Practical Perspective on Photoprotection

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Disclosures

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  - PCORI

Disclosures

- Consultant:
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  - ISDIN
  - Ferndale
  - La Roche-Posay
  - Beiersdorf
- Speaker, educational session:
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  - Cantabria labs

Perspective From:

- Practicing dermatologist (medical dermatology and photodermatology)
- AAD/AADA
  - Former president
  - Chair, TF on Sunscreens
- Former president:
  - Am Soc for Photobiology
  - International Union of Photobiology
  - Photoderm Soc
  - National Council for Skin Cancer Prevention

What is the role of sunscreens in prevention of skin cancers?

Tanning Bed Use and Skin Cancer

- **Strongly associated with the development of keratinocyte carcinoma and melanoma**
  - *Zhang, M, et al. J Clin Oncol 2012;30:1588*
  - *Diehl, K, et al. Int J Environ Res Public Health 2019;16:3913*

Sunscreens and Actinic Keratoses

(Thompson SC. N Engl J Med 1993; 329:1147. Australia
Naylor, MF. Arch Dermatol 1995; 131:170. USA.
Darlington S. Arch Dermatol 2003; 139:451. Queensland, Australia)

- **The use of broad spectrum sunscreens (15+ - 29) resulted in a decrease in the development of actinic keratoses**

Sunscreens and Skin Cancers

(Green, A., Lancet 1999; 354:723.
van der Pols, JC,…. Green, A. Cancer Epidemiol Biomarkers Prev 12/2006; 15:2546.
Brisbane, Australia)

- A 4.5 yr + 8 yr f/u study of 1621 residents of Nambour, Queensland showed that sunscreen used was associated with:
  - Squamous cell carcinoma incidence rates: ↓ 38%;
  - Basal cell carcinoma incidence rates: ↓ 25%;
  - Melanoma: decrease (11, vs 22 in control group)

What is the role of sunscreens in prevention of skin cancers?

Strong evidence that sunscreens would do so

What about the absorption of sunscreens into the blood stream?

Absorption of UV Filters

(Matta, M, et al. JAMA 2019 Jun 4;321:2082. FDA
Matta, MK, et al. JAMA 2020 Jan; 323:256. FDA)

- Two studies by FDA scientists detected active ingredients in the blood following sunscreen application (75% BSA at 2 mg/cm^2)
- Conclusions from the studies:
  - "The systemic absorption of sunscreen ingredients supports the need for further studies to determine the clinical significance of these findings."
  - *"These results do not indicate that individuals should refrain from the use of sunscreens."*

What about the absorption of sunscreens into the blood stream?

FDA continues to recommend the use of sunscreens.

Industry is working with the FDA to do further safety studies

Should we be concerned about the health and environmental effects of sunscreens?

UV Filters and Human Health

(Suh, S, … Smith, J, Meshinkovska, N. Int J Dermatol 2020 Sept; 59:1033. UC Irvine)

- **Systematic review of 29 studies concluded that current evidence is *not* sufficient to support the causal relationship between the elevated systemic level of oxybenzone or octinoxate and adverse health outcomes.**

Environmental Effects of Organic UV Filters

(Michelmore, CL, et al. Environmental Toxicology and Chemistry. 2021 Apr;40(4):967)

- **Review of all published studies till June 2020 (32 studies) showed:**
  - **Organic UV filters in seawater: *nanograms per liter* range.**
  - **Toxicological findings, in the *micrograms per liter* to *milligrams per liter* range (ie, *1000 to 1 million-fold* higher concentrations)**

Environmental Effects of Organic UV Filters

(Michelmore, CL, et al. Environmental Toxicology and Chemistry. 2021 Apr;40(4):967)

Conclusion:

- There is currently limited evidence to suggest that corals are adversely impacted by environmental exposure to UV filters;
- However, there are major data gaps that immediately need to be addressed with high-quality monitoring, fate, and toxicity studies.

Should we be concerned about the health and environmental effects of sunscreens?

No strong evidence, but data is evolving.
More studies need to be done

How should we advise our patients and the public?

How should we advise our patients?

(Schneider, S, Lim, HW. JAAD 2019 Jan;80(1):266. Detroit)

- Adverse effects of sun exposure are well established.
- Practice of photoprotection is essential:
  - Seek shade
  - Wear photoprotective clothing, wide-brimmed hat, sunglasses
  - Apply SPF 30 or higher broad-spectrum sunscreen to otherwise exposed area

How should we advise our patients?

(Schneider, S, Lim, HW. JAAD 2019 Jan;80(1):266. Detroit)

- For those concern about the environmental and health effects of oxybenzone or octinoxate:
  - US: Use mineral (inorganic) sunscreen
- With practice of rigorous photoprotection: vit D 600-800 IU daily

Topics that AADA suggests the National Academies Committee to carefully consider

Public Education

- The deleterious effects of excessive UV is well established
- Topics covered have created confusion and concerns among the public about the benefit of photoprotection
- The latest data on the economic burden of skin disease (based on 2013 claims data):
  - Non-melanoma skin cancer (keratinocyte carcinoma; BCC, SCC): $4.6 billions
  - Melanoma: $1.5 billions
  - *Lim, HW, et al. J Am Acad Dermatol. 2017; 76:958.*

UV filters in 1999 FDA Final Monograph

- Europe: 27 approved filters
- US: only 16 filters are approved
  - Plus: ecamsule – approved through NDA process
- Feb 2019 FDA proposed rule:
  - Category I: 2 (zinc oxide and titanium dioxide): GRASE (= generally recognized as safe and effective)
  - Category II: 2 (PABA, trolamine salicylate): Not GRASE
  - Category III: 12: insufficient safety data to make a positive GRASE determination

UV filters in 1999 FDA Final Monograph

- The only GRASE filters are titanium dioxide and zinc oxide:
  - They are not very efficient filters (approved max incorporation concentration: 25%, vs organic filters at 3-15%)
  - Leave whitish residue on skin – not acceptable by many individuals with skin of color

UV filters in 1999 FDA Final Monograph

- Oxybenzone is commonly used in the US; it is a good UVB and short wavelength UVA (UVA2) filters.
  - Approved by FDA in 1978
  - Due to the lack of alternatives, it is challenging to remove oxybenzone from broad spectrum products in the US
  - Not an issue in Europe

Concluding Perspective - I

- Public is confused with the issue of sunscreens
- Decreased photoprotection practice by the public would have a deleterious effect on US public health, and would add significantly to economic burden of skin cancers (2013: $6.1 billions)
- As with any intervention, risk-benefit ratio of skin cancer prevention needs to be carefully considered:
  - Science on photocarcinogenesis is well-established
  - Data on side effects are still evolving

Concluding Perspective - II

- National Academies of Sciences, Engineering and Medicine is in an excellent position to provide a clear, scientifically-based guidance to the public
  - As IOM did with vitamin D in 2011
- FDA should be encouraged to expedite the review and approval of new filters
  - No new filter has been added since the 1999 Final monograph