Sunscreen Use and Duration of Sun Exposure: a Double-Blind, Randomized Trial

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Background: In epidemiologic studies, sunscreen use is associated with increased risk of cutaneous melanoma, basal cell skin cancer, and higher numbers of nevi. It has been proposed that sunscreens may encourage prolonged sun exposure because they delay sunburn occurrence. We examined whether, under habitual conditions of sunscreen use, the sun-protection factor (SPF) had an influence on sun-exposure duration. Methods: Before the 1997 summer holidays, we randomly assigned 87 French and Swiss participants who were 18–24 years of age to receive an SPF 10 or an SPF 30 sunscreen. Neither medical personnel nor study participants were aware of their sunscreen assignment. Participants were asked to complete daily records of their sun exposure. To avoid influencing the recreational sun-exposure habits of the study participants, no recommendation was made about sun exposure or sun protection. Furthermore, participants were told that the trial end point was the number of pigmented skin lesions before and after the holidays. One subject was lost to follow-up. All statistical tests were two-sided. Results: The SPF 10 (n = 44) and SPF 30 (n = 42) groups had equivalent mean holiday durations (19.4 days versus 20.2 days) and mean quantities of sunscreen used (72.3 g versus 71.6 g). The mean cumulative sun exposures for the two groups were 58.2 hours and 72.6 hours, respectively (P = .011). The mean daily durations of sunbathing were 2.6 and 3.1 hours, respectively (P = .0013), and, for outdoor activities, they were 3.6 and 3.8 hours, respectively (P = .62). There was no difference in sunburn experience between the two groups. Conclusions: Use of higher SPF sunscreen seems to increase the duration of recreational sun exposure of young white Europeans. [J Natl Cancer Inst 1999;91:1304–9]

Sun exposure is believed to be the main environmental determinant of skin cancers (1), and sunburn experience is associated with skin cancer occurrence (2). Sunscreens are able to delay sunburns and to reduce some UV-induced skin lesions, such as nonmelanoma tumors in rodents, local immunologic depression, mutations of the p53 (also known as TP53) gene in keratinocytes, and the incidence of actinic keratoses in humans (2–7). As a consequence, sunscreen use has become recommended as a sun-protection method, and that protection is deemed to increase with increasing sun-protection factor (SPF). The SPF indicates the ability of a sunscreen to delay the skin erythematous reaction induced by the solar radiation.

In contrast to the results of experimental studies, observational studies have repeatedly found sunscreen use to be associated with higher risk of cutaneous melanoma and basal cell skin cancer and with higher counts of nevi (8–16). By way of explaining this difference, it has been hypothesized that, because they delay sunburn occurrence, sunscreens could allow prolonged sun exposure, a situation that could lead to increased skin cancer risk (1,9).

If the hypothesis that sunscreen use encourages longer sun exposure is correct, then higher SPF should lead to greater sun-exposure duration (17). We conducted a two-center, double-blind, randomized study to determine whether, in the habitual conditions of sunscreen use by European young adults, the SPF had an influence on duration of sun exposure.

Subjects and Methods

Study Subjects

Study subjects were healthy, paid volunteers 18–24 years old recruited in universities in Lyon (France) and Lausanne (Switzerland) and from nonmedical disciplines. Participants had to have a positive history of sunburn in the past and to be regular sunscreen users intending to have at least 15 days of holidays in sunny areas during the next 2 months. Volunteers with a current skin disease, even minor, or who had a history of a skin disease that lasted for 1 year or more were not eligible. Pregnant women, subjects with a chronic physical illness, or subjects taking a photosensitizing medication were also ineligible.

Participants were randomly assigned to receive an SPF 10 or an SPF 30 sunscreen. The two sunscreens used in this study were broad-spectrum, commercially available, high-quality preparations from the same brand. The two sunscreens were prepared with the same chemical absorbents and mineral–oxide reflectants active in the UV A and B wavelengths, but the SPF 30 sunscreen contained a higher concentration of these substances. Both sunscreens had the same appearance, fragrance, color, and texture. They were bought from a local retailer and repackaged in unidentifiable tubes. Five tubes of 60 mL per participant were prepared by an experienced pharmacist (average, 373-g gross weight).

The study was conducted in accordance with the principles of the Helsinki declaration and was submitted for approval to an Ethical Review Committee of the Centre Léon Bérard (Lyon) and of the Centre Hospitalier Universitaire Vaudois (Lausanne). Each participant signed a written informed consent before randomization.

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See “Notes” following “References.”

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Study Design

The trial design is shown in Fig. 1. The study end point was the duration of recreational sun exposure. Recreational sun exposure included sunbathing and other outdoor activities, such as walking, playing, and enjoying sport (e.g., swimming or boating) in the sun. To avoid the possibility that knowledge of the actual end point could influence sun-exposure behavior, the stated study end point for participants and all persons in contact with them was the influence of different types of sunscreens on pigmented lesions of the skin. Since nevus counting and the assessment of the freckling index merely served to distract subjects from the real study objective, data on pigmented skin lesions are not presented.

Data from a 1992 survey in Connecticut (18) suggested a difference of 0.33 hour in daily sun exposure (standard deviation of 2 hours) between sunscreen users and nonusers. Assuming an average of 10 days with sun exposure per participant, to detect a 0.33-hour difference in daily sun exposure, with 90% power and a two-sided alpha error of 5%, at least 80 subjects had to be included.

A person who had no contact with the participants or the medical personnel involved in the study performed the randomization on an individual basis. By use of a table of random numbers, a five-digit random number was assigned to each set of five sunscreen tubes. Next the sets were ordered by successive random numbers.

Potential participants were invited to attend a medical examination. Following eligibility checking, the freckling index (face, arms, and shoulders) was assessed and the numbers of nevi were counted on both arms and on the back. A photograph of the back was also taken. Randomized sets of five sunscreen tubes were given to participants on a consecutive basis. To keep the trial close to participants' habitual conditions of recreational sun exposure, no recommendation was made either about sun exposure or about sunscreen use. Participants were asked to complete a standard daily diary recording detailed data on their sun exposure: hours and type of sun exposure (e.g., sunbathing, swimming, and boating), amount of clothing (e.g., nude, naked breasts, and one- or two-piece swimming suit), number of sunscreen applications, time of application (i.e., before or after starting sun exposure), and sunburn or skin-reddening experience (sunburn was defined as an episode of painful skin erythema; skin reddening was defined as an episode of painless skin erythema). If another sunscreen was used, the participant was asked to record the day and time of day the other sunscreen was used, the commercial name, the SPF, and the motive for changing to another product.

In September, the participants attended a second medical examination during which all sunscreen tubes were taken back and weighed. The daily diaries were collected and verified for completeness. In case there were missing data, the participants were directly asked to provide the missing information during that follow-up (French, female, skin type III, SPF 30 group) after she did not attend the second medical examination in September and did not return the daily record diary to study investigators. This subject could not be included in the analysis.

In June through July 1997, 87 healthy participants who were 18–24 years old (51 females; 36 males) were recruited in Lyon and Lausanne for the trial. One participant was considered lost to follow-up (French, female, skin type III, SPF 30 group) after different types of sunscreens on pigmented lesions of the skin. Since nevus counting and the assessment of the freckling index merely served to distract subjects from the real study objective, data on pigmented skin lesions are not presented.

Statistical Analysis

Sun-exposure durations were calculated from the daily record diaries. Missing or imprecise data on sun-exposure hours remained for 5 (0.4%) of the 1312 days with sun exposure. Sun exposures during these 5 days could thus not be included in the calculations of sun-exposure duration. After data entry, the randomization code was broken and the analysis was performed. Student’s t test, the uncorrected $\chi^2$, and the Wilcoxon rank sum test were used for testing univariate statistical associations. Least-squares regression multivariate analysis was used to assess the influence of different factors on study end point. All statistical tests were two-sided.

RESULTS

In June through July 1997, 87 healthy participants who were 18–24 years old (51 females; 36 males) were recruited in Lyon and Lausanne for the trial. One participant was considered lost to follow-up (French, female, skin type III, SPF 30 group) after she did not attend the second medical examination in September and did not return the daily record diary to study investigators. This subject could not be included in the analysis.

There was no major imbalance in the distribution of baseline characteristics between the two groups (Table 1), who showed similar patterns of skin phototype, skin complexion, past sun-exposure habits, sunburn experience, and sunscreen use. SPF 10 participants spent their holidays in 139 different areas, of which 47% were countryside or lakes, 26% were very sunny areas (e.g., the Mediterranean coast), and 27% were other places (e.g., swimming pools in cities). SPF 30 participants spent their holidays in 127 different areas, of which 50% were countryside or lakes, 28% were very sunny areas, and 22% were other places.

In both groups, the duration of holidays and the number of sunny days during which they either sunbathed or had outdoor activities were equivalent (Table 2). Participants used nearly equal quantities of sunscreen, and none exhausted the sunscreen received at the initial medical visit. The average quantity of sunscreen used represented 20% of the quantity received, ranging from 0% to 65% (one participant in the SPF 30 group did not use any sunscreen at all). Sunscreen use was associated more with sunbathing activities than with outdoor activities (data not shown).

The use of the SPF 30 sunscreen was associated with a greater number of hours

Fig. 1. Trial design.
The numbers of sunburns or of skin-reddening episodes were comparable in both groups (Table 2). Despite the use of potent sunscreens, 45% of the participants reported one or more sunburns and 81% reported one or more skin-reddening episodes. There was no association between the quantities of sunscreen used and the number of sunburn or skin-reddening episodes (data not shown). Body sites involved in skin-reddening or sunburn episodes were similar in the two groups (data not shown), except for the anterior part of the trunk, where nine women in the SPF 10 group and three in the SPF 30 group reported at least one skin-reddening or sunburn episode (*P = .075*).

Because clothes normally cover them during time spent outdoors, women’s breasts are highly sensitive to the sun. Five women in the SPF 10 group and eight in the SPF 30 group sunbathed with naked breasts (Table 3). All sunbathing sessions with naked breasts were preceded by sunscreen applications to the trunk. While duration of holidays and numbers of skin erythemal episodes were identical in the two groups of women, the use of the SPF 30 sunscreen was associated with five times longer sunbathing with naked breasts. Also, while women in the SPF 30 group were more inclined to sunbathe with naked breasts in the early days of their vacation, most women in the SPF 10 sunscreen group waited at least 1 week before exposing their breasts to the sun.

To verify that our results were not the consequence of multiple small confounding effects, we fitted a least-squares regression model using accumulated hours of sun exposure as the dependent variable. The model included number of days of holidays, number of sunscreen applications, randomization group, number of sunburns, sex, and study site. The main predictors of accumulated sun exposure were the duration of holidays (*P<.001*) and the number of daily sunscreen applications (*P = .008*). These results are not surprising, since duration of sun exposure is positively associated with duration of holidays and staying in the sun encourages sunscreen use. The SPF of the sunscreen used was a statistically significant predictor of duration of total sun exposure (*P = .010*), independent of the effect of other variables. The remaining variables were not associated with sun-exposure duration (*P>.20 for all*).

Eleven French participants, seven in the SPF 10 group and four in the SPF 30 group, used another sunscreen than that provided. Alternative products were used, for a total of 18 days in the SPF 10 group and 7 days in the SPF 30 group. The SPFs of the alternative sunscreens were 5, 6, 6, 10, 10, 20, and 20 in the SPF 10 group and 8, 30, 30, and 60 in the SPF 30 group (Wilcoxon rank sum test for the difference in SPF: *P = .070*), suggesting that alternative products used by SPF 30 participants were of higher SPF than alternative products used by SPF 10 participants.

**DISCUSSION**

The results of this randomized trial demonstrate that recreational sun exposure is of longer duration when a high SPF sunscreen is used than when a low SPF sunscreen is used. Similar results were found in two independent study sites and mainly concerned sunbathing activities. Two findings in particular attest
to the sense of security conferred by potent sunscreens. First, the use of the SPF 30 sunscreen led to a greater amount of sunbathing during hours of the day during which the UV radiation usually reaches its peak value. Second, women using the SPF 30 sunscreen sunbathed longer with naked breasts while incurring a lower number of sunburns or skin-reddening episodes on that part of the body.

Participants in the two study arms were similar in terms of natural susceptibility to sunlight, history of sun exposure and sunburn, duration of holidays, and the types of places they vacationed. Furthermore, our data suggest that those participants who used SPF 30 sunscreen actually increased their sun exposure over the course of the holidays (Fig. 2). Therefore, it is unlikely that the difference in sun-exposure duration stemmed from differences in baseline characteristics and choice of holiday location; rather, it appears to be related to protection from burning conferred by the stronger sunscreen.

Data collection was done prospectively by use of standard diaries completed on a daily basis. Therefore, biases in the recording of sun-exposure duration have probably been minimal. If some bias was present, however, it is reasonable to assume that it has been equally distributed among the two study groups.

Table 2. Sun exposure and sunburn experience during holidays*

<table>
<thead>
<tr>
<th></th>
<th>SPF 10 (n = 44)</th>
<th>SPF 30 (n = 42)</th>
<th>P†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. of holiday days</td>
<td>854</td>
<td>848</td>
<td></td>
</tr>
<tr>
<td>Mean No. of holiday days (range)</td>
<td>19.4 (12–43)</td>
<td>20.2 (14–46)</td>
<td>.57</td>
</tr>
<tr>
<td>No. of days (% of total No. of holiday days) during which</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant did not go outside‡</td>
<td>146 (17)</td>
<td>107 (13)</td>
<td></td>
</tr>
<tr>
<td>Participant went outside but did not become exposed to the sun</td>
<td>65 (8)</td>
<td>77 (9)</td>
<td></td>
</tr>
<tr>
<td>There was sun exposure</td>
<td>643 (75)</td>
<td>664 (78)</td>
<td></td>
</tr>
<tr>
<td>There was sunbathing</td>
<td>328 (38)</td>
<td>347 (41)</td>
<td></td>
</tr>
<tr>
<td>There were outdoor activities</td>
<td>467 (55)</td>
<td>514 (60)</td>
<td></td>
</tr>
<tr>
<td>There were sunbathing and outdoor activities</td>
<td>152 (18)</td>
<td>197 (23)</td>
<td></td>
</tr>
<tr>
<td>Mean (95% CI) quantity of sunscreen used, g</td>
<td>72.3 (60.2–84.4)</td>
<td>71.6 (53.7–89.5)</td>
<td>.95</td>
</tr>
<tr>
<td>Range, g</td>
<td>12–167</td>
<td>0–244 §</td>
<td></td>
</tr>
<tr>
<td>Accumulated hours of</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sun exposure</td>
<td>2559</td>
<td>3048</td>
<td></td>
</tr>
<tr>
<td>Sunbathing</td>
<td>852</td>
<td>1075</td>
<td></td>
</tr>
<tr>
<td>Outdoor activities</td>
<td>1707</td>
<td>1973</td>
<td></td>
</tr>
<tr>
<td>Mean (95% CI) total hours of sun exposure per participant</td>
<td>58.2 (52.0–64.4)</td>
<td>72.6 (63.5–81.7)</td>
<td>.011</td>
</tr>
<tr>
<td>French participants</td>
<td>62.3 (55.2–69.4)</td>
<td>74.9 (63.6–86.2)</td>
<td>.063</td>
</tr>
<tr>
<td>Swiss participants</td>
<td>45.8 (35.4–56.2)</td>
<td>65.1 (52.9–77.3)</td>
<td>.027</td>
</tr>
<tr>
<td>Exclusion of three participants with highest exposure</td>
<td></td>
<td></td>
<td>56.6 (51.0–62.2)</td>
</tr>
<tr>
<td>Range for all participants</td>
<td>17–126</td>
<td>30–199</td>
<td></td>
</tr>
<tr>
<td>Mean (95% CI) hours of daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sun exposure‡</td>
<td>4.0 (3.3–4.7)</td>
<td>4.6 (3.9–5.3)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Outdoor activities¶</td>
<td>3.6 (2.9–4.3)</td>
<td>3.8 (3.0–4.6)</td>
<td>.62</td>
</tr>
<tr>
<td>Sunbathing¶</td>
<td>2.6 (2.1–3.1)</td>
<td>3.1 (2.5–3.7)</td>
<td>.0013</td>
</tr>
<tr>
<td>Skin complexion pale at initial examination, h</td>
<td>1.9 (1.2–2.6)</td>
<td>3.0 (1.9–4.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Skin complexion medium at initial examination, h</td>
<td>2.6 (2.1–3.2)</td>
<td>3.0 (2.4–3.5)</td>
<td>.034</td>
</tr>
<tr>
<td>Skin complexion dark at initial examination, h</td>
<td>2.8 (1.9–3.7)</td>
<td>2.9 (1.9–3.9)</td>
<td>.73</td>
</tr>
<tr>
<td>No. of sunburn or of skin-reddening episodes</td>
<td>159</td>
<td>159</td>
<td>.99</td>
</tr>
<tr>
<td>No. of sunburn episodes</td>
<td>42</td>
<td>34</td>
<td>.90</td>
</tr>
<tr>
<td>No. of skin-reddening episodes</td>
<td>117</td>
<td>125</td>
<td>.85</td>
</tr>
</tbody>
</table>

*SPF = sun-protection factor; 95% CI = 95% confidence interval.
†Student’s t test for testing of difference between means, χ² statistics for testing of difference between numbers; P values are two-sided.
‡Because of bad weather, or of absence of eagerness to go outside, or of a sunburn in the previous days.
§One participant in SPF 30 group did not use any sunscreen.
¶Exclusion of participants with total sun exposure three standard deviations above the mean: one participant in the SPF 10 group (126 hours of total sun exposure) and two participants in the SPF 30 group (127 and 199 hours of total sun exposure).
¶¶Accumulated hours of sun exposure, outdoor activities, or sunbathing divided by the number of days during which there was sun exposure, outdoor activities, or sunbathing.

Fig. 2. Mean hour of start of sunbathing activities in days with sunbathing. Days without sunbathing were skipped. The time in the figure is the so-called “summer hour” in Continental Europe, equivalent to the solar hour plus 2 hours. Blank squares represent sun-protection factor (SPF) 30 participants; black circles represent SPF 10 participants. Error bars represent 95% confidence intervals. Student’s t test for the difference in mean hour: P >.90 for the first day; P <.050 for days 2–9 (P values are two-sided).

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We thus consider that the reported sun-exposure durations in this study are a valid reflection of the true sun exposure of participants during their holidays and that our findings are unlikely to be due to bias.

An adult should use roughly 35 mL of sunscreen per single whole-body application to correspond to the doses used by laboratories for measuring the SPF of a sunscreen (20). In that respect, our study participants should have consumed at least three to four times the quantities actually used, and it is thus probable that, in most participants, the effective SPF of the sunscreens used was about three to four times lower. However, our study shows that an increased ability to delay sun-induced skin erythemal reactions is sufficient to cause longer sun exposure, even when moderate quantities of sunscreen are used.

The increase we observed in sun-exposure duration may explain why sunscreen use has been reported to be a risk factor for melanoma, basal cell cancer, and nevus development. It also demonstrates that the longer sun exposure allowed by sunscreen use is an unconscious phenomenon, which makes individual control difficult, particularly where children are concerned.

Sunburn or skin-reddening experience among participants was independent of the SPF and of the quantity of sunscreen used. This observation suggests that sunscreen use during recreational sun exposure does not imply protection against sunburns. Sunburns are essentially due to the UV B radiation (1). Equivalence of sunburns and skin-reddening experiences in the two groups suggest that doses of UV B radiation received by skin cells were probably similar in the two groups. However, the delivery of these doses to skin cells of SPF 30 participants would have taken a longer time than that to skin cells of SPF 10 participants.

The issue addressed by this study is common to all sunscreens. Because we did not want to single out the products of a specific company, we chose not to disclose the commercial name and the exact composition of the sunscreens used in this trial.

From our results, it is reasonable to infer that equivalent or greater differences in sun-exposure duration would have been observed if one had compared subjects using a sunscreen with subjects not using any sunscreen. One could have considered a placebo-controlled trial using as placebo a lotion without any chemical or physical substance able to block UV radiation. In this study, a placebo group was not possible. First, it was ethically difficult to allow a placebo sunscreen when the sun-protection virtues of sunscreens are widely acknowledged. Second, it was not easy to provide a placebo sunscreen without informing subjects of both study groups that they should be careful in their sun exposure to avoid severe sunburns. Third, many subjects in the placebo group would have rapidly changed to a real sunscreen, which would have endangered the trial.

Experiments that tested the ability of sunscreens to reduce the incidence of UV-induced lesions have not examined the possibility that these products could modify the sun-exposure behaviors of subjects eager to acquire a tan or to stay in the midday sun with large parts of the body uncovered. The two human placebo-controlled trials that showed the ability of sunscreen use to reduce the incidence of actinic keratoses (6,7) enrolled subjects having a mean age of 64 years who had a history of nonmelanoma skin cancer or of other sun-induced skin lesions, who were highly aware of the hazards of sun exposure, who were not keen to acquire a suntan, and who apparently never had sunburn during the trials. Clearly, these trials did not reproduce the normal or reasonably foreseeable conditions of sunscreen use in North America and Europe, where sunscreen use by younger people remains largely driven by the desire to enjoy the sun and to acquire a “safe suntan” (21–24).

The protective effect of sunscreen use against skin cancer, particularly melanoma, has not been demonstrated in the general population, but there are compelling data that show a strong relationship between duration of recreational sun exposure and skin cancer. It is therefore desirable that people should be warned against the danger that using a sunscreen may inadvertently prolong recreational sun exposure.
REFERENCES


NOTES

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