Rating the 4-Star UVA Protection Rating System

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The sun protection factor (SPF) currently displayed on sunscreen labels has been a well-recognized measurement of a sunscreen's ability to provide protection from UVB radiation for many years. Recent findings regarding the role of UVA radiation in photoaging and the development of skin cancer have prompted the US Food and Drug Administration (FDA) to improve the testing methods and labeling of UVA protection on sunscreens. In 2007, the FDA proposed changes to address these concerns; however, those changes have not been received with unanimous support, leading to a delay in their acceptance and further approval. This article reviews some of the concerns about the proposed rating systems for UVB and UVA protection, including how these new proposed rating systems may increase confusion among consumers.

Sunscreens help protect skin against sunburn by absorbing and/or reflecting some of the UV radiation (290–400 nm) from the sun. Sun protection factor (SPF), a measurement of the ability of the sunscreen to protect against sunburn, is a standard, well-recognized tool in the testing and marketing of sunscreens today. It is expressed as the ratio of the least amount of UV energy needed to produce erythema (ie, the minimal erythema dose) on sunscreen-protected skin to the amount of energy required to produce the same erythema on unprotected skin. Besides the continuing interest in the SPF, which measures protection against UVB radiation (290–320 nm), measurement of the UVA radiation (320–400 nm) protection provided by sunscreens has currently taken the attention of consumers and clinicians alike. Improvement in the testing and labeling methods for UVA protection on sunscreens is needed.

In order to offer solutions to concerns with SPF and the current inadequate UVA testing methods and labeling of sunscreens, the US Food and Drug Administration (FDA) proposed in 2007 the inclusion of a new type of qualitative descriptors for the UVB-SPF rating system.[1,2] For example, SPF 2 to 14 will be described as "low," 15 to 29 as "medium," 30 to 50 as "high," and 50+ as "highest." In addition, they proposed an increase in the SPF labeling cap from 30+ to a cap of 50+, as well as replacement of the term "waterproof" on labels with "water resistant" or "very water resistant." In regard to UVA, the FDA proposed the implementation of better in vitro and in vivo methods of UVA-filter testing, along with an innovative UVA rating system that will translate into a comprehensive sunscreen label.[1,2] However, the proposed changes have not been received with unanimous support, leading to a delay in their acceptance and further approval. In this article, some of the concerns are discussed, including how the proposed rating systems for UVB and UVA may increase confusion among consumers.

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INTRODUCTION

Multiple protective measures are available to reduce the risk of developing skin cancer and photodamage caused by UV radiation from the sun, including the use of clothes, hats, sunglasses, and sunscreens. Sunscreens have become the most commonly used mode of protection,[3,4] and are regulated by the FDA. When topical sunscreens were introduced, photoprotection was biased towards UVB, as it was the target of protecting against sunburn and skin cancer. UVB radiation induces damage by directly injuring cellular DNA, leading to the formation of cyclobutane pyrimidine dimers and 6-4 photoproducts. Until recently, the damaging effects of UVA radiation were not recognized, and UVA protection was not appropriately implemented in the available sun protection products. UVB was the only type of UV radiation proven to be involved in the development of skin cancers, while UVA was believed to be involved solely in photoaging (ie, the development of wrinkles, dryness, telangiectasias, and pigmentation). However, studies have now shown that deep penetration of UVA into the skin indirectly damages cellular DNA mainly through the formation of reactive oxygen species, which can lead to the development of skin cancer as well.[5-7]

Consumers purchase sunscreens with a high SPF believing they will be reducing their exposure to the full spectrum of UV irradiation and therefore will prevent photodamage and ultimately reduce their risk of developing skin cancer. In reality, the SPF numerical value on sunscreen labels only attests to the protection offered in the wavelength range corresponding to UVB irradiation (290–320 nm). Whether UVA filters (eg, avobenzone, ecamsule) are present is not always indicated on a sunscreen label. Therefore, sunscreens with the same numeric SPF value (eg, SPF 30) may vary in their ability to provide protection in the wavelength corresponding to UVA (320–400 nm), yet fail to convey that information to the consumers. This lack of information may lead to inadequate amounts of sunscreen applied and promote rather than prevent the development of skin cancer such as malignant melanoma,[8] as individuals tend to be overexposed to the sun believing that they are fully protected, when in fact, they are ultimately being exposed to high doses of UVA radiation.

The UV protection factor developed for fabrics in protective clothing or garments is advantageous over topical sunscreens because there is no sunscreen/skin interaction to interfere with the protection mechanism. Wearing protective clothes decreases exposure to all types of UV radiation, which is why they can be called broad-spectrum sun blockers. They provide the same continuous coverage independent of the environment, while most sunscreens on the market provide only partial coverage and vary in the quality of the protection they provide depending on location, season, and timing in addition to variation in the uniformity in the application and application thickness.[9] For example, UVA intensity in winter is only half that of summer, spring, or fall in locations farther from the equator due to lower sun angle and shorter daylight hours,[10] and therefore a particular sunscreen may offer more protection in the winter.

Attempts have been made to differentiate between sunscreens that provide UVA protection and sunscreens that do not by adding the term "broad-spectrum" to labels of sunscreens that contain UVA protection. Even sunscreens labeled as broad-spectrum frequently include only UVA filters that have not undergone in vitro/in vivo testing, and therefore are inaccurately rated as per the quality of protection they provide. However, most consumers are not aware of this and believe that broad spectrum indicates full adequate protection against the whole spectrum of UV radiation.

TESTING METHODS FOR UVA PROTECTION

The International Standardization Organization (ISO) is a group dedicated to the study of SPF and UVA protection (both in vivo and in vitro). The main objective of the ISO is to achieve global harmonization of testing methods. In the future, their methodology will help align the influencing parameters in the SPF measurement that are responsible for the existing discrepancies between regions, countries, and laboratories. The in vivo UVA testing method supported by the ISO is the persistent pigment darkening (PPD) method, which is explained below.[9]

The FDA proposed the use of both in vitro and in vivo testing methods in order to determine the UVA rating to be assigned to a sunscreen. Some of these proposed tests are already applied in other countries.[2,11] For example, the in vivo testing method proposed by the FDA is adopted from that used by the Japan Cosmetic Industry Association for measurement of UVA protection.[12] This test measures PPD, or tanning that remains visible at least 2 hours after the completion of UVA exposure, as the end point. This type of pigmentation is due to photons in the 330- to 370-nm wavelength range, which make up part of the UVA spectrum. A ratio of the amount of radiation causing pigmentation with the sunscreen divided by the amount of radiation causing pigmentation

without the sunscreen is calculated. The results are translated into one of 3 protection grades of UVA (PA): PA+, indicating some UVA protective effect (2:4 ratio); PA++, indicating a moderate UVA protective effect (4:8 ratio); and PA+++, indicating a good UVA protective effect (>8 ratio). The validity of this method has been tested in Fitzpatrick skin types I through V with consistently positive results.[12]

As stated before, the FDA also plans to use in vitro testing methods for rating UVA protection.[2,11] However, one concern with in vitro testing stems from the fact that the biological responses after UVA exposure (ie, erythema and pigmentation) occur after relatively long exposure to UVA at high intensities. This can lead to extremely long dosing and testing periods. One method proposed by the FDA, known as the Diffey/Boots method, uses a thin film technique to determine the ratio of the sunscreen's protection from UVA 1 radiation (340–400 nm) to the protection from total UVA plus UVB radiation.[13] This test eliminates the issue of operator dependence seen with other in vitro testing methods.[10] The closer the ratio is to one, the higher the product is rated. In an alternate in vitro method, both UVA 1 and UVA 2 are taken into consideration, and also controls for operator dependence. In this method, the absorbance of a thin film of sunscreen is summed successively, starting at 290 nm, until the sum total reaches 90% of the total absorbance of the sunscreen in the UV region. The wavelength at which 90% of the absorbance is reached is called the *critical wavelength*. Because this represents a relative measurement of UVA protectiveness, products with similar critical wavelengths may have varying in vivo protection indices, indicating the need for both in vivo and testing.[10] Preirradiation of the product to be tested will occur in both in vitro testing methods to control for the chemical breakdown that occurs with some filters during UV exposure, affecting their ability to absorb UV radiation.

Because the Diffey/Boots method of testing sunscreens only examines the role of UVA 1 (340–400 nm) and does not take into account UVA 2 (320–340 nm), which is thought to play a larger role in the generation of skin damage, critical wavelength is the method preferred by the American Academy of Dermatology.[13] In addition, the European Commission proposed a testing scheme that uses critical wavelength measurement in combination with the in vivo PPD method of measurement (mentioned above).[14]

UV RATING SYSTEM CONCERNS

Besides the difficulties in finding a testing method that will be universally accepted and will adequately test sunscreen filters, there is concern regarding the translation of test results into a rating score to be included on sunscreen labels. There have been various arguments about the need for grading and labeling of UVA protection. Consumers expect to be able to quickly compare and select the best sun protection product for their needs. In order to facilitate easy selection it is crucial that sunscreens have a simple yet informative label that includes key information about both UVA and UVB protection. The European Commission has recommended that the UVA protection factor be greater than one-third of the SPF value for sunscreen products.[14] If this was universally accepted, UVA would be automatically linked to UVB coverage and a separate UVA rating system would not be needed, avoiding confusion among consumers. Nevertheless, the FDA has proposed the addition of a UVA rating system to add to sunscreen labeling.

To translate the in vitro and in vivo testing into a sunscreen rating system, the results of the above tests that rate the sunscreen with a lower score is converted to a star value to appear on the product.[11] The star rating system proposed by the FDA consists of 4 stars, with 1 star representing low UVA protection and 4 stars representing the highest UVA protection available. No star will be given for those sunscreen products with ratios of 0 to less than 0.20, in vitro or less than 2 in vivo; 1 star for those with a ratio of 0.20 to 0.39 in vitro, or 2 to less than 4 in vivo; 2 stars for those with a ratio of 0.40 to 0.69 in vitro, or 4 to less than 8 in vivo; 3 stars for a ratio of 0.70 to 0.95 in vitro, or 8 to less than 12 in vivo; and 5 stars for those with a ratio higher than 0.95 in vitro, or 12+ in vivo.[12] The star rating will be displayed on the label along with text explaining the rating system, such as "low" or "highest." If no UVA protection is offered, this must be indicated on the product label. This star rating system for UVA protection in combination with the new SPF category descriptors mentioned above for UVB (ie, low, medium, high, highest) leads to 20 different types of sunscreen that the consumers will have to choose from, potentially increasing the risk of confusion.

There are some concerns regarding the proposed star rating system. First, the "star" symbol may not be the most suitable to represent the level of UVA protection. Consumers may be led to believe that the stars represent the overall UV (including UVA and UVB protection) rating of the sunscreen as "good protection" or "bad protection," because stars sometimes represent a comprehensive rating system for other applications. As a result, the SPF value that indicates UVB protection may be ignored.

Second, proposed FDA layouts show the star rating system and the SPF value to be side-by-side on a product label, occupying an equal amount of space, which may lead consumers to the conclusion that the ratings are equally important. Although both UVA and UVB radiation are involved in photodamage and skin cancer development, and UVA is the most prevalent UV radiation coming from the sun, UVB radiation causes chronic skin damage more effectively.[13]

Third, using a rating system with multiple values (eg, 1–4 stars and an SPF value) may not be the easiest for a consumer to understand. Two studies[15,16] evaluated consumer preference of 3 different sunscreen-labeling schemes, one with pass/fail descriptors, one with 3 verbal descriptions, and one with 3 numeric values (similar to the 4-star system). The pass/fail system received a substantially higher score in the "ease of choice" category, while the verbal descriptions received the lowest rating. It is evident that the simpler the label is with the least amount of choices for a consumer to choose between (ie, a pass/fail system), the more likely they will be to understand the information on the label.

In addition to the issues with the sunscreen labeling, some of the UVA filters that are currently approved in the United States are imperfect.[17] Avobenzone, which is the most widely used and most powerful UVA filter, is photo-unstable, and loses 50% to 90% of its molecules after approximately one hour of UV exposure. In another example, the combination of avobenzone with one of the strongest UVB filters available in the United States, octinoxate, leads to damage of the 2 filters, and all UVA and UVB protection is lost. There are currently UVA filters pending FDA approval for use in the United States including bisoctrizole, bemotrizinol, and octyl triazone, which if strong and stable may lead to further alterations in a better sunscreen product creation and therefore product labeling.[17]

COMMENT

The addition of a UVA rating system to sunscreens, as proposed by the FDA, is necessary to increase awareness about the importance of protection from UVA irradiation. The most controversial issues with the testing and the labeling were discussed. Current testing methods are suboptimal due to difficulty in creating a substrate that will behave exactly like the skin. It is important that the ISO continues to work towards the universal acceptance of accurate and reliable in vitro and in vivo SPF and UVA protection factor testing methods.

Sunscreens with adequate protection against both UVA and UVB irradiation should be marketed with labels that show a rating with 3 or 4 stars and an SPF higher than 30 reflecting that the sunscreen provides "good protection." Sunscreens with low UVA and high UVB protection, or vice versa, will leave consumers with many options and possible confusion about which rating is most important. Sunscreens with 0 to 2 stars should not even be placed on the market. This would eliminate inadequate protection and also would decrease the number of choices (ie, 1–4 stars [4 choices] would be 3 or 4 stars [2 choices]) consumers have to take into account.

In reality, removing weak and unbalanced sunscreens from the market is unlikely to happen; thus, to increase simplicity and comprehension the FDA may want to convert the 4-star system into a more understandable, simpler system, with fewer choices. Three and 4 stars could be listed as "adequate UVA coverage" and 1 to 2 stars could be listed as "minimal UVA coverage." Currently, the proposed 4-star rating system is far from a perfect solution and therefore does not deserve "5 stars" and further modifications are warranted.

In addition to UVA and UVB, infrared radiation-A (760–1440 nm) comprises one-third of solar radiation that reaches the earth's surface. Infrared radiation-A (IRA) has the ability to deeply penetrate the skin and alter gene expression, leading to acceleration of skin aging and an increase in the risk of developing skin cancer.[18-21] While some protection against IRA is offered by antioxidants in sunscreens, such as vitamins and polyphenols, there are no current sunscreen ingredients that are designed specifically to protect against IRA.[21] With the recent developments IRA and its damaging effects on the skin, additional controversies may arise regarding the testing and labeling of sunscreens.

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