A 60 year Native American woman presents to her vascular surgeon with some mild claudication. Her surgeon explains some life style modifications she can make, and suggests that she starts taking daily ASA 325 mg. The patient responds, “I don’t know doc, I really don’t like taking medication—are you sure this will help me?” The doctor responds, that are decades of literature showing that aspirin decreases cardiovascular mortality.

Is that the whole story?
Representation
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FINAL REPORT ON THE ASPIRIN COMPONENT OF THE ONGOING PHYSICIANS’ HEALTH STUDY

STUDY COMMITTEE OF THE PHYSICIANS’ HEALTH STUDY RESEARCH GROUP

Abstract: The Physicians’ Health Study is a randomized, double-blind, placebo-controlled trial designed to determine whether low-dose aspirin (325 mg every other day) decreases cardiovascular mortality and whether beta carotene decreases the incidence of cancer. The aspirin component was terminated earlier than scheduled, and the preliminary findings were published. We now present detailed analyses of the cardiovascular component for 22,071 participants, at an average follow-up time of 5.8 months.

There was a 44 percent reduction in the risk of myocardial infarction (relative risk, 0.56; 95 percent confidence interval, 0.45 to 0.70; P = 0.00001) in the aspirin group (294.9 per 100,000 per year as compared with 428.7 in the placebo group). A slightly increased risk of stroke among those taking aspirin was not statistically significant; this trend was observed primarily in the subgroup with hemorrhagic stroke (relative risk, 1.24; 95 percent confidence interval, 0.96 to 1.67; P = 0.16). No reduction in mortality from all cardiovascular causes was associated with aspirin (relative risk, 0.96; 95 percent confidence interval, 0.82 to 1.15).

Further analyses showed that the reduction in the risk of myocardial infarction was greatest among those who were 50 years of age and older. The benefit was present in all levels of cholesterol, but appears greatest at low levels. The relative risk of death in the aspirin group was 1.25 (95% confidence interval, 1.03 to 1.50) compared with the placebo group. The relative risk of death in the placebo group was 1.21 (95% confidence interval, 1.03 to 1.45).

This trial of aspirin for the primary prevention of cardiovascular disease demonstrates a consistent reduction in the risk of myocardial infarction, but the evidence concerning stroke and total cardiovascular death remains inconclusive because of the inadequate numbers of patients with these endpoints. (N Engl J Med 1989; 321:139-155.)

Although choosing a different endpoint, which has aspirin-like properties, was prescribed for pain relief by Hippocrates in the 5th century B.C., the possible role of aspirin in reducing the risk of cardiovascular disease has been recognized only very recently. Such a possibility derives from the capacity of aspirin to lower doses to inhibit cyclooxygenase-dependent platelet aggregation, thereby decreasing the risk of stroke. These effects are not profound that higher doses add little benefit but do increase the risk of side effects. Although this early case-controlled study suggests the possibility of a large benefit, more observational studies have suggested a cardiovascular benefit of about 20 percent. In such circumstances, the amount of uncertainty resulting from case-control or cohort studies may be as large as the small-to-moderate effects being sought; consequently, conclusive results can only come from a randomized clinical trial whose sample is sufficiently large.

The Physicians’ Health Study is a double-blind, placebo-controlled, randomized trial designed to test two primary prevention hypotheses in a population of healthy male physicians: whether aspirin in low doses (81 mg) reduces mortality from cardiovascular disease, and whether beta carotene decreases the incidence of cancer. Although the beta carotene component of the trial is continuing at least through 1996, the Data Monitoring Board recommended the early termination of the aspirin component of the study.
Fig 4. Proportion of elderly and women patients: trial participants and US population, 1990 to 2012. (A) Elderly among patients with regional non–small-cell lung cancer (NSCLC). (B) Elderly among patients with distant NSCLC. (C) Women among patients with regional NSCLC. (D) Women among patients with distant NSCLC. The annual percentage change (APC) P-value corresponds to testing whether the APC is different from 0. The solid lines represent the fitted values of the joinpoint regression. The year 1990 was excluded from analysis because of the small number of trial participants with regional or distant NSCLC.
2,347 articles

1,729 articles excluded with human data

618 articles with cells and animals

531 articles with animals
118 articles with cells

A
Animals

Sex Stated: 78%
Sex Not Stated: 22%

B
Cells

Sex Stated: 76%
Sex Not Stated: 24%

C
Animals

80%
17%
3%

D
Cells

71%
21%
7%
On Racism: A New Standard For Publishing On Racial Health Inequities

Rhea W. Boyd, Edwin G. Lindo, Lachelle D. Weeke, Monica R. McLemore

JULY 2, 2020
10.1377/hblog20200630.699347
Critiquing the data
Operationalizing
Case Study 1

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