an area of around 1.5 million people, sees around two cases of eosinophilic fasciitis per year and he says that the guideline outlined how they would handle it, so it was useful to have in a written form.

However, while the guideline labels many of its approaches and criteria as “strongly recommended,” it qualifies that there is “almost no conviction about the estimated effect,” highlighting the lack of firm evidence to support many of the diagnostic criteria and treatment approaches in use and endorsed.

The proposed treatment algorithm for eosinophilic fasciitis is brief – effectively it says try systemic corticosteroids if they are ineffective try another treatment. Other treatment options include: immunosuppressants such as methotrexate, mycophenolate mofetil, cyclosporin, azathioprine and cyclophosphamide; phototherapy; and rehabilitation for improving limb contractures.

Some reports have found that dapsone, ketotifen, cimetidine, infliximab, chloroquine and hydroxychloroquine have therapeutic effects on eosinophilic fasciitis, and these drugs have been proposed as adjuvant therapy options for refractory cases. And in some patients the disease may resolve spontaneously, the guideline says.

Reference

2018 AAAAI and World Allergy Organization Joint Congress.

Reference

There is increasing patient injury and legal action from cutaneous laser surgery, particularly when performed by non-physicians and especially when performed outside of traditional medical settings such as medical spas, according to a study.

“In fact, non-physician operators account for the majority of cases of legal action,” says principal study author Saami Khalifi an, M.D., dermatology fellow, Massachusetts General Hospital. He presented findings earlier this year at the annual conference of the American Society for Laser Medicine and Surgery (ASLMS) in Dallas.

The study, which culled data from a single online legal database, WestlawNext (now renamed Thomson Reuters Westlaw), from 2012 to 2017, is consistent with the results of previous research by Dr. Khalifi an and his colleagues about trends in litigation for cutaneous laser surgery from 1985 to 2012.

“Since about 2008 there has been an increasing trend in a higher proportion of cases being performed by physician extenders and non-physician operators,” Dr. Khalifi an tells Dermatology Times. “Despite physicians acting as supervisors and not as the actual laser operator, they are named as defendants in legal claims.”

Laser rejuvenation recently edged out laser hair removal as the most litigated laser procedure, encompassing fractionated and non-fractionated, ablative and nonablative resurfacing, and intense pulsed light (IPL).

“The laser rejuvenation modalities, particularly the ablative resurfacing lasers, are associated with potentially more risk and require more skill to perform safely and correctly,” he said. “The caveat, though, is that laser rejuvenation is an umbrella term that includes several different types of laser procedures, whereas laser hair removal is just one type of procedure. The current study found 15 litigated cases for rejuvenation and 14 cases for hair removal. But if you separated rejuvenation into individual procedures, I suspect you would find that hair removal is still the number one litigated procedure.”

For cutaneous laser surgery in general, cases performed by non-physicians were most likely to result in legal action, regardless of the supervising physician’s subspecialty. In the current study, 66 percent of all legal suits occurred when non-physician operators performed the surgery.

“Cases involving medical spas uniformly had unsupervised non-physician operators in non-medical office settings and therefore had one of the highest litigation rates and number of cases,” Dr. Khalifi an said. “What is interesting about these findings, however, is that medical spas that are run by non-physicians are also less likely to have medical liability insurance to satisfy a potential malpractice claim and hence, would be less likely to be pursued by a plaintiff’s attorney.”

The number of patient injuries at a medspa is likely underrepresented due to the lack of malpractice insurance.

In 22 percent of identified claims, physicians were alleged to have caused patient injury. Dermatologists and plastic surgeons each represented about 6 percent of these overall claims.

The two leading causes of legal action among the 32 cases with public decisions were negligence and lack of informed consent, representing 50 percent and 34.4 percent of cases, respectively.

Other causes were breach of contract (6.3 percent), battery (6.3 percent), personal injury (6.3 percent), fraud (3.1 percent), negligent misrepresentation (3.1 percent), improper service (3.1 percent) and other malpractice (18.8 percent).

Burns, pigmentary alterations and scarring were the three most frequent injuries sustained (with some cases involving more than one type of injury) for a total of 56 injuries, representing 75 percent, 46.9 percent and 37.5 percent.
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percent of injuries overall, respectively. Other injuries included pain and suffering (9.4 percent), ocular injury (3.1 percent) and missed neoplasm (3.1 percent).

“Letting a patient know in advance through informed consent that a burn or dyschromia is possible might have reduced the number of litigated cases,” Dr. Khalifian said.

Of the 32 cases with a public decision, 53 percent had judgments in favor of the plaintiff, with indemnity payments ranging from $2,245 to $1.5 million. The mean and median payments were $318,000 and $142,000, respectively.

“The total data compiled since 1985 represents a relatively large sample size, spanning three decades in almost every U.S. state, and highlights the current legal framework, precedent and jurisprudence surrounding energy-based device litigation,” he said. “The data on allegations and causes of legal action should serve as a guide to help improve patient safety and decrease professional liability.”

Because injuries will likely continue to occur, physicians seeking to undertake laser surgery in their practice should ensure they have proper training in the physics, safety and techniques of each procedure.

“Legal precedent has demonstrated that non-physicians performing laser surgery are expected to have appropriate training to use energy based devices safely and provide the same standard of care that one would reasonably expect from a physician performing the same procedure,” Dr. Khalifian said. “Therefore, physicians who delegate laser operations to their non-physician agents must understand that they are ultimately responsible for the actions of their agents and should determine what their local and state regulations are regarding the type of supervision required for such delegation to occur.”

It is critical that physicians take steps to mitigate risk to patients by ensuring robust and adequate training for their agents and by directly supervising procedures.

“Our data clearly shows that these treatments are performed safest by physicians directly who have had dedicated training in laser and light sources,” he said.

In terms of study limitations, this study was limited to one legal database with cases restricted to those where legal action actually commenced. It does not include cases settled through arbitration.

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**Study: Novel 670 nm wavelength works for benign pigmented lesions**

**INGRID TORJESEN | Staff Correspondent**

A novel picosecond/nanosecond 670 nm wavelength is safe and effective for the treatment of benign pigmented lesions, suggests the results of pilot study presented at the American Society for Laser Medicine and Surgery annual conference this spring in Dallas.

Patients commonly seek treatment for benign pigmented lesions, but selective photothermolysis can be accompanied by side effects, including hyper- and hypo-pigmentation, so researchers decided to assess the clinical efficacy of a novel 670 nm wavelength.

While the 532 laser has relatively high absorption, absorption of the 1064 is very low level, explained Omar A. Ibrahimi, M.D., Ph.D., of the Connecticut Skin Institute in Stamford. The 670 nm was considered to be in the “Goldilocks range,” offering relatively good absorption and relatively good penetration depth.

The 10 patients in the study received up to ten treatments at six to eight week intervals using a picosecond/nanosecond laser platform consisting of a novel 670 nm wavelength. Ninety days after the last laser treatment they attended a follow up visit where digital pictures of the lesions were taken.

Three blinded dermatologists assessed the digital pictures taken at follow up with those taken at baseline, and scored improvement on a five-point scale, where zero represented no improvement, and four very significant improvement (75-100 percent clearance). Eight patients finished the study, and the average clearance of the pigmented lesions was between significant and very significant.

A novel picosecond/nanosecond 670 nm wavelength is safe and effective for the treatment of benign pigmented lesions, the researchers concluded.

“Well defined discrete lesions respond to as little of a single treatment,” Ibrahimi pointed out. “Side-effects are minimal and resolved within three months follow-up.”

**Reference**

Radiofrequency appears safe for non-surgical brow lift

LISETTE HILTON | Staff Correspondent

Cosmetic dermatologist Paul M. Graham, D.O., noticed a side effect after using the radiofrequency Pelleve device (Hologic) to treat periocular lines. It appeared patients were emerging from the noninvasive treatment with higher eyebrows.

So, Dr. Graham and David H. McDaniel, M.D., investigated whether it made sense, clinically, to use Pelleve as a brow lifting option. The study of 30 male and female patients looking at safety and effectiveness of radiofrequency for brow lifting, was presented in April at the American Society for Laser Medicine & Surgery (ASLMS) annual meeting in Dallas.

“Radiofrequency has been used for a long time — usually for facial wrinkles and skin rejuvenation,” Dr. Graham said. “...but our study demonstrated an innovative new nonsurgical, no-downtime, radiofrequency procedure for nonsurgical brow lifts.”

Study subjects had brow laxity and were between ages 35 and 65, with Fitzpatrick skin types ranging from II to VI. They received five treatments with the 4 MHz monopolar radiofrequency device at four-week intervals, on the forehead and in the periorbital area.

Researchers used Pelleve’s existing attachments — FDA cleared for other indications — for off-label brow lifting. They used both the 10 & 15 mm hand piece to treat the forehead and eye area, targeting an epidermal temperature of 40 to 44 degrees centigrade. Average treatment time was 20 minutes, according to the abstract.

“We treated the forehead, which contains the orbital retaining ligament.... Then we treated the upper and lower eyelids,” he said. “What sets that device apart is the small hand piece and the articulating arm. The hand pieces move and are able to conform to the treatment area. It’s not just one rigid rod that we’re putting on the skin. It has an articulating end to it, where we’re able to put it in an area of concavity or convexity, and it’s able to conform.”

The study found that 81% of study participants responded to treatment. And, 82% were satisfied at 120 days post treatment.

In some cases, the brow lift radiofrequency treatment resulted in a noticeable skin contraction right after the first treatment.

“The immediate changes were temporary. When we brought the patients back, though, after a cumulative amount of treatment, that’s when we were able to see that eyebrow lift,” Dr. Graham said.

Side effects included erythema and edema for up to 24 hours post treatment.

“Twenty-four hours is an overstatement. Most patients are not even red when they leave the office,” he said.

Radiofrequency brow lifts are among the more conservative treatments that cosmetic physicians perform.

“It’s for patients looking for skin tightening and subtle brow lifting, but don’t want to undergo the downtime associated with more invasive lasers or procedures, such as surgery,” Dr. Graham said.

The radiofrequency device to lift brows is a viable alternative to ultrasound for the same indication, he said. While patients say that radiofrequency brow lifting feels like a hot stone massage, ultrasound treatment can be painful.

Radiofrequency might also offer a different alternative than using neuromodulator injections to relax the forehead and lift the brows.

“... people looking more for a brow lift with [neuromodulators] may get an unpredictable brow lift, meaning we don’t know how far that [neuromodulator] is going to diffuse. There’s no exact location to inject that’s going to give a defined amount of lift. It’s all based on how active the patient’s lateral frontalis muscles are and how much depressor movement or pull-down there is from the orbicularis oculi muscles,” he said.

This radiofrequency device tested in the study creates heat in the skin and has been shown to cause collagen to contract and stimulate wound healing and new collagen, thus it lifts the brows.

Since conducting the study, Dr. Graham says the Virginia Beach, Va., practice where he is completing his fellowship has been promoting the use of Pelleve for brow lifting.

“If we’re using this device on someone with a lot of photodamage and skin laxity, you’re not going to see that effect, because we have to harness that collagen percentage in the skin and that skin elasticity to get that lift.

“This is a good treatment for patients in their 30s and 40s with only minimal to early photodamage.”

Disclosures: Dr. McDaniel was paid for the study and consulting. The equipment was loaned by Hologic.
Study: laser safely removes submental fat, tightens skin

LISETTE HILTON | Staff Correspondent

The 1060 nm diode laser SculpSure (Cynosure) is safe and effective, confirms a study presented at the American Society for Laser Medicine & Surgery annual meeting in April.

“This is really the first laser that has been shown to work for removing fat in the submental area,” says Bruce E. Katz, M.D., director of Juva Skin & Laser Center in New York City. “It’s a quick treatment of about 25 minutes. We found that, in addition to removing fat, it actually tightens the skin.”

The SculpSure device, which is FDA cleared to treat the abdomen, flanks, back, inner and outer thighs and the submental area, which requires changes to the device’s software so the heat from the laser is more superficial under the chin than it may be for other treatment areas.

David H. McDaniel, M.D., a dermatologist in Virginia Beach, Va., presented clinical study findings on the safety and efficacy of the 1060 nm diode laser for treating the submental area. The study included men and women between 20 and 65 years old with significant submental fat and body mass indexes of 45 or less. Each received two 25-minute treatments.

Improvements were measured on a five point scale and by week 12, the average physician-rated score was four. But patients settled on a score of 2.5 on average. In the subset analysis, researchers reported an average improvement of 21.5% in lift; -3.0% in skin tightening; -5.3% minor strain median measurements; and an average reduction of 5.6 cc in volume.

SCULPSURE, COOLSCULPTING AND KYBELLA

SculpSure uses heat to disrupt fat cells. Other options for nonsurgical submental fat reduction include CoolSculpting’s CoolMini (Zeltiq). Its applicator is held in place with mild suction. Kybella (deoxycholic acid, Allergan) is chemical lipolysis injected into the fat. One benefit for Kybella is that it doesn’t require investment in a device or additional space, said Dr. McDaniel who created a special room for the device in his practice with spa beds and a television.

He uses all three options in his practice because each has a unique role. CoolMini’s applicator is an oval which may be better suited for specific areas of the body, while SculpSure’s is a rectangle. In people who have double chins that run east, west or ear to ear, there may be a difference in which applicator is the best fit for the anatomy, he said.

“Right now, both devices are one-size-fits-all. In some patients, CoolSculpting or SculpSure will fit and the other may not. It depends on anatomy and on which direction your fat runs,” Dr. McDaniel said.

Kybella can be used on almost any shape or geometric pattern of submental fat, and it doesn’t depend on contact with suction or straps. Some doctors hesitate to use Kybella because it has been associated with posttreatment edema.

“Patients can get anything from a very tiny bit of swelling to an extreme case, termed ‘bullfrog neck,’ which can last for a long time. There’s research now on how to minimize or avoid that,” he said.

Dr. Katz, who did the FDA trials for Kybella, says the swelling associated with Kybella use is a big problem when one considers that Kybella requires three or four treatments.

The treatment is typically done at one-month intervals, so it may be months before results show. “Whereas, with the laser it’s usually one or two treatments and you don’t get any swelling or discomfort after.”

TREATMENT INSIGHTS

Addressing double chins could result in patients wanting more.

“Once people aren’t fixated on their double chin, they notice other things,” Dr. McDaniel says.

For example, platysmal muscle bands might become more visible after submental fat treatment; or, patients might want more skin tightening after the noninvasive treatment.

“Sometimes, we’ll use the CoolMini or SculpSure on the submental area and, if there’s a little residual fat left, touch up the area with Kybella,” he said.

Physicians offering any of these treatments should be careful treating around the marginal mandibular nerve, Dr. McDaniel said.

“The nerve can be fairly variable and you don’t want to treat that nerve. The insulation of the nerve is a lipid. If you damage it, you can have sensory or motor changes which typically resolve with time,” he said.

Disclosures: Dr. McDaniel has been a consultant, advisor and researcher for Cynosure, which sponsored both studies.
INTRODUCING

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Despite the popularity of fractional ablative resurfacing, full-field erbium (2,940 nm) resurfacing still plays an important role, says Joel L. Cohen, M.D., a dermatologist in Greenwood Village, Colorado.

Dr. Cohen spoke with Dermatology Times about fractional resurfacing vs full-field resurfacing.

“Our excitement for fractional resurfacing has led us to use so much fractional that there are times where the results for specific areas, such as perioral and periorcular etched lines, may be suboptimal after a couple of treatments. So, I revert back to full-field resurfacing in the areas that really need it,” he said.

“In my practice, I like to use a combination of lasers on the face – different lasers for different areas. I might use full-field 2,940 nm erbium often around the mouth or eyes, then either fractional CO2 or fractional erbium on the rest of the face.”

With full-field erbium, “The reality is, it’s worth the downtime. The mouth and eyes typically have more etching than other areas of the face. But when other areas have extensive photodamage, we can use full-field erbium in those areas as well.”

FULL-FIELD ERBIUM

Many patients have more photodamage around the mouth or eyes, and sometimes the forehead or cheeks, he said. With full-field erbium, “I believe it’s picking the right tool for the right job. It provides more significant results,” often achieving marked improvement with just one treatment.

But the healing time is longer with 7-10 days for re-epithelialization. And, persistent erythema is an issue for patients. “We cannot yet predict who’s going to have more persistent erythema. But usually in my practice, it’s in the range of 3-7 weeks. I typically do not treat that with topical steroids or other topical products – we just try to color-match patients (with concealer makeup) and make sure that they use photoprotection very diligently to prevent hyperpigmentation as they heal.”

PATIENT COUNSELING

Considering the very real incidence of post-inflammatory erythema after full-field erbium resurfacing, Dr. Cohen counsels patients to plan accordingly and avoid scheduling the treatment immediately prior to a planned event, like a wedding. “I give everybody antivirals two days before the treatment until about 10 days after. I don’t use prophylactic antibiotics.” Additionally, patients may use a growth factor product such as Tensage (Biopelle), Bio-Cream (NeoCatis) or TNS Essential (SkinMedica) for several weeks, along with a topical retinoid, pre-procedure. “I no longer have them stop topical retinoids a week prior, and just have them use topical retinoids right up to the treatment.”

PREPARATION FOR TREATMENT

In preparation for full-field erbium resurfacing, “I give everybody antivirals two days before the treatment until about 10 days after. I don’t use prophylactic antibiotics.” Additionally, patients may use a growth factor product such as Tensage (Biopelle), Bio-Cream (NeoCatis) or TNS Essential (SkinMedica) for several weeks, along with a topical retinoid, pre-procedure. “I no longer have them stop topical retinoids a week prior, and just have them use topical retinoids right up to the treatment.”

TREATING THE MOUTH AREA

For treatment around the mouth, “I typically give patients an infraorbital and a mental block, and supplement those with a perioral sulcus block. Then I’ll perform full-field erbium with no coagulation. I do 100 μ passes.” Depending on the depth and severity of the etching (facilitated by incorporating a scale he co-authored), total treatment depth ranges from a typical 400 μ up to even 700 μ for very severe etched-in lines. “I perform passes until reaching an endpoint of pinpoint bleeding, also going
back to certain persistent lines focally at 30 μ until I see them effaced. That’s why there’s a range of treatment depths.”

5 TREATING THE EYE AREA

Around the eyes, “I do things a little differently than around the mouth.” After giving patients internal stainless steel eye shields, he employs the erbium laser with coagulation at around 50, treating at approximately 80 μ depth and blending outward as he gets outside the orbital rim and lateral to the lateral canthal rhytids.

6 TREATING OTHER FACIAL AREAS

“Then for the rest of the face, I’ll use fractional CO2 or fractional erbium, usually at around 25% density.” In counseling, he advises patients that different areas will look different after treatment, showing them pictures of other patients at various healing stages. “I want to make sure they understand that the mouth and eyes will have yellow fibrin, and the rest of the face will be pretty red and swollen.”

7 SIDE-BY-SIDE TREATMENTS

Because patients will experience significant healing downtime, and then some degree of persistent erythema after full-field resurfacing, Dr. Cohen often performs same-day treatment of the neck and chest with an Arctic Peel (515 nm BBL broadband light, Sciton, plus microlaser erbium peel) or the Halo laser (Sciton).

8 WOUND CARE

Dr. Cohen encourages good wound care with a mild cleanser and a fragrance-free, hypoallergenic moisturizer such as white petolatum. “I also give patients hypochlorous acid (Lasercryn Dermal Spray, IntraDerm) so that they spray the whole treatment area for several days post-treatment.” Along with being antimicrobial, “Hypochlorous acid has been found to help with itching, burning and stinging. And it is eye-safe. We use it as a skin prep in the office as well.” Once skin has healed over, patients may start (or resume) a skin-care regimen that includes growth factors and a retinoid.

9 THE FOLLOW-UP

He typically schedules follow-up appointments a few days later and often a week later as well— if patients are willing to return while they are healing. “Not everybody is able to do that. Because of the significant wound-healing reaction of the skin, some patients aren’t comfortable leaving the house. We try to make it work at times where there may be fewer people in the waiting room.”

These post-laser visits provide an opportunity to review care instructions. “The post-laser care is important. I don’t want people using potentially irritating or immunogenic ingredients like acidic products or fragrant products. Because the skin barrier is not intact, these products could increase the risk of irritant or contact dermatitis.”

Disclosures: Dr. Cohen has been a consultant for Sciton and IntraDerm.

Reference

Physicians writing in the *Journal of the American Academy of Dermatology* say that physicians should counter the proliferation of fake news on climate change.

“There is a trend to delegitimize facts which is most evident today with climate change,” said Saami Khalifian, M.D., a clinical fellow in dermatology at Massachusetts General Hospital who wrote the article with Misha Rosenbach, M.D., associate professor of dermatology at The Hospital of The University of Pennsylvania.

Publishing original research as a resident “is almost a prerequisite,” Dr. Khalifian said in an interview with *Dermatology Times*. “So, as physician scientists, the credibility of scientific discovery and discourse is paramount. However, once we lose agreement on what constitutes facts or real scientific discoveries or breakthroughs, that discourse breaks down.”

More than 95% of climate scientists agree that climate change is due to anthropomorphic causes, he said. “Yet there is still a significant subset of the population that is unsure that climate change really exists. I believe this creates a disconnect,” he said.

Fake news is threatening the concept and credibility of any kind of expertise and the credibility of any type of scientific research. “Therefore, it is important that dermatologists stand up for the integrity of science and scientific research,” Dr. Khalifian said.

In the past, scientists and physicians strived to remain apolitical, but being apolitical today may be a disservice to the profession, to the institution of science and to patients, he said.

“If we don’t fight the fight, who will? The notion that we are stewards of the public trust is something we should and do take very seriously — not only in how we practice medicine, but how we shape perception, how we counsel and how we encourage people to live healthier lifestyles.”

Saami Khalifian, M.D.,
Clinical fellow, Massachusetts General Hospital
Combination therapy

Encorafenib plus binimetinib promising treatment option for melanoma

ANDREW D. BOWSER | Staff Correspondent

T he combination of encorafenib plus binimetinib significantly improved overall survival versus vemurafenib in patients with BRAF-mutant melanoma, updated results of the randomized, phase three COLUMBUS trial show.

Median overall survival was 33.6 months for the BRAF/MEK inhibitor regimen, versus 16.9 months for vemurafenib with an “impressive” hazard ratio of 0.61, said investigator Rinehard Dummer, M.D., of the Department of Dermatology, University of Zurich Hospital, Switzerland.

“We can conclude — based on the favorable tolerability profile — that this combination provides a new efficacy benchmark for targeted therapy and is a promising treatment option for patients with BRAF-mutant metastatic melanoma,” Dr. Dummer said in a presentation of the results at the 2018 annual meeting of the American Society of Clinical Oncology (ASCO).

The BRAF/MEK inhibitor combinations that are already established as a standard of care for this patient population have demonstrated median overall survival of approximately 24 months in clinical trials, he said.

Those combinations have some unique toxicities that may impact the ability to deliver optimal treatment, he added. Toxicities include the pyrexia associated with dabrafenib plus trametinib, and the photosensitivity associated with vemurafenib/binimetinib.

Douglas B. Johnson, M.D., director of the Melanoma Program at Vanderbilt Ingram Cancer Center, Nashville, Tenn., said these results help establish encorafenib plus binimetinib as another option for BRAF V600 mutant melanoma.

“It has at least equivalent efficacy (versus other BRAF/MEK combinations) and there’s certainly suggestions that it might have superior efficacy,” Dr. Johnson said in a podium discussion of the study results. “It has a distinct toxicity profile, and at least much of this is driven by the fact that encorafenib is a more active BRAF inhibitor therapy.”

OVERALL SURVIVAL ADVANTAGE

The COLUMBUS trial included 577 patients randomized to one of three arms: encorafenib plus binimetinib, encorafenib monotherapy, or vemurafenib. The first analysis of the trial, published recently in Lancet Oncology, showed that progression-free survival was 14.9 months for encorafenib/binimetinib, versus 7.3 months for vemurafenib (hazard ratio, 0.54; 95% CI, 0.41–0.71; P < 0.0001) at a median follow-up of 16.6 months.

The study showed a median overall survival of 33.6 versus 16.9 months for the combination versus vemurafenib (hazard ratio, 0.61; 95% CI, 0.47-0.79; P < 0.0001) based on a median duration of the follow-up of 36.8 months. A landmark analysis additionally showed that at three years, 47% of patients randomized to encorafenib plus binimetinib were living, versus 32% in the vemurafenib arm.

The encorafenib monotherapy arm had an overall survival that was not statistically different from that in the encorafenib plus binimetinib arm. However, there was a clear trend favoring the combination. Median overall survival for encorafenib alone was 23.5 months, versus the 33.6 months seen for encorafenib in combination with binimetinib.

Encorafenib had a statistical advantage over vemurafenib monotherapy, with its 23.5 months median overall survival comparing favorably with the 16.9 months for vemurafenib.

In terms of safety, the encorafenib combination provided a new efficacy benchmark for targeted therapy and is a promising treatment option for patients with BRAF-mutant metastatic melanoma.”

Rinehard Dummer, M.D., University of Zurich Hospital, Switzerland

“...
Melanoma staging

ASCO presentation questions survival differentiation between IIIA and IIIB

Quick Takes

Stage III melanoma differentiation is comparable for 7th and 8th editions of the AJCC melanoma staging system.

8th edition of the staging system shows differentiation between IIIA and IIIB.

8th edition redefines AJCC prognostic stage IIIA groupings.

Researchers reporting at the American Society of Clinical Oncology annual meeting on June 4 presented a study in which they compared the seventh and eighth editions of the American Joint Committee on Cancer (AJCC) melanoma staging systems. The eighth edition differentiates melanoma survival slightly worse than the previous edition, they said.

Max Fullah Madu, M.D., a physician with the Netherlands Cancer Institute in Amsterdam who led the study, sought to determine if the 8th edition offered an improvement in prognostic accuracy.

The study is based on the treatment outcomes of 640 melanoma cases from a Netherlands Cancer Institute database. The patients were treated between 2000 and 2016 and followed for 59 months.

In terms of survival discrimination, which is a measure of prognostic accuracy, both staging systems performed similarly with no statistical difference between systems.

Researchers analyzed prognostic factors for melanoma-specific survival and distant metastasis-free survival finding a median melanoma-specific survival rate of 138 months and 96 months for patients with distant metastases-free survival.

The findings were mixed for stage IIIA melanoma for both the 7th and 8th editions. In estimating survival, both the 7th and 8th editions were comparable, but the 8th edition failed to differentiate melanoma-specific survival between stage IIIA and IIIB.

For patients with sentinel node metastasis of less than one, researchers found excellent melanoma-specific survival and distant metastasis-free survival rates.

In looking at survival differentiation between the stage III subgroups using the eighth edition, they saw an overlap in the three A and three B survival curves over the first four years of follow-up, resulting in a differentiation that reached only borderline statistical significance (P = 0.047). By contrast, the 7th edition criteria produced a clean separation in IIIA and IIIB survival curves, resulting in a significant difference (0.002).

Given the lower proportion of patients in the 8th edition IIIA group, Dr. Madu said the results should be viewed with some caution. By 8th edition classification, 12% of the Netherlands patients were considered IIIA, compared to 25% of patients using 7th edition classification.

CAN SENTINEL NODE TUMOR BURDEN REFINe III A STRATIFICATION?

Survival within the 8th edition IIIA subgrouping might be stratified further using European Organization for Research and Treatment of Cancer (EORTC) criteria for sentinel node tumor burden, Dr. Madu said.

In a large EORTC study, patients with a maximum diameter of the largest metastatic deposit in the sentinel node of 1 mm or less had much better survival compared with those with a maximum diameter more than 1 mm.

I hope for a future in which AJCC criteria, combined with sentinel node tumor burden without the need for completion lymph node dissection, will allow precise and minimally invasive tumor staging in melanoma patients.”

Max Fullah Madu, M.D., Netherlands Cancer Institute, Amsterdam
For the Netherlands data set, using 7th edition staging, stage III A patients with a maximum diameter of 1 mm or less had a five-year survival of 89%, versus 65% for those with a maximum diameter greater than 1 mm (P < 0.001). The difference was slightly less, but still significant, using the 8th edition criteria with five-year survival of 91% versus 72% for 1 mm or less and greater than 1 mm, respectively (P = 0.020).

The finding was corroborated by a study recently published in the *European Journal of Cancer* that included a multicenter cohort of more than 1,000 sentinel node-positive patients. Comparing four different prognostic models, investigators found that the combination of eighth edition AJCC staging plus sentinel node tumor burden was the best prognostic model.

“The EORTC tumor burden criteria can be a powerful adjunct to AJCC staging, especially in a post-completion lymph node dissection era where less staging information will be available,” Dr. Madu said. “I hope for a future in which AJCC criteria, combined with sentinel node tumor burden without the need for completion lymph node dissection, will allow precise and minimally invasive tumor staging in melanoma patients.”

**NEW CRITERIA, NEW QUESTIONS**

One of the most significant changes in the eighth edition is having redefined AJCC prognostic stage three A groupings, including the addition of a new ultra-high-risk stage three D subgroup.

In a presentation on re-evaluating the staging and management of stage three melanoma, April K.S. Salama, M.D., director of the melanoma program at Duke Cancer Institute, said: “The way I think of this is that it has essentially become more selective at each end of the spectrum.”

Dr. Salama said three A includes patients who may have a more favorable prognosis versus the previous three A criteria. While three D is designated for patients who are at the highest risk of recurrence.

The AJCC melanoma expert panel also changed the TNM criteria needed to gain entry to the subgroups, making it difficult to translate between versions, Dr. Madu said.

“A patient who was stage three A in the previous edition can now be stage three C in the current edition. This raises a few questions — especially in this time of rapidly changing melanoma treatments,” Dr. Madu said. ◼

**References**


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Pembrolizumab has antitumor activity that is durable long after treatment is stopped in patients with advanced melanoma, researchers reported at the American Society of Clinical Oncology (ASCO) annual meeting on June 4.

This study, called the KEYNOTE-006 trial, showed that about 86% of patients remained progression-free 20 months after they had completed two years of treatment with anti-PD-1, an immunotherapy for patients with advanced melanoma, investigator Georgina V. Long, M.D., Ph.D., reported in her presentation.

Dr. Long, who is of the Melanoma Institute Australia and Royal North Shore Hospital of the University of Sydney, said that eight patients who progressed were treated with pembrolizumab. Half of those patients reported ongoing responses.

“Re-treatment with pembrolizumab upon progression can provide additional antitumor activity and acceptable safety,” she said.

In a podium discussion of the study, Douglas B. Johnson, M.D., director of the Melanoma Program at Vanderbilt Ingram Cancer Center in Nashville, said that eight patients who progressed were treated with pembrolizumab. Half of those patients reported ongoing responses.

“We have no idea whether anti-PD-1 rechallenge is effective in this population,” Dr. Johnson said.

**UPDATED SURVIVAL**

Dr. Long’s presentation also included recently updated survival results for both the pembrolizumab and ipilimumab arms of the KEYNOTE-006 trial.

The phase three KEYNOTE-006 trial included 834 patients with advanced melanoma randomized evenly to three arms: pembrolizumab every two weeks, pembrolizumab every three weeks, or ipilimumab, the anti-CTLA-4 antibody. Investigators enrolled both treatment-naïve patients and patients who had received one prior treatment, excluding anti-PD-1, anti-PD-L1, or anti-CTLA-4 agents.

With a median follow-up of 22.9 months, median overall survival had not been reached in either pembrolizumab arm, compared to 16.0 months for ipilimumab, according to final results published in October 2017 in The Lancet.

Those results established the superiority of pembrolizumab over ipilimumab for treatment of advanced melanoma.

With a median follow-up of 45.9 months, the updated data now show a median overall survival of 32.7 months, versus 15.9 months for ipilimumab. The four-year overall survival was 41.7% and 34.1% for pembrolizumab and ipilimumab, respectively.

Specifically, in the treatment naïve subset of patients, overall survival was 38.7 versus 17.1 months for pembrolizumab and ipilimumab, respectively, with four-year overall survival of 44.3% and 36.4%.

**POST TREATMENT OUTCOMES**

Pembrolizumab yielded durable treatment responses in patients who completed two years of planned treatment. Out of 556 patients who received pembrolizumab, 103 (18.5%) completed the full two years, and of those, 80% were progression-free at 20 months after the end of therapy.

Patients who had a complete response after those two years of treatment had an 18-month progression-free survival of 95.8%, compared with 91.3% for those who had partial response, and 66.7% for those with stable disease.

**PEMBROLIZUMAB RECHALLENGE**

In the KEYNOTE-006 study, patients who stopped pembrolizumab or completed the full two years of planned treatment could receive a second course of the immune checkpoint inhibitor for up to a year of additional therapy.
Of the eight patients, four have ongoing responses after the second course of pembrolizumab, three have stable disease, and only one patient had progressive disease as the best response."

Georgina V. Long, M.D., Ph.D., University of Sidney, Australia

A total of eight patients have had a second course of pembrolizumab with recurrences after first course occurring mainly in lymph nodes and skin. Of those eight patients, only one discontinued the second course due to disease progression, while three completed one full year of pembrolizumab, two are in ongoing treatment, and one discontinued due to a respiratory infection.

Adverse events for these patients were mild in both their first and second course of pembrolizumab.

“Of the eight patients, four have ongoing responses after the second course of pembrolizumab, three have stable disease, and only one patient had progressive disease as the best response,” Dr. Long said. ▶

Disclosures: Dr. Long reported honoraria from Bristol-Myers Squibb, Incyte, Merck, Novartis, and Roche, and a consulting or advisory role with Amgen, Array BioPharma, Bristol-Myers Squibb, Incyte, MERCK, Novartis, Pierre Fabre, and Roche/Genentech.

References


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1: https://www.carpelotion.com/carpetestresults.pdf
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Melanoma diagnosis by partner

WAYNE KUZNAR | Staff Correspondent

Married patients present earlier with localized melanoma than their unmarried counterparts. In a retrospective population-based study that used the Surveillance, Epidemiology, and End Results (SEER) database, among 52,063 adult patients identified with cutaneous melanoma, 45.7% of the married patients presented with T1a disease compared with 43.0% of never married patients, 39.0% of divorced patients, and 32.2% of widowed patients (P<0.001).

Led by Cimarron E. Sharon, from the Hospital of the University of Pennsylvania, investigators queried the SEER database for adults with a pathologically confirmed diagnosis of melanoma with marital status recorded and known sentinel lymph node status. Patients had no evidence of regional or distant metastases. Their median age was 64 years, 59% were men, and 69.7% were married.

As published in JAMA Dermatology, patients who were never married (OR, 1.32; 95% CI, 1.26-1.39), divorced (OR, 1.38; 95% CI, 1.30-1.47), or widowed (OR, 1.70; 95% CI, 1.60-1.81) were more likely to present with a later T stage compared with married patients (P< 0.001 for all) in multivariable analysis.

Widowed patients were more likely to present with T4 disease (T4a, 5.6%; T4b, 9.4%) compared with married (T4a, 2.6%; T4b, 3.3%), never married (T4a, 2.9%; T4b, 4.8%), and divorced (T4a, 3.1%; T4b, 5.1%) patients (P< 0.001).

Further, never married, divorced, and widowed patients are less likely to undergo sentinel lymph node biopsy for appropriate lesions.

The findings support increased consideration of spousal training for partner skin examination and perhaps more frequent screening for unmarried patients, according to the authors.

“This study has important implications for counseling patients and recommending frequency of follow-up surveillance,” they wrote. “Clinicians may, for instance, recommend that unmarried patients initiate regular skin examinations at an earlier age and continue them more frequently to detect lesions at an earlier stage. For married patients, encouragement of partners to be present at clinic appointments and undergo basic training for performing a skin examination could perhaps further increase early detection of primary lesions.”

Reference


Dosing schedules that optimize melanoma outcomes

WAYNE KUZNAR | Staff Correspondent

Changing the schedule of targeted therapies has been shown to improve the response rate in a mouse model of melanoma, according to a report in Cancer Discovery. Continuous MEK inhibition with intermittent CDK4/6 inhibition led to a higher rate of complete responses compared with other combination schedules.

“We are looking to optimize the combinations of targeted therapies and the scheduling of those therapies, so we can improve tumor shrinkage and minimize potential toxicities for a patient,” said Andrew Aplin, Ph.D., co-investigator and program leader for Cancer Cell Biology and Signaling in the Sidney Kimmel Cancer Center at Jefferson Health, Philadelphia.

Dosing schedules of combination therapy two using targeted agents on human melanomas grafted onto mice were studied. Both agents given intermittently (3 weeks on/1 week off) was the least effective schedule, with tumor regrowth during drug treatment and partial response to retreatment following the drug holidays. By the third cycle, most tumors no longer responded to therapy.

More effective inhibition of tumor growth was observed with continuous dosing of either the CDK4/6 inhibitor or MEK inhibitor with intermittent dosing of the other drug. Exploring that result further, continuous MEK inhibition with intermittent CDK 4/6 inhibition was found to inhibit tumor growth the most, with some shrinking to undetectable levels. There was no significant anemia or neutropenia with any of the various dosing schedules.

Several mechanisms leading to tumor resistance were discovered, providing the researchers insight into which drugs could combat resistant cancer. “The surprising part was that the mechanisms of resistance all funneled through one signaling pathway, ultimately, but the way that they start is frequently different,” said Dr. Aplin. When that common pathway was blocked with an mTOR inhibitor, in addition to continuing the optimized Mek inhibitor and CDK 4/6 inhibitor therapies, resistance was effectively turned off, and the tumors resumed shrinking.

Reference

Science: Dermatology should lead the way for all other specialties
FROM PAGE 48

plus binimetinib combination had a favorable tolerability profile and no new concerns emerged with longer follow-up, according to Dr. Dummer. In the earlier Lancet Oncology report, investigators said the most common grade 3/4 adverse events in the combination group were increases in γ-glutamyltransferase, increases in creatine phosphokinase, and hypertension.

HOW DOES THE COMBO FIT IN?
The biggest question facing the encorafenib plus binimetinib is where the combination fits in with the other available BRAF/MEK inhibitor combinations: namely, dabrafenib plus trametinib and vemurafenib plus cobimetinib, said Vanderbilt University’s Dr. Johnson in his commentary on the trial.

“I’ll now engage in a very time-honored and historic tradition of discussions everywhere, by saying that I should not compare cross-trials, but then I will proceed to do so,” Dr. Johnson said, eliciting a laugh from attendees.

Response rate data are similar for the three combinations in their respective and separate clinical trials, including complete response and progressive disease rates, Dr. Johnson said.

“The overall survival and progression-free survival is where you start to see maybe a bit of a difference here,” he added. “Really the numeric overall survival with encorafenib plus binimetinib, and progression-free survival, is quite impressive, and does compare very favorably with the other available options.”

On the other hand, the rate of grade 3/4 toxicity does seem to be higher with encorafenib plus binimetinib; however, as noted in the ASCO presentation, that does not translate into an increased rate of drug discontinuation or an increased rate of dose decrease and dose holding.

Even if efficacy is superior and toxicities are objectively similar, there is perhaps one other important question that would need to be answered regarding the encorafenib plus binimetinib combination.

Given the non-significant difference in overall survival between encorafenib alone and in combination with a MEK inhibitor, it’s legitimate to ask whether the single agent approach would be preferable, Dr. Johnson said.

Several points argue in favor of the combination, however.

Complete response rates, at least numerically, favor encorafenib in combination, at 11% versus 7%. Moreover, updated progression-free survival data from ASCO show a significant difference in favor of combination over encorafenib monotherapy. Finally, the rate of grade 3/4 toxicities was very similar for the combination versus monotherapy, and notably the rate of dose decreases and dose holding was lower in the combination arm.

“I think that we can say that the combination is the preferred option based on moderately better efficacy, as well as moderately better tolerability,” Dr. Johnson said. “However, for patients that can’t tolerate MEK inhibitor-based therapy, either for cardiac comorbidities or ocular toxicity, I think the single agent encorafenib is a pretty good treatment option as well.”

REFERENCES


RESOURCES

Physicians for Social Responsibility (www.psr.org)
American Academy of Environmental Medicine (www.aamonline.org)
Children’s Environmental Health Institute (www.cehi.org/or-professionals)
World Medical Association’s statement on the role of physicians in environmental issues. (bit.ly/2yuCZ4P)
U.S. Environmental Protection Agency lists online resources for healthcare providers on pediatric environmental health. (bit.ly/2lezILE)
Greening the Physician’s Office by the American College of Physicians (bit.ly/2laLh6j)
Dermatofibrosarcoma protuberans (DFSP) is an uncommon, cutaneous tumor characterized by aggressive local growth and a tendency to recur after surgical excision. DFSP typically presents as an asymptomatic, indurated plaque or firm cutaneous nodule in early adulthood. The plaque can be red-brown, flesh-colored, or blue-red and often is described with a previous history of trauma to the site. On palpation, the lesion is firm and is most commonly located on the trunk (60%), followed by the proximal extremities (30%) and head and neck (10%).1 Clinically, DFSP lesions may be mistaken for keloids, dermatofibroma and dermatomyofibroma.

The fact that the tumor is usually slow growing and asymptomatic often results in it being ignored by patient and physician and therefore treatment is frequently delayed. As DFSP slowly enlarges it may develop protuberant nodules. Once these nodules appear, growth can rapidly accelerate and the tumor can ulcerate and bleed, as in the case of the first patient.2 Even when DFSP become large, it is still uncommon for them to become fixed to underlying structures.3 However recurrent DFSP may invade fascia, striated muscle, and bone.4 DFSP is a tumor that arises in the dermis and shows the characteristic appearance of large spindle-shaped cells in a storiform pattern, which is a proliferation of fibroblastic tumor cells arranged around a central “hub” that resembles the spokes of a cartwheel.5,6 This finding has been shown to be histologically unique to DFSP.2 The condition can occasionally be confused histologically with other neoplasms such as fibrosarcoma, malignant fibrous histiocytoma, atypical fibroxanthoma, and dermatofibroma. Fibrosarcomas are composed of highly pleomorphic cells arranged in a herringbone pattern, which aids in differentiating them from DFSP. Dermatofibromas show overlying epidermal hyperplasia, small size, and occasional presence of many multinucleated giant cells.7 Immunoperoxidase staining has also proven to be a very useful tool in differentiating between these tumors. Dermatofibromas usually stain negative for CD34 but positive for factor XIIIa, while DFSP stain positive for CD34 and negative for factor XIIIa.7 Nearly all cases of DFSP have a gene mutation leading to the fusion of the collagen type 1a1 gene with the platelet-derived growth factor B-chain – a 17;22 translocation.8

DFSP accounts for less than 0.1% of all malignancies.2 The local spread of the tumor and its high likelihood to cause local recurrence after resection are due to the tentacle-like projections of tumor cells that invade between normal collagen bundles.1 Although DFSP is a very aggressive local tumor, it rarely metastasizes or leads to death. A high mitotic rate may indicate a greater potential for metastasis than tumors with a low mitotic rate.1,4 Complete surgical excision, especially Moh’s micrographic surgery (MMS), is the standard treatment for DFSP.9 High local recurrence rates are attributed to the tentacle-like growth pattern. The advantage of MMS is that it allows the surgeon to examine the deep and lateral margins of all the tissue that has been removed and therefore permit the detection of the tentacle-like growth pattern.
Test yourself on fibrotic skin lesions

KAIVON SOBHANI, B.S., AND EVE LOWENSTEIN, M.D., PH.D., FAAD

Q Which of the following images requires a biopsy?
Dermatofibrosarcoma protuberans (DFSP), dermatofibromas, keloids and hypertrophic scars are four separate conditions requiring assessment, but only one requires a biopsy.

DFSP (photo 1) is an uncommon, cutaneous tumor characterized by aggressive local growth and a tendency to recur after surgical excision. Clinically, DFSP lesions may be mistaken for keloids (photo 2), however keloids are benign growths with no metastatic potential and are the consequence of aberrant scar formation. Keloids extend beyond the site of injury, unlike hypertrophic scars (photo 3), which are confined to the site of injury. Dermatofibromas (photo 4) are benign dermal proliferation of fibroblasts.

ANSWER: Photo 1

Q Which of these is best managed with Mohs micrographic surgery (MMS)?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Keloid and hypertrophic scar

Q Which of these is best managed with injection of Triamcinolone acetonide (Kenalog)?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Keloid

Q Which of these exhibits pleomorphic cells arranged in a storiform pattern?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: None of the above. The correct answer is fibrosarcoma.

Q Which of these can metastasize?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP). A Bednar tumor (also called pigmented DFSP) is a rare variant of DFSP that has cells with melanin pigment. The majority are located on the trunk and proximal extremities.

Q Which of these is more common in black and Hispanic populations?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q Which of these is CD34 positive and factor VIII negative?

1. Dermatofibrosarcoma protuberans (DFSP)

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q True or false: Genetics play heavily into the propensity to make keloids?

ANSWER: True. Keloids are seen much more commonly in darker skin individuals. Furthermore, certain syndromes have a propensity to make keloid including Rubinstein-Taybi syndrome 1, Geominne syndrome, Ehler-Danlos and possibly Turner’s Syndrome. Furthermore, in Caucasians of northern European ancestry, the HLA-DRB1*15 allele has recently been shown to be associated with keloid formation.

Q True or false: Genetics play heavily into the propensity to make DFSP?

ANSWER: True. DFSP has a tendency to recur due to tentaclelike growth pattern of tumor cells. Thus, MMS provides the best chance of excising the tumor with clear margins.

Q Which of these has thickened hyalinated collagen bundles arranged haphazardly with an increased number of fibroblasts?

1. Dermatofibrosarcoma
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma

Q Which of these is CD34 positive and factor VIII negative?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q True or false: Genetics play heavily into the propensity to make hypertrophic scar?

ANSWER: True. Hypertrophic scars are a consequence of aberrant wound healing and are more commonly in darker skin individuals. Furthermore, certain syndromes have a propensity to make keloids including Rubinstein-Taybi syndrome 1, Geominne syndrome, Ehler-Danlos and possibly Turner’s Syndrome. Furthermore, in Caucasians of northern European ancestry, the HLA-DRB1*15 allele has recently been shown to be associated with keloid formation.

Q Which of these is CD34 positive and factor VIII negative?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q True or false: Genetics play heavily into the propensity to make keloid?

ANSWER: True. Keloids are more common in darker skin individuals. Furthermore, certain syndromes have a propensity to make keloid including Rubinstein-Taybi syndrome 1, Geominne syndrome, Ehler-Danlos and possibly Turner’s Syndrome. Furthermore, in Caucasians of northern European ancestry, the HLA-DRB1*15 allele has recently been shown to be associated with keloid formation.

Q Which of these is increased number of collagen bundles arranged in a haphazard pattern observed in DFSP can be contrasted to the herringbone pattern observed in fibrosarcoma and the haphazardly arranged bundles of collagen seen in keloids.

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q Which of these exhibits pleomorphic cells arranged in a storiform pattern?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: None of the above. The correct answer is fibrosarcoma.

Q Which of these has a propensity to make keloid?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q Which of these is CD34 positive and factor VIII negative?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q Which of these has thickened hyalinated collagen bundles arranged haphazardly with an increased number of fibroblasts?

1. Dermatofibrosarcoma
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma

Q Which of these exhibits pleomorphic cells arranged in a storiform pattern?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q Which of these is more common in black and Hispanic populations?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q Which of these is CD34 positive and factor VIII negative?

1. Dermatofibrosarcoma protuberans (DFSP)
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma protuberans (DFSP)

Q Which of these has thickened hyalinated collagen bundles arranged haphazardly with an increased number of fibroblasts?

1. Dermatofibrosarcoma
2. Keloid
3. Hypertrophic scar
4. Dermatofibroma

ANSWER: Dermatofibrosarcoma
DFSP may be mistaken clinically with a keloid.

**POST TEST QUESTIONS:**

**DFSP/DF/Keloids/Hypertrophic scars**

**QUESTION 1**

True/False? Both keloids and hypertrophic scars have genetic predisposition?

**ANSWER:** False: Keloids do not but hypertrophic scars do not.

**QUESTION 2**

What gene translocation is present in nearly all cases of Dermatofibroma-sarcoma protuberans?

A. Chromosome 9; 22
B. Chromosome 17; 22
C. Chromosome 11; 14
D. Chromosome 8; 14

**ANSWER:** Chromosome 17; 22

**case PRESENTATION #2**

By KAIVON SOBHANI, B.S., AND, EVE LOWENSTEIN, M.D., PH.D., FAAD

A 74-year-old African American male presents with several dark brown skin colored, firm, raised lesions extending across his chest to his axilla and extending below his breast (photo 2). They first appeared thirty years ago after he was severely burned in an accident. The lesions are occasionally itchy, but not painful. Recently, he experienced chest tightness with difficulty breathing deeply. He has no history of cancer or heart disease.

**What is the diagnosis?**

A. DFSP
B. DF
C. Keloid
D. Hypertrophic scar

**ANSWER:** C. Keloid
Quick TAKES

Patient-performed teledermatology, with or without the use of dermoscopy devices, is an acceptable and useful tool to triage individuals.

Melanoma patients must follow a strict follow-up schedule following melanoma resection.

Self-skin examinations and teledermatology may aid in fewer office-based follow-ups.

Teledermatology may lead to fewer office visits.
Electronic consultations with dermoscopy increased access, reduced wait times and identified several skin cancers that might have otherwise gone undiagnosed among underserved patients at community health centers, shows a study published earlier this year in the *Journal of the American Academy of Dermatology*.

Electronic consultations, also known as eConsults, have been shown to improve patient access to dermatology and other specialty care. This study looked specifically at the impact of teledermatology with use of dermoscopy for Medicaid and uninsured patients in Connecticut who sought primary care at community health centers.

The study provides a model for how primary care and dermatology practices can collaborate to offer teledermatology services — with dermoscopy — to these underserved populations.

**ACCESS HURDLES**

Less than half of patients referred to dermatologists from primary care providers receive appointments. Medically underserved patients, such as those on Medicaid, are even less likely to get appointments with specialty providers. For example, less than 40% of dermatologists in Connecticut where the study was conducted accept new Medicaid patients. Nationally, Medicaid patients have been shown to wait 38% longer than Medicare or private insurance patients for appointments.

Researchers looked retrospectively at 2,385 dermatology referrals from a large, multisite federally qualified health center in Connecticut. More than 60% of the more than 140,000 patients who receive comprehensive primary care services from the center are minorities and more than nine out of 10 are at or below 200% of the federal poverty level. Most have state-funded Medicaid insurance.

**D-CONSULT ELEMENTS, OUTCOMES**

For the teledermatology intervention, each primary care practice received a camera and dermatoscope. Two dermatologists from the UConn Health Center reviewed eConsults for the study. The Connecticut Department of Social Services reimbursed providers for the eConsults provided to Medicaid patients.

Primary care providers could send eConsults to dermatologists for review or bypass the teledermatology option and request a traditional in-person referral. Dermatologists reviewing the eConsults weren’t necessarily the same dermatologists who saw patients for face-to-face appointments.

“Dermatologists act as consulting physicians who provide consultation in terms of diagnosis and management plan. It’s the primary care physician’s responsibility to implement the plans,” said study author Jun Lu, M.D., dermatologist, UConn Health, Farmington, Conn. “If the patients need to come in for face-to-face visits, the consulting dermatologists help to provide easy and quick access although patients could choose to go to other providers.”

Dr. Lu explains that to guarantee the quality of referrals, she and colleagues provided referring providers and
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DR. JILL LEZAIC
Jacksonville Beach, FL
(SCC Faculty)
their staffs with video and real-time tutorials and training on how to submit a dermatology-focused history and relevant information, how to take high-quality photos and how to use dermoscopy to take photos.

Researchers compared results six months before implementing the teledermatology eConsults to six months after implementation.

Before eConsult implementation 11% of 1,258 referrals to dermatologists resulted in confirmed appointments, with an average wait time of 77 days. After implementation, 44% of 1,127 consults were electronically sent and all received dermatology consultations within less than 24 hours on average. Of those, 16% required a face-to-face visit with a dermatologist, with an average wait time of 28 days. Meanwhile, only 16.3% of the patients who chose traditional face-to-face appointments received care, with an average waiting time of 104 days. Dermatologists diagnosed a spectrum of cutaneous conditions with the eConsults, from dermatitis, to acne, benign neoplasms, psoriasis, pigmentation disorders, alopecia and suspicious neoplasms.

All 29 patients who had suspicious neoplasms on eConsults received dermatology appointments. Ten of those were no-shows. Of the 15 patients who had face-to-face appointments, all were biopsied and 10 had malignancies, including either basal cell or squamous cell carcinomas.

Of the 60 primary care providers who participated in the study, 39 responded to questions about their satisfaction with the intervention. Eighty-five percent were satisfied or very satisfied with eConsults, while 2.9%, or one of the providers, reported being dissatisfied.

IMPLICATIONS
The study suggests dermatology eConsults can be done on a large scale within a network of primary care providers who are free to decide whether or not to use eConsults. And they can be done where dermatologists who review the eConsults are not necessarily the dermatologists who see patients face-to-face.

The author writes that previous research has shown these eConsult elements help reduce face-to-face appointments; patient selection; high-quality image production; dermoscopy use; and an effective infrastructure. This intervention resulted in a substantial reduction of in-person visits by including not only these elements but also protocols for which consults to electronically submit and image acquisition training.

“We made it clear that patients with history of skin cancers or dysplastic nevi that need full-body skin examination are not good candidates for teledermatology. These patients need face-to-face visits,” Dr. Lu writes.

An important benefit to providers is eConsults might reduce no-shows in the medically-underserved population, which has been shown to have especially high no-show rates.

Still, these findings might not be generalizable to all patients in all settings. Non-Medicaid populations may see e-Consults as undesirable, as they don’t experience the same access issues, according to the authors. And reimbursement for teledermatology isn’t universal, but that’s improving. The success of this program led Connecticut to pass legislation allocating Medicaid funding to cover teledermatology service, according to Dr. Lu.

She and her colleagues also have been contacted by private insurers interested in similar collaborations, she writes.

There are different models and platforms available for teledermatology, Dr. Lu said.

“The ultimate goal is to provide high-quality care to patients in need. Therefore, it’s very important to have full access to complete medical histories, including medication and allergy information. It’s also very important to have a system set up in a way to guarantee patients easy access to face-to-face evaluation or treatment if needed,” she writes. “… teledermatology should be part of comprehensive coordinated care, rather than a curb-side consult.”

References


How effectively do you follow up?

By Bob Kronemyer

No matter how good your marketing efforts are, your bottom line will suffer if you don’t have the time or staffing available to respond in a timely fashion. That’s according to eRelevance cofounder and CEO Bob Fabbio and what inspired the company to launch their Response Follow-up Service.

“Our patient engagement service generates significantly more responses than our aesthetic practice customers have received through other prior email blasting efforts,” Fabbio says. As a result, practices have had a hard time keeping up with the response and thus, the service was born.

“Our new follow-up service does the work for businesses — chasing people down according to best practice to ultimately increase conversion and revenue,” Fabbio explains.

eRelevance data shows that up to 60% of marketing-generated patient requests never convert to revenue, due in large part to businesses with a small-sized staff that lack the time and resources to keep up with the number of responses that their marketing campaigns generate.

By successfully overcoming this critical marketing need, clients are ensured they do not miss out the finite window of opportunity when a prospective patient may be ready to schedule an appointment, according to Fabbio.

THE SERVICE OFFERS PROACTIVE RESPONSE MANAGEMENT THAT:

- Offloads the work required to connect with patients and prospects to get them scheduled.
- Uses best practices for effective follow-up that combines phone, email and text.
- Helps reduce revenue leakage from unscheduled patient and prospect requests.

Fabbio notes that while industry best practice is six follow-up attempts within three days of a customer reply, eRelevance data reveals that the average number of follow-up attempts across the company’s entire client base is less than one attempt per patient or prospect response.

An eRelevance suite of tech-powered follow-up services starts as low as $400 dollars a month.

“Our goal is to help small businesses grow in a more cost-effective way,” Fabbio states.

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Doctors and patients ease into digital health

LISSETTE HILTON | Staff Correspondent

The future of healthcare technology was center stage in Las Vegas this spring at the HLTH Future of Healthcare conference that attracted payors, policy makers and innovators seeking technological advances in healthcare.

The meeting included a session on the future of digital health with a presentation by Michael L. Hoeldkins, M.D., chief medical officer for the American Medical Association.

Although the industry may still be in its infancy, digital health tools are in practice today. Among the more common technology solutions include online patient portals, secure text messaging, telemedicine, mobile clinical decision support services and online provider communities.

But as with any new technology, there are startup challenges. In medicine, that challenge centers on trust and malpractice fears. Some providers and patients are reluctant to the take the plunge for fear that these tools are not secure, Dr. Hoeldkins said.

“Aside from medical malpractice, there’s the concern about privacy and security. As the physician, you are held accountable for breaches of patient information under HIPAA. Your patients’ trust depends on the security and privacy of their data being preserved,” he said.

Dermatologists and dermatology patients are especially interested in exploring the benefits of digital health technology — after all, the specialty is visual-centric. This interest has been documented in telemedicine surveys and studies, including a March 14 study published in the Journal of Dermatological Treatment showing that 90.80% of 841 surveyed patients would schedule appointments online, but the interest dropped from there.

There are four questions physicians should ask when considering using digital healthcare technologies, says Michael L. Hoeldkins, M.D., chief medical officer for the American Medical Association.

1. Is there evidence that supports the use of the particular technology? Dermatology, an image-centric specialty, is particularly vulnerable to apps that lack good science, including those that promise to diagnose skin cancer. Two such apps, MelApp and Mole Detective, settled with the Federal Trade Commission (FTC) in 2015 for deceptively claiming they could detect melanoma risk. The validity of these tools is critical for dermatologists who are considering using them as part of treatment plans, he said.

2. Are providers reimbursed for using the tool in practice? And, from the patient’s perspective, is use of the tool covered by insurance?

3. What about liability issues related to the use of this tool? At this time, the medical malpractice underwriters don’t have a standard way of dealing with the use of these digital health tools in practice, Dr. Hoeldkins said.

4. From the physician’s perspective, how does use of these digital capabilities seamlessly fit into practice, and in a way that results in greater practice efficiency and better outcomes?
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My belief is that as we evolve as a field, there will be a lot of new technologies. As dermatologists, the best thing we can do is to stay in front of it — as opposed to being reactive. ... if you’re creating technology and implementing it, you’re creating a niche that can support your practice.”

Dhaval Bhanusali, M.D., a practicing dermatologist in New York, N.Y., and Miami, Fla.

Digital health technology requires physician input

84.41% would complete online patient registrations
76.56% prefer electronically-placed prescriptions
76.34% would use digital healthcare services for medical consults
65.37% of patients would personally cover the cost of an online consult
42.03% would view online learning videos
40.89% would send photos of skin changes by email to their doctor
40.61% would send photos of skin changes by mobile apps to their doctor
34.53% would agree to an online consultation

“I think physicians are rightfully concerned about the use of digital medicine and whether it’s actually going to deliver more efficient and better care, or if it’s just going to add to the frustration,” Dr. Hodgkins said.

IN A MORE PERFECT DIGITAL WORLD

Imperfections aside, the march toward increasing use of digital health tools is going forward, he said.

“Let’s say you have a patient with a chronic skin condition, like psoriasis, do you have to see them in the clinic as frequently? Possibly not. If you could get needed information in an immediate way from a patient without the patient having to come to the clinic, and if it wasn’t going to negatively impact your clinic revenue, why wouldn’t you use one of these tools?” Dr. Hodgkins asked.

Triaging patients with skin lesions is another promising area for digital health apps in dermatology. Patients could send dermatologists high-definition images of lesions they’re concerned about. The dermatologist could take a look, first, to decide whether the patient needs to come in for a visit and then whether findings could be discussed via a virtual tool, such as video conferencing.

PHYSICIAN-DRIVEN INNOVATION

Dr. Hodgkins serves as chair of Xcertia, an independent nonprofit collaboration with the Consumer Technology Association that is focused on strengthening guidelines and standards for digital health tools. The group published its first set of guidelines in 2017, and they are due to be updated this year.

But one set of guidelines will not suffice. Provider specialty organizations, such as the American Academy of Dermatology, should also include the use of digital health tools in clinical guidelines they publish, he said.

“The Xcertia guidelines would be a good starting point for specialty societies as they evaluate which of these digital medicine tools they might want to recommend as part of clinical guidelines they may develop,” Dr. Hodgkins said.

Digital health tools are better when physicians contribute to the development process.

The “Physician Innovation Network,” a website of the AMA, is designed to connect physicians and technology developers. This is where developers with a new idea can get physician input on new healthcare technologies and physicians can approach technology experts with ideas of their own.

A dermatologist who has done precisely that is Dhaval Bhanusali, M.D., who practices dermatology in New York, N.Y., and Miami, Fla.

“When I was young in my career, I saw a lot of inefficiencies in healthcare that tech could solve. Now, my dream is to inspire physician-driven innovation,” he said.

When Dr. Bhanusali was a resident, he created a teledermatology platform that addressed access issues for nursing home patients by triaging patients.

Today, he is founder and CEO of the healthcare technology company Health Digital. The company is currently developing a digital platform for prescribing medications. And, they are currently designing technologies designed to make clinical trials more accessible to patients.

“Times are changing. My belief is that as we evolve as a field, there will be a lot of new technologies. As dermatologists, the best thing we can do is to stay in front of it — as opposed to being reactive. When you’re reactive, you have to adapt to someone else’s terms. But if you’re creating technology and implementing it, you’re creating a niche that can support your practice,” Dr. Bhanusali said.

“We’re seeing disruption in a lot of different industries. I think dermatology is going to be targeted for specific conditions, such as acne. So, I hope my colleagues will be proactive,” he said.

References


Visit the AMA’s “Physician Innovation Network” website at: https://innovationmatch.ama-assn.org
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Maximize ROI using advanced practice providers

LISA A. ERAMO, MA | Staff Correspondent

When leveraged correctly, advanced practice providers (nurse practitioners, physician assistants, clinical nurse specialists, and clinical social workers) can generate a sizeable return on investment, said Suzan Hauptman, CPC, senior principal at ACE Med Group, a coding and compliance consulting company in Pittsburgh, Penn., who spoke during AAPC’s HEALTHCON, April 8-11 in Orlando, Fla.

HEALTHCON offers educational sessions and networking opportunities for medical coders, billers, payer representatives, practice managers, attorneys, physicians, and other healthcare business professionals.

However, some physicians don’t fully understand how to maximize these providers and are thus unable to afford to employ them long-term, said Hauptman.

Answering phones, rooming patients, and submitting refill requests shouldn’t be a primary responsibility of advanced practice providers. “If you want someone to actually share the practice, that’s when you need an APP,” she said. “This is a human resource that you’re paying a lot of money for.”

Here are three tips to help practices get the most out of advanced practice providers.

**#1 PUT APPS TO WORK SEEING PATIENTS.** Advanced practice providers can provide a variety of E/M services, Hauptman said. The question is whether payors will require practices to bill directly under the advanced practice provider number or whether they’ll allow practices to bill the service provider under the supervision of the physician, she said. When billing directly, practices receive a portion of the physician’s fee schedule amount for that service. When billing under a physician’s supervision, the practice receives the entire fee schedule amount.

Regardless of the billing specifics, one point remains clear: When advanced practice providers are busy seeing patients, practices benefit financially, said Hauptman. For example, some practices allow advanced practice providers to see post-op patients because these services are bundled into the payment for the procedure, said Hauptman.

This allows physicians to focus on services that generate separate revenue.

Other practices allow advanced practice providers to see all new patients and bill directly for them, thus freeing up physician accessibility for hospital visits, procedures, or higher-level E/M services. Some payers may even allow advanced practice providers to bill new patients under a physician’s supervision if documentation indicates that the physician developed the actual treatment plan, said Hauptman. However, practices should check with their specific Medicare Administrative Contractor for more information, she added.

Specific schedules are a must, said Hauptman. “If the physician sees patients on Tuesdays and Fridays, what is the PA doing on Monday, Wednesday, and Friday? Is he or she acting as an MA and answering phone calls?” she said.

Practices can also staff emergency or weekend clinics with advanced practice providers. “The space is yours, so why not see patients more often?” she said.

**#2 DO YOUR HOMEWORK BEFORE HIRING.**

Ask your practice manager to research licensure requirements in your state. What services are included within each advanced practice providers scope of practice, and will your payers allow direct billing for each of these services? When billing under a physician’s supervision, what type of supervision is required for each service? For example, payers may require that a physician is immediately available or even in the same room for certain services. For other services, they may only need to be accessible by phone. Documentation should clearly support the supervision requirements, Hauptman said.

**#3 INVOLVE YOUR CODERS.** They understand billing requirements, opportunities and limitations. They may be able to determine how much revenue you can generate by hiring an advanced practice providers.

She cited a hypothetical example in which a practice hired a physician assistant to see most new and established patients. The physician assistant also saw some post-op patients and performed some consultations.

Hiring the physician assistant helped the practice increase its patient volume and allowed the physician to add hospital visits and an additional cases to the operating room schedule weekly, yielding more than $200,000 annually.

“The revenue is absolutely there if you use the APP correctly,” Hauptman said.
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Non-invasive body contouring has recently begun to outperform invasive procedures in popularity. With all the modalities available, what makes ultrasound technology the ideal option for practices that would like to offer body contouring?

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listen to this podcast at dermatologytimes.com/bodycontour
**The medical community can reallocate and reduce overall costs for treating skin cancer. “Before care delivery can be improved, we need to understand how resources are allocated.”**

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**Emily Ruiz, M.D., Brigham and Women’s Hospital, Boston**

Malignant melanoma may be the costliest diagnosis per person from Page 1.

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The medical community can reallocate and reduce overall costs for treating skin cancer. “Before care delivery can be improved, we need to understand how resources are allocated.”

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St. Luke’s University Health Network is seeking candidates to be Dermatology Residency Program Director to start a new Dermatology Residency Program at St. Luke’s Anderson Campus. As Founding Program Director, they will be responsible for leading, administering, and supervising all aspects of the Dermatology Residency Program in accordance with the ACGME Program Requirements and Institutional Goals and Objectives. The Program Director will have dedicated time for administrative, educational, strategic, and research initiatives and provide oversight and development of the Dermatology Residency program and participate in our academic mission through our Temple/St. Luke’s School of Medicine partnership. In addition, the Program Director will be expected to develop a clinical practice with allocated time to develop and lead the residency program.

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- A culture in which innovation is highly valued
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Qualifications:
Candidates must be Board-Certified in Dermatology and have demonstrated clinical, administrative and/or educational leadership accomplishments as well as an aptitude for mentoring and staff development. Excellent leadership, management, and communication skills are necessary. In addition, candidates must have:
- A minimum of four years of clinical experience in family medicine
- Three years as a teacher in an ACGME-accredited dermatology residency program.
- Must be willing to combine administrative and teaching responsibilities with clinical practice (25/75)
- PA and NJ State medical licenses (at the time of employment)

About St. Luke’s Anderson Campus:
Opened in 2011 in Bethlehem PA, Anderson Campus consists of a four-story, 108 bed acute care hospital soon to be 210 beds, state-of-the-art cancer center, a 75,000 square foot ambulatory surgical center, and medical office building. Private inpatient rooms are state-of-the-art with the latest technology and amenities. Consisting of over 500 acres, Anderson Campus also includes auxiliary gardens, a two-mile walking path, and a pond with a fountain and sitting area to promote wellness.

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We are the region’s largest, most established health system with 10 hospitals spanning 9 counties. In partnership with Temple University, St. Luke’s created the region’s first Medical School. Repeatedly, including 2017, St. Luke’s has earned Truven’s 100 Top Major Teaching Hospital. St. Luke’s is a member of the AAMC Council of Teaching Hospitals and a Regional Branch Campus and major affiliate of Temple University School of Medicine. To learn more about St. Luke’s, please visit us at www.SLUHN.org

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**A** Vivascopes 1500 captures cellular-level images of skin

**DERMATOLOGISTS HAVE** a new noninvasive option for examining cellular structures within the skin. Caliber Imaging & Diagnostics unveiled its Vivascopes 1500 System, a reflectance confocal microscopy product that uses real-time digital imaging of the epidermis down to the stratum. After digital images are captured in the system, they are available for immediate review by medical professionals. The device has 510(K) clearance by the Food and Drug Administration and is designed for exam rooms of various configurations. It has an extendable arm and its imaging head has greater flexibility, allowing for ideal positioning during use. Additionally, images taken with Vivascopes 1500 can be shared and referenced using the company’s Vivavnet communication system.

FOR MORE INFORMATION: www.caliberid.com

**B** Probiotic-infused serum soothes, hydrates skin

**THE PROBIOTICS SKINCARE COMPANY, TULA, HAS** released Aqua Infusion Power Liquid, a probiotic-infused hydrating serum designed to hydrate and soothe the skin. This serum was designed with a microfluidics system that creates the microbubbles by suspending them in a hyaluronic acid gel. The bubbles are activated with a release of probiotics and active ingredients when applied to the skin. The microbubbles soothe and hydrate the skin, while the probiotics strengthen the skin’s barrier and improve its ability to retain moisture. The prickly pear extract helps bind water to the skin while blocking the release of stress markers from the skin’s sensory nerve cells, thereby reducing the skin’s reaction to stress.

The Aqua Infusion Power Liquid can be used before applying makeup or the Aqua Infusion Oil Free Gel Cream.

FOR MORE INFORMATION: www.tula.com

**C** Cleanser, moisturizer address acne and sun protection

**NESTLE SKIN HEALTH and Galderma’s two newest Differin products aim to clear acne and protect from damaging UV rays. The Differin Daily Deep Cleanser contains benzoyl peroxide to address acne, but with reduced redness and irritation. It is a sensitive skin formulation, meant to leave the skin thoroughly cleansed without stripping it of moisture. The Differin Oil Control Moisturizer with SPF 30 is a lightweight, oil-free product that can be used with Differin Gel as part of a regular skin-care routine. Both products are available online and at major retailers.

FOR MORE INFORMATION: www.differin.com

**D** MTI’s 830 PROCEDURE CHAIR

MTI HAS LAUNCHED** the 830 Procedure Chair, a chair that complies with Title 36 of the Code of Federal Regulations 1195 Standards for Accessible Medical Diagnostic Equipment. MTI’s goal was to design the perfect procedure chair. The journey began on the Medical Diagnostic Equipment Accessibility Standard Advisory Committee. Committee member and MTI president Jeff Baker played a role in improving ADA regulations for patients and caregivers with disabilities.

In January 2017, the Access Board added Part 1195 Standards for Accessible Medical Diagnostic Equipment to Title 36 of the Code of Federal Regulations as a published document in the Federal Register. This regulation requires that the medical diagnostic equipment comply with certain requirements to provide accessibility for patients with disabilities. The end result is an ADA compliant standard, swivel and mobile chair with SmartTech, which is a combination of MTI’s Smart Controller and Smart Safety technology using a centralized computer controller that enhances safety, reduces energy consumption, and provides smoother movement; additional memory options, and more user preferences. The MTI 830 Chair also has a power footrest extension, which independently and automatically power extends to seven inches and retracts when the chair is returned to the home position.

FOR MORE INFORMATION: www.mti.net

**E** Targeted treatment for non-melanoma skin cancer, keloids

**SENSUS HEALTHCARE’S SRT-100 Vision** is a compact, portable device that pairs a laser positioning system with ultrasound technology to allow physicians to view areas being treated in real time while they are being treated, the company says. This allows for adjusting the amount of radiation being delivered as needed. The device uses a high frequency ultrasound system to deliver a precise and painless calibrated dose of superficial radiation therapy. Additionally, the device uses a LesionCam to record each treatment session for patient medical records.

In clinical studies, the SRT-100 Vision has demonstrated a 94% cure rate for keloid scars, the company says. Surgical keloid removal alone has a recurrence rate of nearly 90%. Surgical removal followed by treatment with the SRT-100 Vision, however, has a recurrence rate of 0-10%, according to the company.

FOR MORE INFORMATION: www.sensushealthcare.com/superficial-radiation-therapy/srt-100-vision/
Top dermatology mobile apps

Only 20% of mobile dermatology apps designed for patients may be worthwhile, shows an analysis published in February in the online journal Cutis. The analysis included 44 mobile apps available in the Apple App Store. The apps were ranked between 5 and 20 in terms of overall quality, but only nine (20.5%) fell between 16 and 19, and none reached 20, “which indicates a need for improvements in mobile dermatology apps intended for patient education,” the authors wrote.

Apps that scored in the 5-10 range were described as “not thought to be useful and may even be detrimental to patients.” Those that scored between 11-15 “may be used for patient education with some reservations based on short-comings for certain criteria.” Apps that scored between 16-20 were described as “valuable and adequate for patient education.”

The analysis included apps that were available in the store between January-November 2016 and focused on one of the following: general dermatology, cosmetic dermatology, acne, eczema, psoriasis and skin cancer. Apps whose sole focus was promotional, were excluded, as were apps of medical journals or educational apps intended for healthcare professionals.

“The number of dermatology-related apps available to mobile users continues to grow at an increasing rate. It is necessary to create a systematic way to evaluate the quality and utility of each app to assist users in making informed decisions about which apps will best meet their needs in the midst of a wide array of choices,” wrote the authors who were led by Babar K. Rao, M.D., of Rutgers Robert Wood Johnson Medical School and Weill Cornell Medicine.

Editor’s Note: The following three mobile apps also ranked among the top 10, but they are no longer available in the App Store: Dermatology Conditions (score: 16); Acne Causes (score: 14); Most Skin Disorders (score: 13).