

Skin Therapy Letter[®]

Volume 2 • Number 4 • December 2006

Clinical Evidence. Practical Advice.

Editor-in-Chief: Dr Stuart Maddin

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EDITOR-IN-CHIEF

Dr. Stuart Maddin, Chairman of SkinCareGuide, is one of North America's leading dermatologists, and is the author of numerous dermatologic journal articles, monographs and textbooks. In addition to providing consultative input to a number of pharmaceutical and biotech companies, he is the director of the clinical trials unit at the Department of Dermatology and Skin Science, University of British Columbia. Dr. Maddin has also acted in an advisory capacity to a number of drug regulatory agencies, such as the Health Protection Branch (Ottawa), the AAD-FDA Liaison Committee, and WHO (Geneva). He is the founder of the Dermatology Update symposia, now in its 22nd year. As well, he is Past President of the Canadian Dermatology Association and served as Secretary-General of the International Committee of Dermatology — International League of Dermatological Societies.

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**Take our new
Dermatologic Diagnostic Challenge
on Page 8!**

Hyperpigmentation and Its Topical Treatments*

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Hyperpigmentation

- Hyperpigmentation is very common and results from excess cutaneous melanin deposition causing a color change:
 - Epidermal involvement appears as brown discoloration.
 - Dermal deposition is blue-grey.
 - Mixed epidermal-dermal depositions are brown-grey.
- Melanin can be deposited in the epidermis or dermis; dermal hyperpigmentation is much more challenging to treat.
- A Wood's lamp is beneficial for determining the location of melanin deposition.
 - Shows enhancement of color contrast in epidermal lesions, but not dermal lesions. The mixed type has enhancement in some areas of lesional skin, but not in others.
- The most common pigmentation disorders for which patients seek treatment are melasma and postinflammatory hyperpigmentation (PIH).
- Multiple topical modalities can be used, and combination topical therapies are the current first-line approach.

Melasma

- Occurs mainly in women of all racial and ethnic groups, particularly those with Fitzpatrick skin types IV to VI:
 - Type IV (olive) - Rarely burns, always tans
 - Type V (brown) - Very rarely burns, always tans
 - Type VI (black) - Never burns, always tans
- There are multiple factors involved including:
 - A genetic predisposition
 - Ultraviolet light exposure
 - Estrogen exposure, thought to induce melasma
 - During pregnancy, which clears within a few months of delivery.
 - With use of oral contraceptives and hormone replacement therapy in postmenopausal women. However, discontinuation of these drugs rarely clears this condition.
- Presents as brown to grey macules and patches, with serrated, irregular, and geographic borders. The pigmented patches are usually sharply demarcated and symmetrical.
- Melasma has a predilection for sun exposed areas.

Melasma (continued)

- The three major patterns of distribution are:
 - Centrofacial (cheeks, forehead, upper lip, nose, and chin)
 - Malar (cheeks and nose)
 - Mandibular (rami of mandible).

Postinflammatory Hyperpigmentation (PIH)

- Represents a pathophysiologic response to cutaneous inflammation, e.g., acne, atopic dermatitis, lichen planus, and psoriasis.
- More obvious in patients with brown or black skin with no gender or age predominance.
- Lesions characteristically limited to the site of the preceding inflammation and have indistinct, feathered borders.
- Epidermal hyperpigmentation (e.g., associated with acne) occurs when increased melanin is transferred to keratinocytes.
- Dermal pigmentation (e.g., associated with lichen planus and cutaneous lupus erythematosus) occurs when the basement membrane is disrupted and melanin falls into the dermis and resides within melanophages.
- Initial treatments for PIH should involve an attempt at treating the underlying skin condition.

Hyperpigmentation Treatments

- Therapeutic goals include
 - Inhibiting the formation of melanosomes
 - Promoting the degradation of melanosomes
 - Retarding the proliferation of melanocytes.
- Sun exposure is an important etiologic factor, therefore all patients should use daily, broad-spectrum, 15 SPF-minimum sunscreens and minimize sun exposure.
- The same treatment principles hold for PIH and melasma.
- Treatment of melasma in pregnant women is routinely deferred until after delivery.

Hydroquinone (HQ) 2%-4%

- Widely used for melasma therapy.
- Patch testing elsewhere on the body, e.g., the upper inner arm, should be done to confirm nonallergenicity prior to attempting a trial of bleaching agents.
- Side-effects include irritant and allergic contact dermatitis, PIH, nail bleaching, and rarely, ochronosis-like pigment.
- Under no circumstances should monobenzylether of hydroquinone or other ethers of HQ be used to treat melasma as they can lead to a permanent loss of melanocytes with the development of a disfiguring confetti-like leukoderma.
- HQ regulatory safety issues may pose availability issues.

Retinoids

- Tretinoin (0.05%-0.1%) reduces pigmentation by inhibiting tyrosinase transcription, and interrupting melanin synthesis.
- Typically takes at least 24 weeks to see clinical improvement.
- May increase pigmentation secondary to irritation.
- May cause erythema and peeling.
- Other retinoids including adapalene, tazarotene and topical isotretinoin have also been used.

Azelaic Acid (15%-20%)

- A reversible inhibitor of tyrosinase.
- May have cytotoxic and antiproliferative effects on melanocytes.
- Was shown to be as effective as HQ 4% without HQ's side effects.[Balina LM, et al. *Int J Dermatol* 30:893-5 (1991).]
- Adverse effects include pruritus, mild erythema, scaling, and burning.

Kojic Acid (2%)

- Produced by the fungus *Aspergillus oryzae* and is a tyrosinase inhibitor.
- Generally equivalent to other therapies but may be more irritating.
- May be effective if a patient has difficulty tolerating other first-line therapies. [Cayce KA, et al. *Derm Nursing* 16(5):401-6, 413-6 (2004).]

Glycolic Acid (5%-10%)

- An alpha-hydroxy acid
- Reduces pigment by
 - thinning the stratum corneum.
 - enhancing epidermolysis.
 - dispersing melanin in the basal layer of the epidermis.
 - increasing collagen synthesis in the dermis.

Combination Therapy

- Combination therapy is more effective than single agents used alone.
- Kligman formula (HQ 5%, tretinoin 0.1% and dexamethasone 0.1%) is the most widely used combination therapy for melasma worldwide. [Kligman AM, et al. *Arch Dermatol* 111:40-8 (1975).]
- The combination of azelaic acid with 0.05% tretinoin or 15-20% glycolic acid may produce earlier, more pronounced lightening. [Finlay AY. *Br J Dermatol* 136:305-14 (1997).]
- Kojic acid 2% combined with HQ 2% was shown to be superior to glycolic acid 10% and HQ 2%. [Lim JT. *Dermatol Surg* 25:282-4 (1999).]
- Glycolic acid 5% with either HQ 4% or kojic acid 4% for 3 months proved equally effective with reduction of pigmentation in 51% of patients. [Garcia A, et al. *Dermatol Surg* 22:443-7 (1996).]
- Glycolic acid 10% plus HQ 4% in a cream of vitamins C and E and sunscreen was effective in 75% of patients. [Guevara IL, et al. *Int J Dermatol* 43:966-72 (2003).]
- A new combination of HQ 4%, tretinoin 0.05%, and fluocinolone acetonide 0.01% (Tri-Luma[®]) proved effective with 77% of patients showing complete or nearly complete clearing in this multi-centre, randomized, double-blind, control trial. [Taylor SC, et al. *Cutis* 72:67-72 (2003).]

Over-the-Counter Medications

- Are readily available.
- HQ for OTC use not as effective as stronger prescription formulations. [Halder R, et al. *Skin Therapy Lett* 9(6):1-3 (2004 Jun-Jul).]
- Alpha and beta hydroxy acid home chemical peels and topical vitamin A are also available.
- New formulation: 2% N-acetyl glucosamine (NAG) and 4% niacinamide (Olay[®] Definity[®])
 - Recently shown to reduce facial hyperpigmentation in Japanese and Caucasian subjects with facial hyperpigmentation in two double-blind, vehicle-controlled, split-face, left-right randomized clinical studies. [Bissett D, et al. Topical N-acetyl glucosamine reduces the appearance of hyperpigmented spots on human facial skin. Presented at: the 64th Annual Meeting of the American Academy of Dermatology, San Francisco, CA; March 3-7, 2006. Poster#236.]
 - In another double-blind, vehicle controlled, full-face, clinical study, a significant reduction in facial hyperpigmented spots was seen in patients with facial hyperpigmentation using the NAG 2% + niacinamide 4% formulation when compared with the vehicle regimen. [Kimball AB, et al. Topical formulation containing N-acetyl glucosamine and niacinamide reduces the appearance of hyperpigmented spots on human facial skin. Presented at: the 64th Annual Meeting of the American Academy of Dermatology, San Francisco, CA; March 3-7, 2006. Poster #235.]
 - There were no adverse effects reported in any of the studies.
 - Improvement seen in 4-8 weeks.

Miscellaneous Treatments

Other topical therapies have been used including ascorbic acid, licorice extract, and in the past, mercury. [Rendon M, et al. *J Am Acad Dermatol* 54(5 Suppl):S272-81 (2006).]

*This article was adapted from Lynde CB, Kraft JN, Lynde CW. Melasma and postinflammatory hyperpigmentation and their treatments. *Skin Therapy Lett* 11(9):1-4 (2006 Nov).

The Red Face and Its Management

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The Problem(s)

Red face is commonly seen, can be transient and come and go (flushing), or be persistent. Sometimes it can be scaly (dermatitis), or there may be papules and pustules (rosacea) present. Red face is occasionally seen in infants or neonates.

Flushing/Blushing

- Transient redness of face and/or neck and upper trunk due to vasodilatation
- Blushing is flushing due to emotion.

Causes of Flushing

- Emotional (blushing)
- Menopausal
- Neurologic
 - e.g., migraine, Parkinson's disease
- Foods and food additives
- Drugs
 - Vasodilators including alcohol
 - Calcium channel blockers
 - Corticosteroids
- Systemic Disease
 - Carcinoid
 - Pheochromocytoma
 - Mastocytosis
 - Cushing's syndrome
 - Polycythemia vera
 - Hyperthyroidism
- Rosacea
 - Persistent and transient

Common Causes of Red Face

- Rosacea (erythema, papules, pustules, telangiectatic vessels, swelling, rhinophyma)
- Acne
- Seborrheic Dermatitis (other types of dermatitis or psoriasis are less common)
- Emotions
- Menopause
- Sunburn
- Keratosis Pilaris
- Systemic Lupus Erythematosus (SLE) (less common)
- Dermatoheliosis/photoaging
- Psoriasis

Important Questions to Ask

- Does the redness come and go or is it persistent?
- Is it exacerbated by temperature change, food, drugs, or emotions?
- Are there visible vessels on the face?
- Is there scaling in addition to redness?
- Is this acne-like with papules and pustules?
- Any symptoms? (e.g., itchy with dermatitis)
- Is the patient menopausal?
- What creams are being applied to the face?
- Are other areas of the body involved?
- Is flushing more generalized?
 - Systemic causes
 - Superior vena caval obstruction

Make a Diagnosis

- History
 - Food, drugs, other diseases
 - Physical exam
- Acne-like, suggestive of rosacea
- Scaly eyebrows and sides of nose, suggestive of seborrheic dermatitis
- Butterfly distribution of acne, suggestive of SLE
- Other areas involved, suggestive of:
 - Psoriasis (nails, scalp, extensor limbs)
 - Keratosis pilaris (upper arms)
 - Atopic dermatitis (other atopic features)

Acne and Rosacea

Acne can be confused with, or coexist with, rosacea particularly in fair-skinned individuals. In some of these patients topical retinoids can be irritating and increase redness. Anecdotally, topical gels combining benzoyl peroxide and antibiotics, e.g., clindamycin 1% + benzoyl peroxide 5% (BenzaClin[®]); erythromycin 3% + benzoyl peroxide 5% gel (Benzamycin[®]) and 1% clindamycin phosphate + 5% benzoyl peroxide (Clindoxyl[®]) may be helpful.

Treatment of Red Face

- Camouflage make up (Cover Fx[®], Covermark[®], Dermablend[®], Dormer[®])
- An esthetician may be helpful
- Stop the flush:
 - Clonidine, 0.05mg, twice daily
 - Treat other symptoms, e.g., scaling/dermatitis
 - Weak, non-fluorinated topical steroids for short term flare
 - Moisturize with non-comedogenic products
- Control
 - Hydrocortisone 1%, (Desonide[®])
 - Topical calcineurin inhibitors
 - Tacrolimus (Protopic[®]), Pimecrolimus (Elidel[®])
- Rule out underlying disease, e.g., SLE, carcinoid

Red Face in Infants or Neonates

Vascular Abnormality

- Hemangiomas
- Port wine stain/nevus flammeus
- Vascular malformations

Inflammatory

- Dermatitis
 - seborrheic
 - atopic
- Keratosis Pilaris
- Uncommon: acute contact dermatitis, psoriasis, erythroderma, etc.

Treatment of Rosacea

Treatment of Rosacea (Acne-like features and flushing)

- Keep cool
- Topical applications
 - Metronidazole cream (Noritate[®] 1%; MetroCream[®] 0.75%), lotion (MetroLotion[®] 0.75%), gel (MetroGel[®] 1%)
 - A cornerstone for the treatment of rosacea
 - Sulfacetamide sodium (Sulfacet-R[®] 25g, Novacet[®] 30g and 60g generic)
 - Rosacure[®], Rosaliac[®]
- Non-comedogenic make up and cosmetic products
- Systemic medications
 - Tetracycline, doxycycline, minocycline
 - Clonidine
 - Isotretinoin (Accutane[®])
- Stop topical corticosteroids
- Trigger avoidance: Avoid hot foods, fluids, alcohol, spicy foods
- Sunscreen use
- BLU-U[®] + photodynamic therapy (Levulan[®])

Treatment of Rosacea (flushing, erythema, telangiectatic vessels)

- Lasers
 - Pulse dye
 - ND:Yag
 - KTP
 - CO₂, Erbium-Yag for rhinophyma
- Intense Pulsed Light (IPL)

Note: One can treat the entire red face with laser or IPL, or one can trace out only the prominent vessels by laser.

Treatment of Infants, Children With Red Face

Vascular Abnormalities

- May need workup for underlying abnormalities.
- Laser, e.g., pulsed dye for port wine stain and some hemangiomas
- Rapidly growing hemangiomas require expert assessment and treatment.

Inflammatory

- Mild topical steroids for dermatitis

Key Points

- Make a diagnosis and follow up for results of treatment
- Many of these causes are common, e.g.,
 - Rosacea
 - Seborrheic Dermatitis
 - Emotions and menopause
 - Flushing

- Take a good history
 - Drugs, foods, and food additives
- Look for other underlying diseases.
- Camouflage redness while deciding on diagnosis and treatment.
- Definitive treatment (topical, systemic, or laser/IPL) may be lengthy and involve several treatment sessions (laser/IPL) and/or several modalities.
- Redness may occur and require additional treatment in the future (topical, systemic, laser/IPL).

New Systemic Treatments for Psoriasis

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The Disease

Psoriasis is a chronic, immune-mediated disease, affecting more than 1 million adults in Canada with more than 250,000 new cases diagnosed each year in North America.[Gupta AK, et al. *J Cutan Med Surg* 8 Suppl:3-7 (2004 Aug).] Up to 35% of people with psoriasis have moderate-to-severe disease, affecting 2%–10% of total body surface area.[Thomas VD, et al. *J Am Acad Dermatol* 53(2):346-51 (2005 Aug).] Up to 30% of Canadians with psoriasis develop psoriatic arthritis (PsA), [The Arthritis Society. Psoriatic Arthritis. URL: <http://www.arthritis.ca/types%20of%20arthritis/psoriatic%20arthritis/default.asp?s=1>.] and half of those with PsA are estimated to have already experienced serious joint damage (e.g., bone loss) upon first diagnosis. As this can lead to progressive and often irreversible bone and joint destruction, early diagnosis is important to prevent long-term effects. The need for effective and safer therapies has been increasing as more studies show the serious psychosocial and sometimes debilitating effects of moderate-to-severe psoriasis. However, even psoriasis confined to palms or soles, although covering a small area, can cause difficulty for patients.

Standard Systemic Therapies for Psoriasis

The standard systemic therapies for psoriasis are methotrexate, cyclosporine, oral retinoids such as acitretin (Soriatane[®]), psoralen + UVA (PUVA), and retinoid PUVA (RePUVA). Less commonly used therapies are hydroxyurea (Hydrea[®]) and mycophenolate mofetil (CellCept[®]).

New Systemic Therapies for Psoriasis

Biologics are new systemic therapies that have given dermatologists and rheumatologists a new tool to treat psoriasis, with several undergoing clinical trials in Canada, the US, and Europe. Biologics are immunomodulators and bioengineered proteins (such as antibodies, fusion proteins, or recombinant cytokines) that target the pathological effects of T cells directly. Targeted biologic therapies are designed to:

- inhibit T cell activation and migration.
- eliminate activated T cells.
- inhibit postsecretory cytokines, e.g., antitumor necrosis factor (antiTNF) agents.
- induce immune deviation. [Lui H, et al. *J Cutan Med Surg* 8 Suppl:8-13 (2004 Aug).]

Biologics approved by the US FDA and Health Canada to treat psoriasis and psoriatic arthritis (PsA) are infliximab (Remicade[®]) and etanercept (Enbrel[®]). Efalizumab (Raptiva[®]) and alefacept (Amevive[®]) are indicated only for psoriasis, and adalimumab (Humira[®]) is currently approved for PsA only.

The availability of biologics has brought about a shift in the treatment approach to psoriasis. In the past, a more stepwise approach was used with a topical being prescribed first and then moving to UV light and/ or systemic drugs. Now the trend is to use the most effective treatment early in the course of the disease. In 2005, Canadian Consensus Guidelines were published recommending that all appropriate treatment options, including biologic agents, be considered together, and a patient's specific characteristics and needs be taken into account.[Guenther L, et al. *J Cutan Med Surg* 8(5):321-37 (2004 Sep-Oct).] The choice of treatment should depend on the severity of the psoriasis and its impact on the patient's quality of life. AntiTNF drugs are particularly effective for treating PsA.

AntiTNF Agents

Infliximab (Remicade[®]) [Infliximab (Remicade[®]) Package Insert. Centocor, Inc., Malvern, PA (2002).]

- Dosage: 5mg/kg IV over 2 hours at weeks 0, 2, 6, then 5mg/kg every 8 weeks.
- Common side-effects: nausea, abdominal pain, back pain, arthralgia, fatigue, headache.
- More serious side-effects: hypersensitivity reactions, infusion reactions, worsening of congestive heart failure, infections, tuberculosis, leukopenia, neutropenia, thrombocytopenia, pancytopenia, invasive fungal infections, and a lupus-like syndrome.
- Relative efficacy using Psoriasis Area Severity Index (PASI): PASI 75 achieved in 75% of patients at week-14 and 60% at week-26; PASI 90 seen in 39% at week-26. Statistically significant reduction in PASI compared with placebo by 2

AntiTNF Agents (continued)

weeks after start. The PASI response was generally maintained through week 54. Reich, et al. reported a PASI 75 in 80% at week-10, 82% at week-24 and 61% at week-50; PASI 90: 57% at week-10, 58% at week-24, and 45% at week-50.[Reich K, et al. *Lancet* 366(9494):1367-74 (2005 Oct).]

- Infliximab is unique among available antiTNF biologic therapies, as specially trained nurses administer, monitor and assist the patients during each infusion in clinic settings that are located throughout Canada.
- This drug is the most potent antipsoriatic agent available at this time.

Etanercept (Enbrel®) [Etanercept (Enbrel) Package Insert. Immunex Corp., Seattle, WA (2004).]

- Dosage: 50mg SC biweekly for 12 weeks, then 50mg SC weekly.
- Common side-effects: injection-site reactions, cough and respiratory symptoms, infections, headaches, and positive antinuclear antibody.
- More serious side-effects: allergic reactions, pancytopenia, new onset or exacerbation of CNS demyelinating disorders (rare), increased incidence of lymphoma (twice the general risk), and infections.
- Relative efficacy using PASI: PASI 75 seen in 47% of patients at 3 months and 54% at 6 months; PASI 50 achieved in 71% at 3 months; Physician's Global Assessment (PGA) "almost clear" or "clear" attained in 47% at 3 months. Median time to PASI 50 and PASI 75 was 1 and 2 months respectively, after start. Seventy-seven percent of patients who achieved a PASI 75 at 3 months maintained their improvement at month 6 with 25mg SC weekly.[Thomas VD, et al. *J Am Acad Dermatol* 53(2):346-51 (2005 Aug).]
- This drug shows efficacy in psoriasis and PsA. It is used continuously, but shows no rebound if it is used intermittently.

T-cell Modulators

Efalizumab (Raptiva®) [Thomas VD, et al. *J Am Acad Dermatol* 53(2):346-51 (2005 Aug).]

- Dosage: begin 0.7mg/kg SC then hold at 1mg/kg (max 200mg) weekly (maintenance therapy).
- Common side-effects: headache, flu-like symptoms with first dose (e.g., fever, headache, myalgia, nausea), infection, elevated alkaline phosphatase.
- More serious side-effects: infection, malignancy, thrombocytopenia, worsening of psoriasis through rebound effect.
- Relative efficacy using PASI: PASI 75 achieved in 22%–39%, and PASI 50 attained in 52%–61% at 12-weeks; PGA "almost clear" or "clear" seen in 19%–32% at 12-weeks. PASI 50 began 4 weeks after start. Seventy-seven percent of patients achieving PASI 75 maintained their improvement through a second 12-week treatment period.
- This drug acts quickly and needs to be used continuously. The benefits long term appear to be maintained.

Alefacept (Amevive®) [Thomas VD, et al. *J Am Acad Dermatol* 53(2):346-51 (2005 Aug).]

- Dosage: 15mg IM weekly x 12 weeks; wait 12 weeks, then consider a second 12-week course provided CD4+ T lymphocyte counts are within normal range.
- Common side-effects: cough, dizziness, nausea, myalgia, chills, pharyngitis, pruritus, injection site reactions, transaminitis.
- More serious side-effects: lymphopenia (10% IM), malignancies, serious infections, hypersensitivity, transaminase (rare), cardiovascular events.
- Relative efficacy using PASI: PASI 75 achieved in 21%, and PASI 50 attained in 42% at week-14 (2 weeks postdosing); PGA "almost clear" or "clear" was 14% at week-14; PASI 50 began 60 days after start. Most patients maintained at least a PASI 50 through the 3-month observation period.
- This drug is used intermittently and can have a prolonged benefit for those patients in which it is effective.

Conclusions

Biologics are one of the more effective and relatively safe options for long-term control of psoriasis. They have reduced the time needed to clear the signs of chronic disease, and are effective in maintaining a disease-free state for longer durations. Biologics can safely be used with other treatment modalities (i.e., methotrexate, cyclosporine, acitretin and hydroxyurea). Clinicians should assess patients' psoriasis and their psychosocial and quality of life issues, before deciding on the optimum treatment modality. With the availability of biologics, all treatment options should be considered equally.

Dermatologic Diagnostic Challenge

Question: A 32 year-old female presented in the summer with a pruritic bullous eruption on bilateral dorsal feet of 2 weeks' duration. She is a nurse who is regularly in contact with patients. She is otherwise healthy, although a recent ankle sprain resulted in a prescription for a topical nonsteroidal anti-inflammatory medication.

What is the diagnosis?

- Porphyria cutanea tarda
- Psoriasis
- Allergic contact dermatitis
- Bullous impetigo
- Bullous scabies

Go online to www.SkinTherapyLetter.ca/cases
to view an image and learn the answer.

Case study submitted by Benjamin Barankin, MD, Toronto, Canada

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RosaceaGuide.ca	SkinCancerGuide.ca	Sweating.ca	UnwantedFacialHair.ca

Medical professional sites:

SkinPharmacies.ca	SkinTherapyLetter.ca	Dermatologists.ca
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