"New and Not so New Dermatology Drugs"
TAPA Fall Conference, Galveston TX
September 19th
Chelsea Barr, PA-C

Learning Objectives

1. Identify the most common dermatology disease states encountered in primary care.
2. Classify the most common medications used to treat these disease states.
3. Differentiate the therapeutic classification and indications for select newly approved medications.

My Background

- Currently practicing in Houston, TX at Clearlake Dermatology with Dr. Joe Apisarnthanarax
- Completed Masters of Science in Physician Assistant Studies from the University of Texas Medical Branch at Galveston
- Received undergraduate degree in Nutrition Science from California Polytechnic School in San Luis Obispo, California
Dermatology Disease States and Treatment Options

Onychomycosis

Common Onychomycosis Treatments

- Lamisil 250mg PO QD x4 months (toenails)
  - Baseline LFT's followed by LFT's Qmonthly
  - Lamisil 250mg PO QD x6 wks (fingernails)
  - Baseline LFT's followed by LFT's Qmonthly
- Fluconazole 400mg once weekly x6 months (toenails)
- Fluconazole 200mg once weekly x3 months (fingernails)
So What’s New Topically??

Onychomycosis

- Jublia (efinaconazole) Topical Solution 10%
- Kerydin (tavaborole) Topical Solution 5%
- Must use QD x48 weeks

Efinaconazole 10% solution in the treatment of toenail onychomycosis

Two phase III multicenter, randomized, double-blind studies

Complete Cure  Almost Complete Cure
Can perform a Nail clipping to confirm onychomycosis

Herpes Labialis
- Sitavig (acyclovir) 50mg buccal tablet
- Apply buccal tablet to the left or right of the incisor tooth
- Leave until dissolves → 6-14 hours
- Helps prevent next episode for longer periods of time
  - Pts treated with Sitavig went an additional 40 days before having another cold sore episode (average 105 days)
  - 36% of pts clear for 10 months after single dose


Chronic Idiopathic Urticaria
- Xolair (omalizumab)- SC injectable medicine for CIU not responding to H1 antihistamine treatment
- MOA: monoclonal antibody that blocks IgE function
- Dosing: Xolair 150 or 300 mg SC every 4 weeks.
  - not dependent on serum IgE level or body weight
- Warnings: anaphylaxis!!
Acne

**The Clinical Significance of Acne Vulgaris**

- Most common skin disease in the United States - More than 85% of adolescents experience acne
- Acne affects >75% of preadolescents aged 8 to 12 years
- Approximately 50% of adults have some degree of facial acne by age 25 years
- 97% of cases affect facial skin; >50% also involve the trunk (i.e., chest, back)

![Image of acne]

---

**Types of Acne**

**Noninflammatory Acne:**
- Whiteheads and blackheads - first visible sign of acne

![Image of whiteheads and blackheads]

**Inflammatory Acne:**
- Papules and Pustules

![Image of papules and pustules]
Acne Pathogenesis

- **↑ Sebum Production**
- Follicular Hyperkeratinization
- Bacterial Proliferation
  - *P. acnes*
- Inflammation

Common Meds Based on Pathogenesis

- **Increased Sebum Production**
  - Hormonal Therapy: Spironolactone
  - ISOTRETINOIN
- Follicular Hyperkeratinization
  - Topical Retinoids: BPO
  - ISOTRETINOIN

Common Meds Based on Pathogenesis

- **Bacterial Proliferation**
  - BPO
  - Topical Abx
    - Clindamycin > Erythromycin
    - ISOTRETINOIN
- **Inflammation**
  - Oral abx
    - doxycycline or minocycline
  - Dapsone gel
  - ISOTRETINOIN
So What is New Topically??

Aczone (dapsone) 7.5% gel

- Phase 3 Trial: designed to assess the safety of efficacy of dapsone 7.5% versus vehicle control once daily for 12 weeks in patients with acne vulgaris
- Dapsone 5% FDA approved for BID dosing
- >12 y/o
- Powerful anti-inflammatory
- Antimicrobial effects
- Safe in patients with G6PD Deficiency??  
  - YES!!! Topical exposure 100-fold less than oral dapsone
Topical Minocycline 4%

- Phase II Clinical Trials
- First Topical Minocycline Foam 4%
- QD
- After 6 Weeks:
  - 71% reduction in inflammatory lesions
  - 55% in non-inflammatory lesions
- After 12 Weeks:
  - 72% reduction in inflammatory lesions
  - 71% reduction in non-inflammatory lesions

https://www.foamix.co.il/lead.asp

Onexton (clindamycin phosphate & BPO Gel 1.2%/3.75%)

http://www.onexton.com/fight-acne#photos

Onexton (clindamycin phosphate & BPO Gel 1.2%/3.75%)

http://www.onexton.com/fight-acne#photos
EpiDuo Forte (adapalene 0.3%/BPO 2.5% gel)

- Epiduo-adapalene 0.1%/BPO 2.5%
- After 12 weeks mean reduction of inflammatory lesions:
  - Epiduo Forte: 68.7%
  - Epiduo: 69.3%
  - Vehicle: 39.2%
- After 12 weeks mean reduction of non-inflammatory lesions
  - Epiduo Forte: 68.3%
  - Epiduo: 68.0%
  - Vehicle: 37.4%


What About Antibiotics?

Doxycycline vs Minocycline

**Doxycycline**
- Anti-inflammatory
- No definite dosing: 100-200mg QD
- Take with a large glass of water with food and do not lay down immediately after taking
- **Major SE:** GI (esophagitis), photosensitivity

**Minocycline**
- Immediate Release and Extended Release
- Weight-based dosing: 1mg/kg/day
- **Major SE:** urticaria, dyschromias of skin/mucosa, drug hypersensitivity syndrome, autoimmune reactions
How long should you treat a patient with an antibiotic???
1-3 MONTHS!!!!!!

If you can’t control in this time then send to Derm

Antibiotic Resistance CDC global threat

- Antibiotic resistance is a worldwide issue. World health leaders have described antibiotic-resistant microorganisms as “nightmare bacteria” that “pose a catastrophic threat” to people in every country in the world.
- Each year in the United States, at least 2 million people acquire serious infections with bacteria that are resistant to one or more of the antibiotics designed to treat those infections.
- At least 23,000 people die each year as a direct result of these antibiotic-resistant infections. Many more die from other conditions that were complicated by an antibiotic-resistant infection.


Decreased Efficacy Over Time

Figure from Simonart T, Dramaix M., Treatment of acne with topical antibiotics: lessons from clinical studies. Br J Dermatol. 2005 Aug;153(2):399, Figure 1
Isotretinoin

- 1982: US FDA approved Accutane
- Synthetic Derivative of Vitamin A
  - Fat Soluble Vitamins: DEAK
- Fasted vs. Fed
  - Plasma Levels are 60% lower in the fasted vs fed state
- Dosing: Weight Based
  - 0.5-1.0 mg/kg/day given in 2 divided doses over 4-6 months
- Cumulative Dose
  - 120-150mg/kg

Isotretinoin requires a High Fat, High Calorie Meal

FDA Example:
- 2 eggs fried in butter
- 2 strips of bacon
- 2 slices of toast with butter
- 4 oz. has brown potatoes
- 8 oz. whole milk
Typical Breakfast

Absorica- Lidose Technology
- Isotretinoin is lipophilic
- Encapsulates isotretinoin with lipid agents
  - Provides more optimal environment for absorption
- Lidose drug delivery system
  - Hard gelatin capsule containing liquid or semi-liquid contents with active drug melted together with lipid excipients then cooled
- Potential Advantages
  - greater tolerability with less GI irritation, rapid absorption, protection of drug against oxidation
  - Greater Bioavailability
  - Greater Clinical Outcomes


Does Diet Matter?
Top 3 Takeaways:

1. Antibiotics for 3 months only
2. Do NOT use antibiotics as monotherapy
3. Use topicals when treating acne—specifically BPO when using topical or oral antibiotics

Rosacea

The Clinical Significance of Rosacea

Rosacea is a common condition characterized by symptoms of facial flushing and a spectrum of clinical signs including:

- Erythema
- Telangiectasia
- Coarseness of skin, and
- Inflammatory papulopustular eruption resembling acne
Rosacea Triggers

- Hot or cold temperatures
- Wind
- Hot drinks
- Caffeine
- Exercise
- Spicy food
- Alcohol
- Emotions
- Topical products that irritate the skin and decrease the barrier
- Medications that cause flushing
- In addition, the use of daily broad-spectrum sunscreen is recommended for all patients with rosacea.

Common Rosacea Medications

**Tried and True Prescription Medications:**

- **First Line Therapy:**
  - Metronidazole, +/- oral abx

- **Others:**
  - Topical azelaic acid, sulfacetamide products, and topical acne medications are also commonly used
  - Oracea (doxycycline 40mg)

- Long term antibiotic

http://www.dermnetnz.org/acne/rosacea.html

So What’s New In Rosacea??
Mirvaso (brimonidine) topical gel 0.33%

- **Indication:** First & only FDA-approved treatment for persistent facial redness of rosacea
- **MOA:** Alpha Adrenergic Agonist
- **AE:** erythema, flushing, skin burning sensation, and contact dermat
- **Onset:** 30 min
- **Last:** up to 12 hours

Soolantra (ivermectin) Cream 1%

- **Demodex mite**
  - No direct date → not possible to culture
  - Normal on facial skin but ↑ in rosacea
  - 15–18 times greater in rosacea patients
- **MOA:** unconfirmed
- **Dosing:** QD
- **Indicated for papulopustular rosacea**
- **Anti-inflammatory**
- **Anti-parasitic**

Soolantra- 12 Weeks


Soolantra 12 Weeks:

http://soolantra.com/hcp/efficacy-and-safety
Soolantra - 12 Weeks

Ivermectin 1% QD vs Metronidazole 0.75% BID

Ivermectin vs Metronidazole
Finacea (azelaic acid) Foam 15%

- A naturally occurring saturated dicarboxylic acid found in plants
- Anti-inflammatory
- Foam has a higher lipid content in oil-in-water including fatty acids and triglycerides
- Improve skin condition
- Improved appearance
- Ease of use
- Pregnancy Cat B

A Phase 3 Randomized, Double-blind, Vehicle-Controlled Trial of Azelaic Acid Foam 15% in the Treatment of Papulopustular Rosacea

Change in Lesion Count over 4, 6, 8, 12 & 16 weeks

Adverse Effects vs. Vehicle

Top 3 Takeaways

1. Educate patients on how to minimize trigger factors
2. Use oral antibiotics only if patients have papules or pustules + topical cream
   - Oracea for long term antibiotic
3. Try Soolantra (ivermectin) cream if patient has failed metronidazole
Psoriasis

SEND TO DERM!!!!

Otezla (apremilast)

- Oral, non-biologic, systemic medication
- MOA: PDE4 Inhibitor → cAMP
- Indication
  - Mod-severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Adults with active psoriatic arthritis
- Labs: NONE
- AE: Most Common include: diarrhea, nausea, URI, tension HA, and HA
  - Diarrhea and nausea within the first 2 weeks, then tend to resolve over time with continued dosing
- Safety Profile: Otezla for 104 wks was similar to that at 16wks
Otezla (apremilast)

Significant increase in PASI-75 response


2. Data on file, Celgene Corporation.


Otezla (apremilast) Results Seen at Wk 16 in Otezla Clinical Trial Patients

PASI-85

PASI-69

Baseline

Baseline

Week 16

Week 16

Visually clear in almost all patients

Visually improved in most patients

*Actual data not shown. Individual results may vary.

One More Topic...
Atopic Dermatitis
“Eczema”

Eczema
“The Itch That Rashes”

MUST STOP ITCHING TO STOP THE RASH!!!
Eczema Treatment Goals

- Prevent from getting worse
- Calm the skin, relieving pain and itch
- Reduce emotional stress
- Prevent Infections
- Stop the skin from thickening
  - Once skin thickens, it itches all the time
  - Lichen Simplex Chronicus (LSC)
  - Prurigo Nodularis (PN)

LSC & PN

Lichen Simplex Chronicus  Prurigo Nodularis

Eczema Treatments

Emollients/Barrier Cream
  - Neosalus, Hylatopic or Epiceram

Topical steroids BID-TID
  - LIMIT: 2 weeks continuous use
  - Class 1-7 & vehicle depending on severity/site

Calcineurin Inhibitors (Topical Immunosuppressants)
  - Use if pt is needing to use steroid for >2 weeks
  - Gives pt a break from the steroid
  - Protopic (Tacrolimus) or Elidel (Pimecrolimus)
  - Indicated for >2 y/o
  - BBW- Lymphoma- rare
Eczema Treatments Cont...

Antihistamine
- Claritin/Allegra QAM, Hydroxyzine QPM
- Sinequan (doxepin)
  - Give only if not being able to sleep due to itching w/hydroxyzine

Anti-itch topical- Aurstat or Atrapro

**If patient is flared consider:
- Oral steroids- Prednisone 3 week taper
- Antibiotics- if a lot of open wounds from excoriation marks
  - Cephalexin (kids) or Doxycycline (>8 y/o, tooth discoloration if younger)
- Light Therapy- helps decrease inflammation

Allergy Group C Corticosteroids

- Cloderm (clocortolone pivalate) cream, 0.1%
  - Has an authorized generic
  - No Lanolin, Propylene glycol, fragrance

- Topicort (desoximetasone) cream & ointment, 0.05% & 0.25%
  - No Propylene glycol, Parabens, or Fragrances

Great Steroid Combination

Mix All 3 Together:
1. Clobetasol Solution
2. Camo Cream
3. Campho-Phenique

Apply to body x2-3 daily.
Limit to using for 2 weeks continuous use.
Daily Products for Eczema Patients

- Cetaphil Restoraderm body wash
- Vanicream products - shampoo, conditioner, lotion
- Cerave
- ALL unscented detergent (no drier sheets)
- Bleach baths or CLN body wash
  - Apply a cap size amount of bleach to bath and sit for 15 min
  - CLN Body Wash - bleach body wash
  - Helps remove bacteria that cause infections.

So What’s New In Eczema?

Barrier Creams

- In eczema the Stratum Corneum (top layer of skin) is compromised
- The SC has 3 types of lipids:
  1. Ceramides
  2. Cholesterol
  3. Free Fatty Lipids
- Eczema = slightly lower ceramides in their SC
- Prescription barrier creams form more than a superficial occlusive barrier (like petroleum) rather they penetrate the SC and increase the strength of the SC and decrease transepidermal water loss
- Repair, Protect & Hydrate
Barrier Creams
- EpiCeram
  - Cream
- Neosalus
  - Cream, Lotion or foam
- Hylatopic Plus
  - Cream, foam

Top 3 Takeaways:
1. Educate patient and/or parent on steroid use
2. Always include a barrier cream
3. If not controlled, then send to Derm

You Made it!
Thank you!
Questions??