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Article

Effectiveness of sunscreens and factors influencing sun protection: a review

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The effectiveness of sun protection depends directly on the photo-protective product employed, the way it is used and the amount applied. Many studies report that sunscreens are often applied incorrectly, at amounts much lower than those recommended for the sun protection factor (SPF) specified on the label. When not used properly, the effectiveness of the product against sun exposure damage is reduced. Currently, sunscreens are available in a variety of different formulations and types, such as stick (bar), aerosol, cream, lotion, oil, tanning formulations and makeup. However, developing an effective stable photo-protective formula that can be correctly applied regardless of type poses a challenge, as effectiveness is dependent on several factors. Factors influencing effectiveness include sun exposure conditions (direct or indirect), level of protection (SPF), amount of product applied, maximum exposure period before reapplication, product type (spray, lotion, etc.), layer thickness required, coverage, and ability to spread and permeate into the skin. Studies comparing the effectiveness of different forms of sunscreens, the amount of product applied by consumers and SPF and UVA protection determined by validated methodologies, are lacking. Therefore, the objective of this study was to review the available literature on the topic and discuss the effectiveness of sunscreen formulations and factors influencing sun protection. This review was carried out on the scientific databases MEDLINE, PubMed and Scielo. Of the many publications retrieved, thirty-nine articles most relevant for this review were selected.

Keywords: Sunscreen agents. Emulsions. Ultraviolet rays. Efficacy. Cosmetics.

INTRODUCTION

Ultraviolet (UV) rays are associated with different forms of damage to human health. It is now recognized that both UVA and UVB wavelengths can contribute to the development of chronic skin lesions as a result of changes in elastin and degeneration of surrounding collagen "mesh" (Seite *et al*., 2000). Excessive sun exposure leads to deleterious effects such as premature aging of the skin, hyperpigmentation, and both pre-malignant and malignant lesions (Liu *et al*., 2012). This recurrent exposure can be reduced by using methods of protection against UV radiation, such as clothing and accessories to protect the most exposed areas, as well as the application of cosmetic products providing a sun protection factor (SPF).

Advertising campaigns have popularized the use of sunscreens, increasing their consumption especially among individuals engaged in sports and outdoor events. Consequently, this has raised people´s awareness on the need to protect themselves from the sun, even in the shade. Daily use of sunscreens has promoted a significant reduction in skin cancer cases and a slowing of the photo-aging process. Studies conducted over an eight-year period of research showed a decrease in basal

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cell cancer after daily application of sunscreen (Wang, Balagula, Osterwalder, 2010).

Topical protection against sun rays began in 1891, when the effects of UV rays on the skin were first elucidated. Many chemical compounds have been used as sunscreens in popular medicine, such as 6,7-dihydroxycoumarin, extracted from Chestnuts (*Castanea sativa*) (Urbach, 2010). However, the history of the production of modern sunscreens really began during World War II, due to the need to protect soldiers who were fighting troops in tropical countries against sunburn (Wolf *et al*., 2001).

The current popularity of sunscreens can be attributed to a consensus in medical recommendations, campaigns against skin cancer and advertisements sponsored by the cosmetic industry. The reasons cited for consumption of these products were to prevent sunburn (91%), skin cancer (87%) and premature skin aging (64%) (Wang, Balagula, Osterwalder, 2010; Chao *et al*., 2017).

However, choosing the ideal product can be confusing for consumers. In order to simplify and standardize these products, a criterion was established for the *in vivo* sun protection factor (SPF) determined by standard scientific protocols. Thus, sun protection factor or SPF is a global definition determined by evaluating effectiveness against UVB radiation, the main cause of erythema (sunburn). Protection against UVA radiation is established through *in vivo* or *in vitro* tests (Young, Claveau, Rossi, 2017).

The objective of this review was to describe the appropriate use of sunscreens to avoid sun damage to the skin and to evaluate the main factors that may influence their effectiveness.

The most relevant publications for this review and a summary of the factors influencing sun protection are given in Table I.

TABLE I - Relevant studies on factors influencing sun protection

Authors (year)	Influencing factors	Procedures	Outcome
Liu et al. (2012)	SPF values and amount of product	Sunscreens with SPF of 4, 15, 30, and 55 were tested *in vivo* at application levels of 0.5, 1.0, 1.5, and 2.0 mg/cm^2	Sunscreens in the 4 to 15 SPF range showed a linear dose-response relationship with application level. Higher SPF (30 and 55) showed exponential relationship between protection and layer thickness.
Couteau et al. (2012)	SPF values and amount of product	*In vitro* measurements of SPF of well-known products from the market.	74% of products tested fulfilled their claims in terms of efficacy. Sunscreens based on inorganic formulas alone did not allow SPF values above 30 to be reached. Higher levels of protection can only be achieved through the association of both organic and inorganic formulas. Reductions in the amount of product applied caused a proportional reduction in SPF.
Couteau et al. (2016)	SPF values, product type (oil and emulsion) and amount of product	PF-UVA i*n vitro* measurements of well-known products from the market (15 sun oils and16 emulsions).	Emulsions correlated exponentially with the amount applied, providing better protection in the UVA range than oils with the same performance. The UVA range also depended on SPF. There was a reduction in the SPF-UVA factor of 2.2, on average, when the value was halved.

TABLE I - Relevant studies on factors influencing sun protection

Authors (year)	Influencing factors	Procedures	Outcome
Pissavini and Diffey (2013)	SPF values, amount and uniformity of application	A simulation model was developed to estimate the variation in protection provided by a sunscreen on exposed skin surface of consumers.	The simulation showed that the extent of erythematous areas of skin in SPF15 sunscreen users was two times greater compared with those using SPF30 sunscreen. The proper amount and spreading ability of the sunscreen proved essential factors to ensure protection.
Ou-Yang et al. (2012)	SPF values and amount of product	SPF values were measured *in vivo* for 6 sunscreen products with label SPF values ranging from 30 to 100, applied at 0.5, 1.0, 1.5, and 2.0 mg/cm².	Sunscreens with SPF 70 or above provided additional clinical benefits when applied by consumers, even at typically used concentrations. Sunscreens with SPF 30 or 50 may not provide the same level of protection.
Williams et al. (2018)	SPF values	The protection against sunburn provided by SPFs 100+ and SPF 50+ in conditions of actual use was clinically assessed using erythema score.	SPF 100+ sunscreen was significantly more effective against sunburn than SPF 50+ sunscreen in actual use conditions.
Alvarez Roman, R et al. (2001)	Sunscreen Formulation	The ability of OMC-nano capsules to protect guinea pig skin against UVB radiation was evaluated.	Sunscreen preparations OMC-NC-gel and OMC-gel significantly reduced UV-induced erythema compared to corresponding OMC-free formulations.
Portilho and Leonardi (2019)	SPF values, amount and type of product	Actual amount, SPF and UVAPF of six different facial sunscreens were evaluated *in vivo*.	The application amount of facial photo-protectors was lower than the recommended value of 2 mg/cm². The misleading protection claimed by some types of sunscreen is a risk to public health as the protection indicated on the label was not reached.

Sunscreen development and mechanisms of action

The first sun protection formulas were developed by using inorganic or physical substances that acted by diffraction and absorption of ultraviolet rays, resulting in a product with a high sun protection factor. However, they were not well-accepted by consumers due to their whitish appearance on the skin. This sensory issue was resolved by reducing the size of the protective particles, providing greater opacity, in addition to increasing effectiveness against UV rays (Wang, Balagula, Osterwalder, 2010; Wolf *et al*., 2001).

By contrast, organic chemicals can absorb UV radiation through their chemical structures of conjugated aromatic rings and provide an alternative whose main property is protection against UVA and UVB rays. However, organic substances are known to be unstable, which means they can quickly lose their photoprotective ability. Some studies have reported that the efficacy of some formulations may be halved after two hours of UVB exposure, which justifies the need for reapplying the product (Wang, Balagula, Osterwalder, 2010; Serpone, Dondi, Albini, 2007). Today, chemical substances and/or a combination of photoprotective inorganic substances are sold in almost every country worldwide. This type of mixture allows broad spectrum UV protection and a higher sun protection factor (SPF) (Serpone, Dondi, Albini, 2007; Binks *et al*., 2017).

A survey conducted by Chao *et al.* (2017) of 711 subjects found that 39% of participants were influenced by the high sun protection factor label of the products in a purchasing event. This percentage was higher among older participants or among those who had a family history of skin cancer. The factors influencing participants´ purchasing decision were water resistance of the product (79%), followed by price (75%) and recommendation by family and friends (45%).

Relationship between influence of amount of sunscreen applied and sun protection factor (SPF)

In addition to the effectiveness of the photoprotective substance itself, effectiveness is also directly related to the amount of product and way it is applied by the consumer (Liu *et a*l., 2012). The determination of SPF has been standardized for the specific amount of 2 mg /cm², which ensures good coverage and formation of an ideal film on the skin (Binks *et al*., 2017; Osterwalder, Herzog, 2010).

The *in vivo* determination of SPF values is carried out through the emission of artificial light by a solar simulator in both exposed unprotected) and protected areas of the body, with application of a sunscreen in the latter condition. After about 24 hours of exposure, the regions are evaluated for pigmentation and erythema response. These testing methodologies may vary according to different regulatory agencies and are harmonized by the ISO (International Organization for Standardization) (Manikrao, Laxman, 2016; Osterwalder, Herzog, 2010).

Many studies report that people typically apply a much smaller amount than that used in the SPF efficacy test process, ranging from 0.5 to 1.2 mg/cm², significantly reducing the protection factor against sun exposure damage. (Liu *et al*., 2012; Young, Claveau, Rossi, 2017; Mancuso *et al*., 2017; Sarkany, 2017).

Surveys conducted in different regions of the globe (Denmark, Australia, Southern Europe and Egypt) show that the amount of sunscreen applied ranges from 0.39 to 0.79 mg/cm² over a 25-year period (Heerfodt *et al*., 2017).

Yashovardhana *et al.* (2018), in a study including 1000 students in India reported that only 11.88% of participants were aware of the optimal amount of sunscreen to apply.

Altieri L. (2018) showed the ineffectiveness of photoprotection in Hispanic children who had a sunburn rate of 59% after sun exposure, compared to an estimated 43% for non-Hispanic children.

Recently, Liu *et al*. (2012) conducted a study in a Chinese population investigating the relationship between SPF and amount of product regularly used. The authors demonstrated there may be a linear decrease in sun protection factor with decrease in the thickness of the sunscreen layer of low and medium SPF and an exponential decrease in protection with decrease in the sunscreen layer of higher SPF.

There is clearly a significant variability in the way products are applied and this behavior may be an important influencing factor for the effectiveness of SPF. It has been shown that amount applied is typically 50-75% of the optimal amount needed to obtain the protection stated on the product label (Couteau *et al*., 2012).

Couteau e*t al.* (2016) suggested that halving the amount of sunscreen may result in a proportional decrease in UVA protection rate. Jansen *et al.* (2013) reported 33% less SPF compared to label rates, after application of 25-50% of the standard amount.

Pissavini M. and Diffey B. (2013) investigated the simulation of sunscreen efficacy of SPF 15 and 30, concluding that the combination of the mean amount applied with the variability in thickness on the skin surface resulted in cutaneous erythema, especially for SPF 15.

A parallel study evaluating a sunscreen emulsions with SPF above 50 showed a linear decrease in protection factor according to amount applied. However, sun damage control was achieved when application was correct, according to recommendations by the FDA for sunscreens with SPF above 30 (Ou-Yang *et al*., 2012). The same result was found in a clinical study evaluating sunscreens with SPF 100+ and 50+ (Williams *et al*., 2012).

Perioli *et al.* (2006) evaluated the controlled release of a sunscreen formula that provided the efficacy and safety claimed, as well as enhanced photo stability. Cozi *et al.* (2018) found similar results, observing an even higher concentration of sunscreen in the skin compared to a conventional formulation.

Alvares-Román *et al.* (2001) reported better skin protection against erythema caused by sun exposure when a uniform film layer is obtained.

Moreover, the amount of sunscreen applied by the consumer and its duration are correlated. The duration of the second application corresponds to 86% of the first (Heerfordt *et al*., 2018). Another important element is the time required immediately after application for photo-protection to commence. The International Cancer Research Agency recommendations are to apply the product around 30 minutes before exposure. However, an *in vivo* study using a standard amount of sunscreen suggested that the photo-protection action is immediate and balanced after 10 minutes maximum (Galvez *et al*., 2018).

Influence of pharmaceutical forms or formulations of sunscreen on SPF

All the parameters discussed above can influence SPF, however, other elements are equally important for the effectiveness of sun protection, such as: exposure conditions (direct or indirect exposure), level of protection (SPF), the amount of product applied, the maximum exposure period before reapplication, product type (spray, lotion, etc.), layer thickness, coverage and ability to spread the formula and permeation into the skin (Liu *et al*., 2012; Couteau, Diarra, Coiffard, 2016; Beani, 2012).

Many of these features are inherent to the formula, i.e., intrinsic factors that may reflect the effectiveness of SPF sunscreen. Strategies should be devised to obtain an ideal product and avoid formulation issues, thereby enhancing the effectiveness of sunscreens.

It is important to develop a formulation capable of evenly coating the skin, through careful selection of the photo-protective substance, formulation stability, specific rheological profile, chemical vehicle and other components (Tanner, 2006). A sunscreen product with the ability to form a uniform film on the skin will provide better distribution and, consequently, a higher SPF (Jansen *et al*., 2013).

An array of pharmaceutical forms of sunscreens are available on the market, such as stick, spray, cream, lotion, oil (tanning or otherwise), as well as photoprotective lip balms. Multifunctional cosmetics are now produced containing photo-protective substances, such as foundations, mousses and moisturizers, and are also used in hair formulations (Latha *et al*., 2013).

Each cosmetic form of sunscreen has specific characteristics determined by the combination of active chemical ingredients and vehicle used, where these can influence product effectiveness. Typically, these products are described according to their polarity and viscosity and/or thickness (Tanner, 2006).

Oil, lotion, cream, gel, butter and ointment-based formulations are commercially approved by the U.S. Regulatory Agency, Food and Drug Administration (FDA), after providing efficacy and safety assessments.

The FDA also highlights some issues regarding the effectiveness of unconventional sunscreens, such as towels, wipes, powder protectors, body washes, and shampoos (Mancebo, Hu, Wang, 2014).

A study conducted in France evaluating the consumption of sunscreen in spray form showed that 45% of participants preferred cream products, in contrast to 27% who chose spray, 18% lotion and 9% oil formulations (Gomez - Berrada, 2018).

Cream formulations and lotions are the main forms of product on the market. These products are based on emulsion systems that allow the incorporation of many ingredients (Tanner, 2006). Emulsions or water-oil systems provide the basis of a wide variety of formulations, particularly due to the lipophilic nature of photo-protective substances (DeBuys *et al*., 2000).

These systems offer excellent compatibility with the physiology of the skin, remaining on the surface, while also allowing evaporation and perspiration. This type of formulation is ideally suited o to water-resistant sunscreens due to evaporation or absorption of water from the skin, since the oil and emulsifying mixture do not incorporate water from the environment (Lionetti, Rigano, 2017).

In a randomized controlled trial on the "off-label" use of low-dose oral isotretinoin for photoaging in women plus sunscreen was compared against sunscreen cream alone in the control group.

After three months of well-targeted regular use, no difference was observed between the treatments in terms of clinical evaluation, instrument measurements or histological findings. The only favorable outcome for oral isotretinoin was a reduction in epidermal p53 expression (Bagatin *et al*., 2010).

Besides creams and lotions, there are many oil-based cosmetic products. This type of cosmetic can provide a high protection factor due to its lipophilic properties, which allow solubilization of a large number of substances to suit the formulation.

Some studies have shown that low SPF oil-based sunscreen has low efficacy (Couteau, Paparis, Coiffard, 2014). Oil formulations are generally not highly effective because of their poor ability to form a skin film (Tanner, 2006). It should be noted that sunscreens in oily cosmetic formulations are not well-accepted by consumers, and are also costly to produce (Lionetti, Rigano, 2017).

Rheological changes in the formulation of oil-based sunscreens may result in another cosmetic form, such as stick. The sunscreen in stick form has ingredients which are easily incorporated given their wax and petrolatum base. These formulations, however, have limited regional application, e.g. in lipsticks (Tanner, 2006; DeBuys *et al*., 2000).

The clinical study conducted by Funasaka *et al.* (2000) evaluated a new stick formulation with SPF 50 for photosensitive diseases, including skin diseases either caused or aggravated by UV irradiation, demonstrating product efficacy and safety.

Apart from oil and emulsion-based formulations, aerosol products can be developed to provide low viscosity, resulting in better cosmetic appeal. This type of formulation allows the consumer to apply the sunscreen in regions of the body that are usually difficult to access. However, this formulation still needs to be spread onto the skin (Durand *et al*., 2007).

According to a study evaluating 25 participants who applied sunscreen spray, effectiveness increased proportional to the uniformity of application (Ou-Yang, Skillman, 2014). Durand *et al.* (2007) also reported that both droplet size and distribution in spray formulations are important elements for producing a good film on the skin, and a resultant high SPF.

Nevertheless the FDA reports that concerns with the aerosol form remain over whether they provide the same protection as other approved forms, and additional efficacy and safety data are required (Mancebo, Hu, Wang, 2014; Hexsel *et al*., 2008).

Lionetti and Rigano (2017) reported that a spray formulation of water-in-oil emulsion (W/O) failed to exhibit photoprotective efficacy with water resistance. The difficulty achieving efficacy for sprays lies in the challenge of developing formulations with good film-forming and spreading ability.

In the 1990s, photo-protective substances were introduced into everyday products such as makeup. The pigments used in these products provided photoprotection with SPF of 3 to 4. Thus, by including an additional photoprotective agent in makeup, increased protection against the UVA spectrum could be achieved (DeBuys *et al*., 2000).

However, Portilho and Leonardi (2019) concluded that the amount of facial photoprotector applied by consumers in different cosmetic forms was lower than the recommended value of 2 mg/cm^2. This false sense of protection represents a risk to public health, given none of the sunscreens evaluated by the authors provided the level of protection indicated on the label, because users failed to apply the recommended amount.

Based on scientific evidence, some factors such as film formation, ease of application and the presence of photo-stable molecules should be considered. Developing an effective stable photoprotective formulation for different climates and geographical regions which can be applied in the optimal amount poses a challenge.

Thus, applying the recommended amount of 2 mg/cm^2 before sun exposure is important to ensure adequate sun protection.

In practice, the application of sunscreen can be carried out using the "modified teaspoon rule" proposed by Isedeh, Osterwalder and Lim (2013), which suggests the application of one teaspoon of product to the head, neck and face; one teaspoon for each arm and forearm; two teaspoons for the back and two teaspoons for each leg and thigh. In addition, it is recommended that sunscreen be reapplied every two hours, as well as the use of physical protectors such as hats and clothing.

CONCLUSIONS

Based on the available literature, it can be concluded that the type and, consequently, the formulation vehicle, are fundamental elements for creating an effective sunscreen. Ensuring that the consumer applies the right amount of sunscreen remains a challenge.

Although there is no consensus on the ideal sunscreen, i.e., the perfect cosmetic form and composition, studies comparing different forms of sunscreen, actual versus ideal amounts applied by consumers, and SPF and UVA protection determined using validated methodologies, are lacking.

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CONFLICTS OF INTEREST

There are no conflicts of interest to declare.

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