Group Collaboration – Week 3

1/24/23

# Suncreen & Skin Cancer

Green et al. (1999). Daily sunscreen application and betacarotene supplementation in prevention of basal-cell and squamous-cell carcinomas of the skin: a randomised controlled trial, *The Lancet*, 354(*9180*): 723-729.

## Methods

In a community-based randomised trial with a 2 by 2 factorial design, individuals were assigned to four treatment groups: daily application of a sun protection factor 15-plus sunscreen to the head, neck, arms, and hands, and betacarotene supplementation (30 mg per day); sunscreen plus placebo tablets; betacarotene only; or placebo only. Participants were 1621 residents of Nambour in southeast Queensland, Australia. The endpoints after 4·5 years of follow-up were the incidence of basal-cell and squamous-cell carcinomas both in terms of people treated for newly diagnosed disease and in terms of the numbers of tumours that occurred. Analysis of the effect of sunscreen was based only on skin cancers that developed on sites of daily application. All analyses were by intention to treat.

## Questions for Discussion

**1. Identify the main research question of the study.**

**2. Who were the subjects in this study, and how many were included?**

**3. What are the variables in the study? Identify each variable as numerical or categorical. If numerical, state whether the variable is discrete or continuous. If categorical, state whether the variable is regular or ordinal.**

**4. Was blocking included in this study? If not, what variable do you believe would have been wise to consider as a blocking variable?**

**5. Identify the population of interest and the sample in this study.**

**6. What type of study was this?**

**7. Were the patients blinded to their treatment? Was this study double-blind?**

## Findings

1383 participants underwent full skin examination by a dermatologist in the follow-up period. 250 of them developed 758 new skin cancers during the follow-up period. There were no significant differences in the incidence of first new skin cancers between groups randomly assigned daily sunscreen and no daily sunscreen (basal-cell carcinoma 2588 vs 2509 per 100,000; rate ratio 1.03 [95% CI 0.73–1.46]; squamous-cell carcinoma 876 vs 996 per 100,000; rate ratio 0.88 [0.50–1.56]). Similarly, there was no significant difference between the betacarotene and placebo groups in incidence of either cancer (basal-cell carcinoma 3954 vs 3806 per 100,000; 1.04 [0.73–1.27]; squamous-cell carcinoma 1508 vs 1146 per 100,000; 1.35 [0.84–2.19]). In terms of the number of tumours, there was no effect on incidence of basal-cell carcinoma by sunscreen use or by betacarotene but the incidence of squamous-cell carcinoma was significantly lower in the sunscreen group than in the no daily sunscreen group (1115 vs 1832 per 100,000; 0·61 [0.46–0.81]).

\_\_8. The researchers stated that “there was no effect on incidence of basal-cell carcinoma by sunscreen use.” Given the study design, can the researchers make causal statements about carcinoma and sunscreen use?

**9. Can the results of the study be generalized to the population at large?**

**10. These researchers concluded the use of sunscreen or betacarotene had “no effect” because their observed differences resulted in a p-value that was greater than 0.05. What issues do you see with this interpretation?**

**11. In March of 2016 the American Statistical Association released a statement on the use of “statistical significance” and p-values. In the statement, the authors outline the following six key misconceptions and misuse of p-values:**

1. P-values can indicate how incompatible the data are with a specified statistical model.
2. P-values do not measure the probability that the studied hypothesis is true, or the probability that the data were produced by random chance alone.
3. Scientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold.
4. Proper inference requires full reporting and transparency.
5. A p-value, or statistical significance, does not measure the size of an effect or the importance of a result.
6. By itself, a p-value does not provide a good measure of evidence regarding a model or hypothesis.

**Which of these misconceptions do you believe apply to this study?**

# Alternative Study

Stern RS, Weinstein MC, Baker SG. (1986). Risk reduction for nonmelanoma skin cancer with childhood sunscreen use. *Arch Dermatol*, 122(*5*): 537–545.

Exposure to ultraviolet radiation is the principle cause of basal and squamous cell carcinomas of the skin, which are the most frequent tumors occurring in white residents of the United States. Using a mathematical model based on epidemiologic data, we quantified the potential benefits of using a sunscreen with a sun protective factor of 15 and estimate that regular use of such a sunscreen during the first 18 years of life would reduce the lifetime incidence of these tumors by 78%. Additional benefits of sunscreen use during childhood include reduced risk of sunburn, retarding the pace of skin aging, and possible reduction in melanoma risk. We recommend that pediatricians encourage sunscreen use and sun avoidance as a regular part of pediatric preventive health care.

**12. Why do you believe the 1999 study found that sunscreen had “no effect” on basal-cell carcinoma, when this 1986 found that “regular use of sunscreen would reduce the incidence of tumors by 78%”?**