EGFR Inhibitor–Related Dermatologic Toxicities: Applying MASCC Guidelines in Prevention and Treatment

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Faculty Disclosures

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EGFR Inhibitor–Related Dermatologic Toxicities

**Targeting Tumors**

- **EGFR overexpressed**
  - CRC: 27% to 77%; pancreatic: 30% to 50%; lung: 40% to 80%; NSCLC: 14% to 91%

- **EGFR mutated**
  - NSCLC: 10%; glioblastoma: 20%

- **Ras mutated**
  - Pancreatic: 90%; papillary thyroid: 60%; colon: 50%; NSCLC: 30%

- **Raf mutated**
  - Melanoma: 70%; papillary thyroid: 50%; colon: 10%

And Targeting the Skin

- 1.6 million people diagnosed each yr
  - Prior to therapy, 45.1% with skin findings (N = 700)
  - Tinea pedis/onychomycosis, xerosis, pruritus, pyoderma

- Consequences of dermatologic conditions
  - Psychosocial impact
  - Financial burden
  - Physical health
  - Anticancer treatment disruption

**EGFR in Skin**

- EGFR is constitutively expressed in the epidermis, follicle, sebaceous, eccrine glands, dendritic APCs
- EGFR inhibition leads to negative effects in skin
  - Apoptosis, inflammation, atrophy, telangiectasias, ↓ photoprotection

Timing of EGFR Inhibitor–Associated Dermatologic Toxicities

- Acne-like rash
- Postinflammatory effects
- Dry skin
- Fissure
- Paronychia

Wk of EGFR-Targeted Therapy

Prevention and Treatment of EGFR Inhibitor–Assoc. Dermatologic Toxicities

Levels of Evidence

- Level I evidence is reserved for meta-analyses of randomized controlled trials or randomized trials with high power
- Level II evidence includes randomized trials with lower power
- Level III evidence includes nonrandomized trials, such as cohort or case-controlled series
- Level IV evidence includes descriptive and case studies
- Level V evidence includes case reports and clinical examples

Recommendation Grades

- Grade A is reserved for level I evidence or consistent findings from multiples studies of level II, III, or IV evidence
- Grade B is for level II, III, or IV evidence with generally consistent findings
- Grade C is similar to grade B but with inconsistencies
- Grade D implies little or no evidence

EGFR Inhibitor–Related Dermatologic Toxicities

EGFR Inhibitor–Induced Rash

- Red papulopustules[^1]
  - Pruritus, tenderness in 62%
- Erlotinib 150 mg QD[^2]
  - All grade: 75%
  - Grade 3: 9%
- Cetuximab[^3]
  - All grade: 85%
  - Grade 3: 10%
- Panitumumab[^4]
  - All grade: 90%
  - Grade 3: 16%
- Lapatinib[^5]
  - All grade: 27%
  - Grade 3: 1%

EGFR Inhibitor–Related Dermatologic Toxicities

EGFR Inhibitor–Induced Rash

- Red papulopustules\(^{[1]}\)
  - Pruritus, tenderness in 62%
- Erlotinib 150 mg QD\(^{[2]}\)
  - All grade: 75%
  - Grade 3: 9%
- Cetuximab\(^{[3]}\)
  - All grade: 85%
  - Grade 3: 10%
- Panitumumab\(^{[4]}\)
  - All grade: 90%
  - Grade 3: 16%
- Lapatinib\(^{[5]}\)
  - All grade: 27%
  - Grade 3: 1%

Impact of EGFR Inhibitor Dermatologic Toxicities on QoL and Cost

QoL\(^{[1]}\)
- Survey of 58 patients with Skindex-16
- Top domain: emotions \((P < .05)\)
- Inverse corr age-emotions \((r = -0.26; P = .03)\)

Cost\(^{[2]}\)
- Mean cost/pt: $2788

Median Overall Skindex-16 Score

<table>
<thead>
<tr>
<th>NCI-CTCAE v3.0 Papulopustular Rash Grade</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Overall Skindex-16 Score</td>
<td>40</td>
<td>50</td>
<td>60</td>
</tr>
</tbody>
</table>

Avg. Cost/Pt for Management of EGFR Inhibitor Dermatologic Toxicities ($)

- Drugs: 1497
- Clinic Visits: 862
- Lab Tests: 338
- Procedures: 91

Impact of EGFR Inhibitor Skin Toxicity on Oncologists

- Survey of 110 oncology practices, 51 questions on EGFR inhibitor rash

Percentage of Responders who Observe Indicated Rash Grade in > 50% of Patients With Rash

- Grade 1: 39
- Grade 2: 34
- Grade 3: 4
- Grade 4: 3

Dose reduction: 60%
Dose interruption: 76%
Drug discontinuation: 32%

Correlation: Rash and Survival/Response in CRC

- Vincenzi 2006\[1\]
  - Rash Grade 0-2
  - Median OS (Mos): 5
  - Vincenzi 2006: $P = .06$

- Saltz 2004\[2\]
  - Rash Grade 0-2
  - Median OS (Mos): 10
  - Saltz 2004: $P = .02$

- Hecht 2007\[3\]
  - Rash Grade 0-1
  - Median OS (Mos): 0
  - Hecht 2007: HR: 0.72; 95% CI: 0.54-0.97

References:
# Tazarotene and Minocycline for Rash Prevention

**Cetuximab therapy for CRC**

### Randomize

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Description</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minocycline 100 mg/day</strong> (N = 24)</td>
<td>0.05% tazarotene cream daily to left half of face (n = 12)</td>
<td>18 Analyzed</td>
</tr>
<tr>
<td></td>
<td>0.05% tazarotene cream daily to right half of face (n = 12)</td>
<td>17 Analyzed</td>
</tr>
<tr>
<td><strong>Daily Placebo</strong> (N = 24)</td>
<td>0.05% tazarotene cream daily to left half of face (n = 12)</td>
<td>2 mos</td>
</tr>
<tr>
<td></td>
<td>0.05% tazarotene cream daily to right half of face (n = 12)</td>
<td>17 Analyzed</td>
</tr>
</tbody>
</table>

Total lesion count each side of face

Minocycline for Rash Prevention: Total Lesion Counts

- Prophylaxis with minocycline results in decreased severity of rash in first mo of cetuximab therapy
- There was no difference with tazarotene treatment

STEPP Study: Preemptive vs Reactive Skin Toxicity Treatment in Metastatic CRC

- Open-label phase II study
- Prophylactic skin treatment regimen administered Wks 1-6 (beginning Day 1)
  - Skin moisturizer
  - Sunscreen (PABA free, SPF ≥ 15, UVA/UVB protection)
  - Topical steroid (1% hydrocortisone cream)
  - Doxycycline 100 mg BID
- Per investigator discretion, reactive skin treatment administered anytime during Wks 1-6

**STEPP: Dermatologic Toxicities**

<table>
<thead>
<tr>
<th></th>
<th>Prophylactic (n = 48)</th>
<th>Reactive (n = 47)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with grade 2 or higher skin toxicity, n (%)</td>
<td>14 (29)</td>
<td>29 (62)</td>
</tr>
<tr>
<td>OR (95% CI)</td>
<td>0.3 (0.1-0.6)</td>
<td></td>
</tr>
</tbody>
</table>

Case 1

- The patient is a 48-yr-old man with colorectal cancer that is EGFR positive and \textit{KRAS} wild type. You opt to initiate treatment with cetuximab plus irinotecan.
Based on the MASCC guidelines, which of the following strategies do you recommend for this pt to prevent acneiform rash during the first 1-6 wks of cetuximab therapy?

A. Topical hydrocortisone 1% cream with sunscreen and moisturizer twice daily

B. Topical tazarotene 0.05% cream daily

C. Systemic tetracycline

D. Systemic minocycline or doxycycline
Based on the MASCC guidelines, which of the following strategies do you recommend for this pt to prevent acneiform rash during the first 1-6 wks of cetuximab therapy?

A. Topical hydrocortisone 1% cream with sunscreen and moisturizer twice daily (level II, grade C)

B. Topical tazarotene 0.05% cream daily

C. Systemic tetracycline

D. Systemic minocycline or doxycycline (level II, grade A)
   - Doxycycline is preferred in patients with renal impairment
   - Minocycline is less photosensitizing and thus preferred in areas that have a high UV index
# Acneiform Rash Management Recommendations

<table>
<thead>
<tr>
<th>Preventive</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>Hydrocortisone 1% cream with</td>
<td>Pimecrolimus 1% cream</td>
<td>II*</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>moisturizer, sunscreen twice daily</td>
<td>Tazarotene 0.05% cream</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sunscreen as single agent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic</td>
<td>Minocycline 100 mg/day</td>
<td>Tetracycline 500 mg BID</td>
<td>II*</td>
<td>A</td>
<td>Doxycycline is preferred in patients with renal impairment; minocycline is less photosensitizing</td>
</tr>
<tr>
<td></td>
<td>Doxycycline 100 mg BID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Recommend</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>Alclometasone 0.05% cream</td>
<td>Vitamin K1 cream</td>
<td>IV*</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluocinonide 0.05% cream BID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clindamycin 1% cream</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic</td>
<td>Doxycycline 100 mg BID</td>
<td>Acitretin</td>
<td>IV*</td>
<td>C</td>
<td>Photosensitizing agents</td>
</tr>
<tr>
<td></td>
<td>Minocycline 100 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Isotretinoin at low doses (20-30 mg/day)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*EGFR inhibitor study.

Additional Dermatological Toxicities to EGFR Inhibitors: Xerosis

- Patients receiving EGFR inhibitors > 6 mos (n = 16)
  - Range on therapy (6-27 mos)
  - Cutaneous toxicities in 100%
  - Dose mod in 37.5%

<table>
<thead>
<tr>
<th>Symptom, n (%)</th>
<th>Any Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xerosis</td>
<td>16 (100)</td>
</tr>
<tr>
<td>Paronychia</td>
<td>9 (56)</td>
</tr>
<tr>
<td>Alopecia</td>
<td>6/12 (50)</td>
</tr>
<tr>
<td>Hair Modifications</td>
<td>14 (87.5)</td>
</tr>
</tbody>
</table>

Case 2

- A 68-yr-old woman has been receiving maintenance erlotinib monotherapy for the treatment of metastatic non-small-cell lung cancer that responded to 4 cycles of first-line chemotherapy. Eight wks after initiating erlotinib, she presents with moderate xerosis on her back and shoulders.
Case 2: Moderate Xerosis
Based on the MASCC guidelines, which of the following strategies do you recommend to treat this pt’s xerosis?

A. Benzoyl peroxide  
B. Fragrance-free, occlusive, emollient creams packaged in a jar/tub  
C. Alcohol-based lotions that can be pumped  
D. Topical retinoids
Based on the MASCC guidelines, which of the following strategies do you recommend to treat this pt’s xerosis?

A. Benzoyl peroxide

B. Fragrance-free, occlusive, emollient creams packaged in a jar/tub (level III, grade B)

C. Alcohol-based lotions that can be pumped

D. Topical retinoids
Xerosis Management Recommendations

<table>
<thead>
<tr>
<th>Preventive</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>Bathing techniques using bath oils or mild moisturizing soaps and bathing in tepid water</td>
<td>III</td>
<td>B</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regular moisturizing creams</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Avoid extreme temperatures and direct sunlight</td>
<td>III*</td>
<td>B</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical (mild/moderate)</td>
<td>Emollient creams that are packaged in a jar/tub that lack fragrances or potential irritants Occlusive emollients containing urea creams, colloidal oatmeal, and petroleum-based creams For scaly areas, ammonium lactate or lactic acid cream</td>
<td>Alcohol-containing lotions Retinoids or benzoyl peroxide</td>
<td>III</td>
<td>B</td>
<td>More greasy creams for use on the limbs, but caution use of greasy creams on the face and chest</td>
</tr>
<tr>
<td>Topical (severe)</td>
<td>Medium- to high-potency steroid creams</td>
<td>III</td>
<td>B</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*EGFR inhibitor study.

## Fissure Recommendations

<table>
<thead>
<tr>
<th>Preventive</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>Wear protective footwear and avoid friction with fingertips, toes, and heels</td>
<td></td>
<td>III</td>
<td>B</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
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</tr>
</thead>
</table>
| Topical    | • Thick moisturizers or zinc oxide (13% to 40%) creams  
• Liquid glues or cyanoacrylate to seal cracks  
• Steroids or steroid tape, hydrocolloid dressings, topical antibiotics  
• Bleach soaks to prevent infection  
• Zinc oxide | | III*† | B | Cream application often impractical |

*EGFR inhibitor study.
†Non–EGFR inhibitor cancer treatment study.

Pruritus

- Pruritus
  - In 30% to 50%
  - Decreased QoL
  - Sleep deprivation
  - Scratching and secondary infections

# Pruritus Recommendations

<table>
<thead>
<tr>
<th>Preventive</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>Gentle skin care instructions</td>
<td></td>
<td>IV*†</td>
<td>D</td>
<td>Consensus of experts</td>
</tr>
<tr>
<td>Systemic</td>
<td>Steroids</td>
<td></td>
<td>IV*†</td>
<td>D</td>
<td>Consensus of experts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Topical   | - Menthol 0.5% pramoxine, 1% doxepin
- Medium- to high-potency steroids (triamcinolone acetonide 0.025%, desonide 0.05%, fluticasone propionate 0.05%, alclometasone 0.05%) | | III† | B | Treat underlying condition first (rash, xerosis) |
| Topical   | - Antihistamines, lidocaine | | II† | C | These agents can become allergens and can be absorbed systemically |
| Systemic  | - Antihistamines† | | I‡ | A | Non-sedating first; some may need adjustment for renal impairment |
| Systemic  | - Aprepitant* | | V* | D | |
| Systemic  | - Gabapentin/pregabalin* | | V*† | D | Recommended as second-line treatment only if antihistamines fail |
| Systemic  | - Doxepin | | V* | D | |

*EGFR inhibitor study.
†Non-EGFR inhibitor noncancer treatment study.
‡Non-EGFR inhibitor cancer treatment study.

**Additional Dermatologic Toxicities to EGFR Inhibitors: Paronychia**

- Patients receiving EGFR inhibitors > 6 mos (n = 16)
  - Range on therapy (6-27 mos)
  - Cutaneous toxicities in 100%
  - Dose mod in 37.5%

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<tr>
<td>Alopecia</td>
<td>6/12 (50)</td>
</tr>
<tr>
<td>Hair modifications</td>
<td>14 (87.5)</td>
</tr>
</tbody>
</table>

Case 3

- A 40-yr-old woman has been receiving panitumumab for the treatment of colorectal cancer. After 4 mos, she developed paronychia and periungual granulation tissue in her fingernails, which limits self-care activities of daily living.
Case 3: Paronychia and Periungual Granulation Tissue
Based on the MASCC guidelines, which of the following strategies do you recommend to treat this pt’s paronychia?

A. Clobetasol ointment daily
B. Obtain bacterial cultures
C. Cephalexin therapy for 10 days
D. Nail avulsion
Based on the MASCC guidelines, which of the following strategies do you recommend to treat this pt’s paronychia?

A. Clobetasol ointment daily (level II, grade A)
B. Obtain bacterial cultures (level IV, grade D)
C. Cephalexin therapy for 10 days
D. Nail avulsion (level IV, grade D)
# Paronychia Management Recommendations

<table>
<thead>
<tr>
<th>Preventive</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Topical    | Dilute bleach baths  
Avoid irritants |  | II* | A | Recommend final concentration of ~ 0.005%‡ |
| Treatment  | Recommended | Not Recommended | Level of Evidence | Recommendation Grades | Comments |
| Topical    | Corticosteroids  
Calcineurin inhibitors  
Antifungals Antibiotics |  | II* | A | Recommend usage of ultrapotent topical steroids as first-line therapy given cost and availability of these agents |
| Systemic   | Tetracyclines  
Antimicrobials: reserved for culture proven infection  
Biotin for brittle nails  
Empiric antibiotics, employed without culturing lesional skin  
Antifungals |  | IV†/II* | D/A |  |
| Other      | Silver nitrate  
chemical cauterization wkly  
Electrodessication  
Nail avulsion |  | IV* | D | Reserved for pyogenic granulomata; consensus of experts |

*Non-EGFR inhibitor noncancer treatment study. †EGFR inhibitor study. ‡Dilution: ~ 1/4-1/8 cup 6% bleach for 3-5 gal water.
Additional Dermatologic Toxicities With EGFR Inhibitors: Hair Changes

- Pts receiving therapy > 3 mos
  - Scalp alopecia and hair curling
  - Hirsutism on face
  - Eyelash trichomegaly

# Hair Changes Recommendations

<table>
<thead>
<tr>
<th>Preventive hair loss</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>For scarring alopecia, follow rash recommendations</td>
<td>Preventive interventions for nonscarring alopecia</td>
<td>V</td>
<td>D</td>
<td></td>
</tr>
<tr>
<td>Systemic</td>
<td>For scarring alopecia, follow rash recommendations</td>
<td>Preventive interventions for nonscarring alopecia</td>
<td>V</td>
<td>D</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment for hair loss</th>
<th>Recommended</th>
<th>Not Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Minoxidil 2%, 5% BID</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Scarring</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Class 1 steroid lotion, shampoo, or foam</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Antibiotic lotion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventive increased hair</td>
<td>Patient education and support</td>
<td></td>
<td>IV</td>
<td>B</td>
<td>Consensus of experts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment for increased hair</th>
<th>Recommended</th>
<th>Level of Evidence</th>
<th>Recommendation Grades</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial hypertrichosis</td>
<td>Eflornithine</td>
<td>IV,[^1] II[^*]</td>
<td>B</td>
<td>Consensus of experts</td>
</tr>
<tr>
<td></td>
<td>Lasers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eyelash trichomegaly</td>
<td>Eyelash trimmings regularly</td>
<td>IV</td>
<td>B</td>
<td></td>
</tr>
</tbody>
</table>

[^*]: Non–EGFR inhibitor noncancer treatment study.
[^1]: EGFR inhibitor study.

Dermatologic Infections With EGFR Inhibitors

- S aureus infection in grade 3/4 radiation dermatitis
- EGFR inhibitor treated pts: 38% with infections
  - Severe radiation dermatitis: 10/14 S aureus+
- In oncology, SSTI may result in bacteremia
  - Skin and mucosa entry in 64%; 16% mortality
- Analysis conducted of 221 pts treated with EGFR inhibitors
  - 38% with bacterial, viral, fungal
  - Higher risk in leukopenic patients ($P < .05$)

Conclusions

- Skin toxicities during EGFR inhibitor therapy are amenable to study and treatment
- Early/proactive approach toward toxicities is advisable
- Characterization of dermatologic toxicities will increase in importance
  - Adjuvant setting
  - Dose escalation and combination studies
  - Longer survival
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