Use of Topical Sunscreens and the Risk of Malignant Melanoma: A Meta-Analysis of 9067 Patients From 11 Case–Control Studies

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Objectives. This study examined the methodology of epidemiological studies that suggest use of topical sunscreen preparations is associated with increased risk of malignant melanoma.

Methods. We pooled data from observational studies using a general variance–based meta-analytic method that employed confidence intervals (previously described). The outcome of interest was a summary relative risk (RR) reflecting the risk of melanoma associated with sunscreen use versus nonuse. Sensitivity analyses were performed when necessary to explain any observed statistical heterogeneity.

Results. Combining studies that used nonheterogeneous data yielded a summary RR of 1.01, indicating no association between sunscreen use and development of malignant melanoma.

Conclusions. The available epidemiological data do not support the existence of a relationship between topical sunscreen use and an increased risk of cutaneous malignant melanoma. (*Am J Public Health.* 2002;92:1173–1177)

Malignant melanoma is 1 of the most increasingly common solid tumors over the last three decades.[1] Although increased detection may possibly account for some of the increase in incidence, other behavioral and environmental factors are likely to contribute to the current "epidemic" of this disease. Sun exposure in the form of ultraviolet-B (UVB) radiation is considered a major risk factor for the development of melanoma. Unfortunately, uncertainties regarding the impact of various host characteristics, frequency and type of sun exposure, and behavioral factors on melanoma development complicate assessment of the exact relationship between sun exposure and cancer risk.[2]

Sunscreens are able to delay sunburns and to reduce some UV-induced skin lesions, such as nonmelanoma tumors in rodents, local immunological depression, mutations of the p53 gene in keratinocytes, and the incidence of actinic keratoses in humans. As a consequence, sunscreen use is often recommended as a sun protection method, although its true impact on melanoma prevention remains obscure.

Despite uncertainties in the available epidemiological data, experimental evidence using both animal models and humans suggests that sunscreen preparations capable of reducing exposure to UVB radiation from the sun can prevent melanoma.[2] Regrettably, this finding has not been universal. In fact, some investigators suggest that sunscreen use could be a risk rather than a protective factor for malignant melanoma.[1] Although it is considered unlikely that available sunscreen preparations contain compounds with carcinogenic effects, other factors may account for this observed relationship; they include uncontrolled confounding caused by host factors and behavioral factors, such as increased sun exposure among patients who use sunscreen preparations.

This article presents the results of a meta-analysis designed to examine the impact of sunscreen use on melanoma risk. In addition to calculating an overall summary estimate of effect, the analysis also explores characteristics of the included studies that may contribute to heterogeneity of observed outcome. The resulting data may provide a clearer understanding of the role of sunscreen in preventing malignant melanoma.

METHODS

The methods used in the design and execution of this study have been described previously.[3,4] The study protocol initially developed outlined a meta-analysis to examine the risk of developing malignant melanoma associated with topical sunscreen use. Eligibility criteria for study inclusion were determined prospectively, as were the specific data elements to be extracted from each published report. The study protocol also included details of the planned statistical analysis.

We used a data extraction form designed for recording relevant information from each selected report. Two researchers performed data extraction, with differences in extraction forms resolved by consensus. Other data collected but not included in the eligibility criteria were number of patients in each study, study odds ratios and 95% confidence intervals (CIs), and type of statistical adjustments made, if any, by individual study authors.

Literature Search

Information retrieval was performed with previously described methods.[3] Briefly, we conducted a MEDLARS search of literature published between January 1966 and December 1999, as well as a review of CancerLit and the CD-ROM version of Current Contents. The search criteria included all languages. If a series of articles was published, all data were retrieved from the most recent article. The literature search also included hand searches of bibliographies of published reports, review articles, and textbooks.

The initial citations (in the form of abstracts) from this literature search were screened by a physician–investigator to exclude those that did not meet protocol-specified inclusion criteria. Reasons for rejection included studies of designs other than case–control; cohort or randomized controlled trials; animal or in vitro studies; stud-

ies including nonmelanoma skin cancer patients not stratified by tumor type; abstracts; and review articles. Copies of full articles for the remaining citations were obtained and screened according to the following additional eligibility criteria: (1) published case–control or cohort studies, (2) studies enrolling adult patients only (i.e., ≥18 years of age), (3) availability of data on frequency of sunscreen use, (4) specified selection criteria for case and control subjects, and (5) availability of data on the outcome of interest (i.e., proportion of patients with a diagnosis of malignant melanoma).

Statistical Analysis

We performed data analysis according to meta-analytic procedures described by Greenland.[5] This method of meta-analysis is a general variance–based method employing confidence intervals. Because the variance estimates are based on the adjusted measures of effect and on the 95% confidence interval for the adjusted measures, the confidence interval methods do not ignore confounding factors and are the preferred methodology for nonrandomized data.

For each included study, we derived odds ratios reflecting the risk of developing malignant melanoma associated with sunscreen use and determined the natural logarithm of the estimated relative risk (RR) for each data set followed by an estimate of the variance. We used the estimate of the 95% confidence interval from each study to calculate the variance of each study's measure of effect.

We calculated a weight for each included study as 1/variance followed by a summation of the weights. We then determined the product of the study weight and the natural logarithm of the estimated relative risk and performed a summation of these products. Finally, we calculated a summary RR and 95% confidence interval.[5]

Before estimation of the summary RR, we performed a statistical test for heterogeneity (Q). This procedure tests the hypothesis that the effect sizes are equal in all studies.[3] If Q exceeds the upper-tail critical value of the χ^2 distribution at $k-1$ degrees of freedom (where k is the number of studies analyzed or the number of statistical comparisons), the observed variances in study effect sizes are significantly greater than would be expected by chance if all studies shared a common population effect size. If the hypothesis that the studies are homogenous is rejected, the studies are not measuring an effect of the same size, and calculation of a pooled estimate of effect must be done cautiously. Possible explanations for the observed heterogeneity must then be sought to provide the most rational interpretation of the summary RR. Therefore, we performed sensitivity and/or further stratified analyses as needed based on the magnitude of Q; these analyses are discussed below.

RESULTS

We obtained a total of 166 citations from the electronic and manual literature search. Initial screening of these citations yielded 13 that appeared to meet specified protocol criteria.[6–18] On further review of the full published manuscripts, we found that 2 articles did not meet inclusion criteria. Herzfeld et al.[17] did not clearly distinguish between the use of suntan lotion and sunscreen preparations. Because of its lack of stratification, this study was not included in the meta-analysis. The study by Autier and Dore[18] also did not meet inclusion criteria, because it examined only the influence of sun exposure during childhood and adulthood on melanoma risk using a "sun exposure index" created by the authors. Data on sunscreen use had been collected in a earlier case–control study by this group[15] that was included in the meta-analysis. The remaining 11 published articles composed the database for the present analysis.

Table 1 provides an overview of the 11 case–control studies in the meta-analysis. Overall, the 11 study reports encompassed a total of 9067 patients. Also shown in the table are the odds ratios calculated for each individual report included in the pooled analysis, along with its 95% confidence interval. An odds ratio greater than 1.0 indicates an increased risk of melanoma associated with sunscreen use. Frequency of sunscreen use is given as noted by the authors of each study. The most frequent reported use was compared with "never used" in the pooled analysis.

All but 3 studies[6,7,16] had odds ratios greater than 1.0, demonstrating that the vast majority of case–control studies indicate that sunscreen users have a greater risk of melanoma than do nonusers. Combining data from all 11 reports gave a summary RR of 1.11 (95% CI=0.37, 3.32), a statistically nonsignificant result. Calculation of Q for this meta-analysis resulted in a value of 42.0 (Table 2). With 10 degrees of freedom, this yielded a *P* value of <.001, a highly significant result. A Q of this magnitude indicates that the pooled studies are heterogeneous—that is, the studies are not measuring an effect of the same size. Therefore, the validity of the summary RR is questionable, and sources of heterogeneity needed to be sought.

We performed several sensitivity analyses to evaluate possible sources of the observed statistical heterogeneity. As indicated in Table 1, all but 2 studies adjusted for potential confounders. The analyses by Klepp et al.[10] and Graham et al.[11] found a positive association between sunscreen use and increased melanoma risk. A sensitivity analysis we performed excluded both of these reports from the meta-analysis. Recalculation of Q yielded a value of 31.2 (*P*<.001), which indicated that heterogeneity remained despite removal of these data from the analysis (i.e., other factors were accounting for the variation across studies).

Our examination of the data presented in Table 2 showed that the study by Rodenas et al.[16] had a variance substantially greater than that of any other study in the pooled analysis (0.674). An additional sensitivity analysis, omitting these data from the calculation of a summary RR, yielded a Q of 37.7; with 9 degrees of freedom, the corresponding *P* value was <.001. A Q of this magnitude indicates persistent heterogeneity.

Table 3 outlines selection criteria for case and control subjects and also indicates whether study data were derived from population-based or hospital-based sources. Seven studies used hospital-derived case and control patients, totaling 4231 subjects.[6,9–11,14–16] Because the source of study subjects may bias results through such factors as referral patterns, we stratified the available data to explore this possibility. We pooled the 4 reports that used population registry–derived subjects[7,8,12,13] and calculated a Q statistic (4836 study subjects total); Q equaled 4.9 (*P*=.18). With 3 degrees of freedom, this result was

TABLE 1—Overview of Included Studies

Reference Authors	No. Patients	No. Controls	Frequency of Sunscreen Use	Odds Ratio (95% CI)	Adjustments
Espinoza Arranz et al.[6]	116	235	Ever vs never	0.48 (0.34, 0.71)	Skin type, nevi count, age
Holly et al.[7]	452	930	Almost always vs never	0.48 (0.33, 0.67)	Sunburns up to 12 yrs of age, skin reaction to sun, host factors
Westerdahl et al.[8]	400	640	Almost always vs never	1.80 (1.10, 2.80)	History of sunburn, history of sunbathing, employment, host factors.
Wolf[9]	193	319	Often vs never	3.34 (1.81, 6.64)	Age, sex, sunbathing, host factors
Klepp et al.[10]	89	227	Often vs rarely or never	2.27 (1.26, 4.12)	None
Graham[11]	404	521	Use vs never used	2.20 (1.2, 4.1)	None
Holman et al.[12]	507	507	Ever vs never	1.15 (0.78, 1.68)	Host factors, age at arrival in Australia, ethnic origin
Osterlind et al.[13]	474	926	>10 yrs vs never	1.2 (0.9, 1.5)	Constitutional factors, sex, age
Beitner et al.[14]	523	505	Very often/often vs never	1.80 (1.2, 2.7)	Age, sex, hair color
Autier et al.[15]	418	438	Regular use vs never	1.50 (1.09, 2.06)	Age, sex, hair color, no. of holiday weeks spent in sunny climate
Rodenas et al.[16]	105	138	Always vs never	0.2 (0.01, 0.8)	Age, skin color/type, no. of nevi, no. of hrs sun exposure

Note. CI = confidence interval.

TABLE 2—Data for Analysis of Heterogeneity

Reference Authors	Weight	Variance	Odds Ratio (95% CI)
Espinoza Arranz et al.[6]	32.3	0.031	0.48 (0.34, 0.71)
Holly et al.[7]	27.0	0.037	0.48 (0.33, 0.67)
Westerdahl et al.[8]	15.9	0.063	1.80 (1.10, 2.80)
Wolf et al.[9]	10.2	0.098	3.34 (1.81, 6.64)
Klepp et al.[10]	11.1	0.090	2.27 (1.26, 4.12)
Graham et al.[11]	10.4	0.096	2.20 (1.20, 4.10)
Holman et al.[12]	25.6	0.039	1.15 (0.78, 1.68)
Osterlind et al.[13]	45.5	0.022	1.20 (0.9, 1.50)
Beitner et al.[14]	23.3	0.043	1.80 (1.20, 2.70)
Autier et al.[15]	37.0	0.027	1.50 (1.09, 2.06)
Rodenas et al.[16]	1.48	0.674	0.20 (0.04, 0.79)

Note. CI = confidence interval

not statistically significant—that is, the data were not heterogeneous and could therefore be pooled to calculate a summary RR. The resultant summary RR was 1.01 (95% CI= 0.46, 2.28), a statistically nonsignificant result. These data failed to show any relationship between sunscreen use and increased risk of melanoma.

Next, we combined the 7 reports that used hospital patient databases in a meta-analysis. Five of the 7 studies had odds ratios greater than 1.09,[9–11,14,15] suggesting an association between sunscreen use and melanoma risk. Our analysis for heterogeneity yielded a Q of 36.9. With 6 degrees of freedom, the corresponding *P* value for a Q of this size was <.001, a highly heterogeneous result. Substantial heterogeneity therefore exists across these 7 studies. We obtained a summary RR of 2.41 (95% CI=0.32, 18.1). This finding provides evidence that bias associated with hospital-derived data is probably accounting for the observed positive association between sunscreen use and melanoma risk in many of the available case–control studies.

DISCUSSION

The sustained increase in malignant melanoma incidence over the past few decades highlights the fact that this disease represents a major public health management issue worldwide. In the United States alone, more than 42 000 cases are diagnosed and more than 7 000 deaths result each year.[19] Sun exposure is recognized as the most important environmental risk factor for malignant melanoma.[20] Behaviors that increase sun exposure have been suggested to be major contributors to the rising incidence. This suggestion has led to the development of measures to protect individuals from the potentially harmful effects of solar ultraviolet radiation (both ultraviolet-A [UVA] radiation and UVB), most notably topical sunscreen preparations.

If solar radiation is a primary risk factor for malignant melanoma, it is reasonable to conclude that reducing sun exposure via topical sunscreen use would be associated with reduced disease risk. However, the available epidemiological data are contradictory. In fact, the majority of studies suggest that sunscreen use is associated with an *increased* melanoma risk (see, e.g., studies cited in references 9 and 10). To address this uncertainty, we designed the present study to systematically evaluate the available data using rigorous meta-analytic techniques.

By pooling data from 11 case–control studies meeting protocol inclusion criteria (yielding a statistically nonsignificant summary odds ratio of 1.11), we demonstrated that sunscreen use is not associated with an increased risk of developing malignant melanoma. Unfortunately, further evaluation showed the data to be highly heterogeneous (i.e., the available studies are not measuring an effect size of the same magnitude), thereby making

TABLE 3—Selection of Cases and Controls

Reference Authors	Hospital- vs Population-Based	Selection Criteria—Cases	Selection Criteria—Controls
Espinoza Arranz et al.[6]	Hospital	Patients referred from Dermatology and Plastic Surgery Service to Medical Oncology Service	Age and sex matched—patients who attended the hospital due to emergencies not related to neoplasms or dermatological diseases
Holly et al.[7]	Population	Women aged 25–59. Derived from SEER cancer registry for San Francisco Bay area.	Women who lived in the same county as cases using random digit dialing. Age frequency matched.
Westerdahl et al.[8]	Population	Patients identified using Regional Tumor Registry for South Swedish Health Care region	Aged and sex matched—identified by "random sampling" from the same Regional Tumor Registry
Wolf et al.[9]	Hospital	Patients presenting to Dept. of Derm. at Univ. of Graz. between 6/93 and 7/94	Same as cases except without history of skin cancer
Klepp et al.[10]	Hospital	Melanoma patients admitted to the Norwegian Radium Hospital with diagnosis of melanoma between 1/74 and 5/75	Same as cases except patients had diagnoses of lymphoma, testicular cancer, and bone and soft tissue tumors
Graham et al.[11]	Hospital	Consecutive patients with melanoma seen between 1974 and 1980	Patients with nonmelanoma cancers seen over the same time period
Holman et al.[12]	Population	Patients aged less than 80 years in Western Australia diagnosed with melanoma between 1/80 and 11/81	Same source. Matched by sex, 5-year birth period, and electoral subdivision.
Osterlind et al.[13]	Population	Patients identified via national population register of residents of East Denmark	Sex and age matched from same source
Beitner et al.[14]	Hospital	Patients seen at the Dept. of Dermatology Karolinska Hospital from 2/78 to 12/83	Age and sex matched. Derived from a population register covering Stockholm county
Autier et al.[15]	Hospital	Consecutive patients seen at 5 hospitals between 1/91 and an unspecified time in 1994	Derived from same hospital registries
Rodenas et al.[16]	Hospital	All patients diagnosed with melanoma seen at Univ. of Grenada Hospital between 1989 and 1993	"Random" selection of controls from visitors to patients at same hospital without acute disease

the validity of the summary odds ratio questionable. We then explored reasons for the observed heterogeneity.

Several constitutional factors are accepted as important risk factors for melanoma; these include presence of nevi, having red or fair hair color, freckling, and having blue eye color.[14] Failure to control for possible confounders could certainly contribute to the observed statistical heterogeneity. Two of the studies used in the meta-analysis[10,11] did not adjust for such factors. Nonetheless, our sensitivity analysis indicated that heterogeneity remained even when the data from Klepp et al. and Graham et al. were dropped from the pooled analysis.

Our careful review of study designs and selection criteria for case and control subjects suggested that the source of study subjects might contribute to a biased estimate of effect (i.e., individual study odds ratios). We found that data from the 4 studies that used population registry–derived subjects[7,8,12,13] were statistically homogeneous compared with data from studies that used hospital-derived databases. This result provided strong evidence that selection bias is an important factor contributing to the spurious finding, seen in much of the literature, of a positive association between sunscreen use and melanoma development.

Hospital-derived data are problematic because referral patterns differ widely depending on hospital location, type of facility (e.g., university vs community hospital), and practice patterns, among other factors. In addition, some studies did not provide adequate information on control patient selection. For instance, Rodenas et al.[16] reported that "controls were selected from the visitors to the hospital on a random basis" without providing details of the "random" selection process. Autier et al.[15] selected case subjects from 5 collaborating hospitals; they noted that "controls were randomly chosen in the same municipality as the cases." Again, no further details are provided on what constituted "random" selection.

Referral patterns may influence study results. If referral patterns among hospitals in a given city or region differ, the overreferral of exposed cases to one hospital implies an underreferral of exposed cases to the others. Due to "differential referral," a factor may be associated with increased disease risk in one hospital-based study and may be protective in another. In an individual study, pooling data across hospitals helps to eliminate bias from differential admission of cases. Pooling data from several sources in a meta-analysis, as done in the study reported here, has partially accomplished this. Although many individual hospital-based studies showed a positive association between sunscreen use and melanoma risk, the pooled analysis indicated that this finding was spurious.

Other factors that may affect outcome in case–control studies include "ascertainment

bias" and misclassification of exposure status (in this case, sunscreen use). One factor not considered in the available studies is the possible influence of socioeconomic status (SES). Melanoma tends to affect white-collar, educated, and urban individuals. SES is known to affect recall of some types of information and could play a role in the studies examined in our analysis in which SES was not generally accounted for.[20]

These factors may all contribute to the wide variation in outcome observed across studies that used hospital registries. In contrast, data from more than 4800 patients enrolled in population-based case–control studies showed no such variation (i.e., the data were not heterogeneous and could reliably be combined in a meta-analysis). The resulting summary RR of 1.01 (95% CI=0.46, 2.28) provides strong evidence for a lack of any positive association between sunscreen use and increased melanoma risk.

CONCLUSIONS

The relationship between sunlight and melanoma is complex. Existing data suggest that the effect of solar radiation on melanoma development is more complex than is the case for other types of skin cancer.[6] Many unanswered questions remain regarding factors that may influence melanoma development, including the type of sunlight exposure most associated with melanoma etiology, interaction with host factors possibly important in disease risk, sunburn history, and tanning ability, among others. Because of this complexity, it has been difficult to separate the effects of sun exposure per se from the effects of host factors.

Nonetheless, because sunlight remains the most important recognized etiological factor in this disease, methods to reduce exposure (including use of topical sunscreens) appear to be a rational approach to disease prevention and risk reduction. We undertook the present meta-analysis to address the counterintuitive findings of multiple case–control studies that suggest sunscreen use as a risk factor for malignant melanoma. The largely positive association seen in the existing literature appears to be due to bias inherent in study designs and uncontrolled confounding.

It is our hope that the results of the present analysis will contribute to the design of future studies addressing this issue. Until more conclusive data are available, recommending use of sunscreens as a cancer prevention strategy would appear to be prudent. ■

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Contributors

M. Huncharek planned the study, collected and analyzed the data, and wrote the article. B. Kupelnick designed the literature search strategy, conducted electronic and manual literature searches, performed literature retrieval, and participated in writing the article.

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