Breast Cancer Screening Series:

Dr. Daniel Kopans

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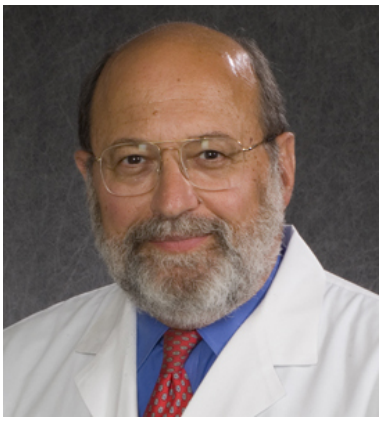
by Daniel B. Kopans, M.D., F.A.C.R., F.S.B.I, Professor of Radiology Harvard Medical School, Founder – Breast Imaging Division – Massachusetts General Hospital

"ALTERNATIVE FACTS" AND BREAST CANCER SCREENING



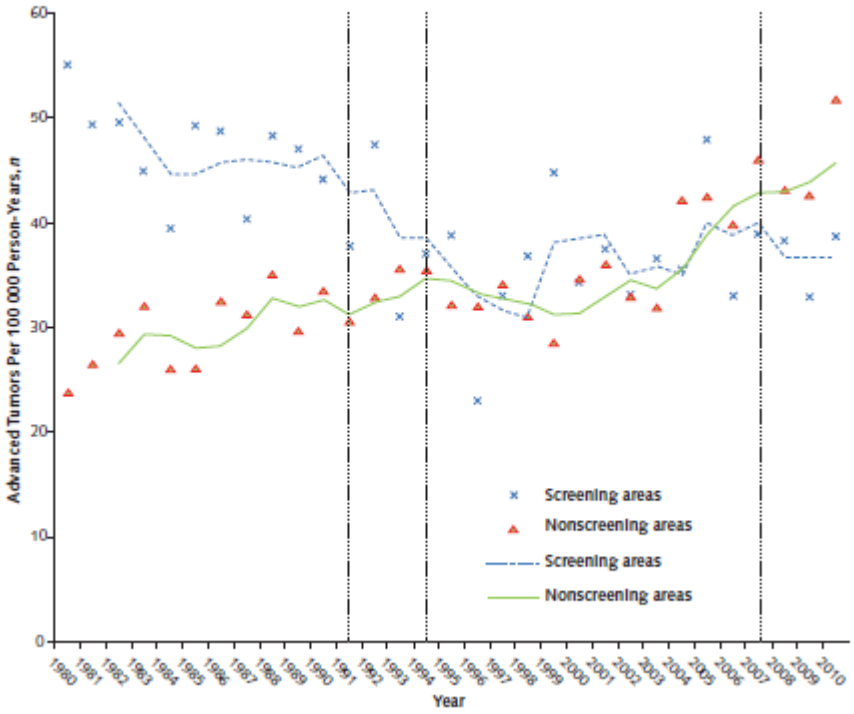
"Alternative Facts" (AF) recently appeared as an outrageous concept in the "political arena". What most do not realize is that "alternative" facts have been promulgated for decades by those seeking to reduce access to breast cancer screening. This has led to the pseudo "debate" about screening that has persisted for decades due to the "alternative facts" that have been manufactured to keep the "debate" going. Each time an "alternative fact" has been generated to cast doubt on screening, it has been refuted by science ([i]). Unfortunately, as each (true) fact has been established, new "alternative facts" have been manufactured. The article in the Annals of Internal Medicine cited by Nicholas Bakalar in the New York Times is an example of misinformation that got past poor peer review at a major journal and was published despite its lack of scientific rigor. The study from Norway ([ii]), cited by Mr. Bakalar ([iii]), claiming massive "overdiagnosis" due to mammography had no data on who actually had mammograms and no data on which cancers were detected by mammography. How can a test (mammography) be faulted when the "investigators" had no information on who actually had the test? In an earlier, scientifically more rigorous study from Denmark, Njor, et al looked at actual individual patient data and they found that there was little if any "overdiagnosis" due to screening ([iv]) and, another study found, contrary to the conclusions of the paper reviewed by Bakalar, that screening had in fact resulted in a marked decline in deaths from breast cancer in Denmark ([v]).

Mammography screening has been one of the major advances in women's health over the last half century. Prior to 1990 the death rate from breast cancer had been unchanged for at least 50 years. Screening began in the U.S. in the mid 1980's and soon after the death rate began to fall. As more and more women have participated in screening the death rate has continued to fall so that now there are more than 35% fewer women dying from breast cancer each year than would have died had the decades-long rate continued. The fact that screening and the detection of cancer earlier could save lives was proved by the randomized, controlled trials ([vi],[vii]). Claims that the decline in deaths is not due to screening, but rather to improvements of therapy, have been belied by numerous "observational" studies where, among women who presumably have access to the same therapy, deaths are markedly reduced among

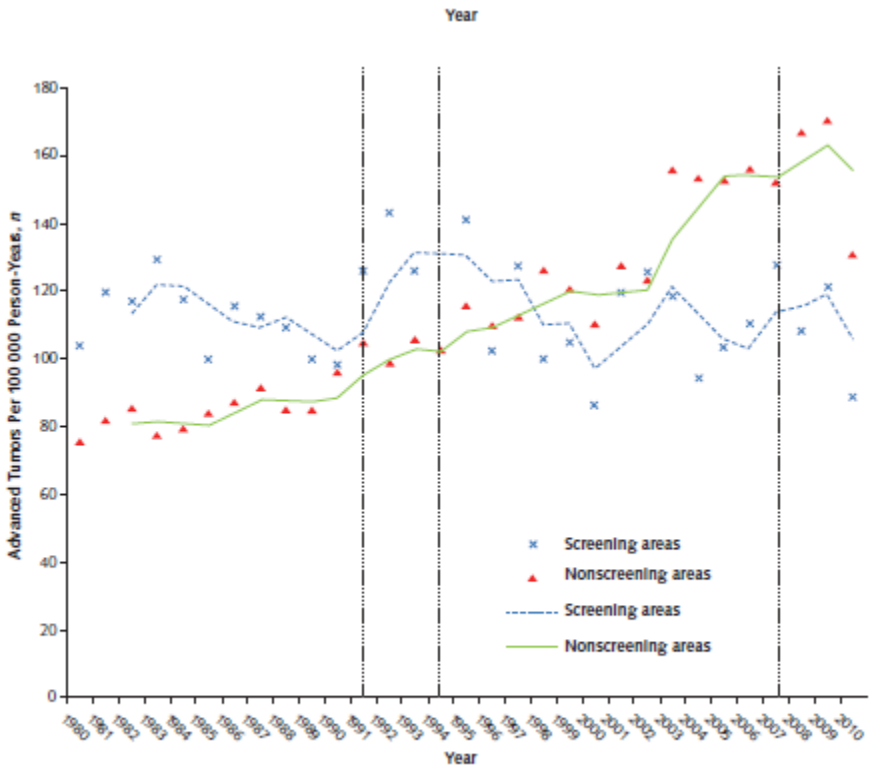
the women who participated in screening compared to those who did not ([viii],[ix],[x],[xi],[xii],[xiii],[xiv],[xv],[xvi],[xvii],[xviii],[xix],[xx],[xxi],[xxii],[xxiii]). The final evidence in support of screening comes from two of Harvard's largest teaching hospitals where we found that more than 70% of the women who died from breast cancer were among the 20% who were not participating in screening ([xxiv]). Although not proof that screening is the main reason for the decline in breast cancer deaths, the death rate from breast cancer in men (having access to the same treatments as women) rose after 1990 while it was beginning to decline among women. It returned to 1990 levels where it has remained for men, while the death rate for women has continued to decline. What is the difference? Women are being screened, while men are not being screened. Therapy has improved, but screening saves lives when breast cancers are treated earlier.

The paper cited in the New York Times is just another example of poor peer review that has allowed scientifically unsupportable "alternative facts" get published. The authors claimed to have compared women in areas where there was, supposedly no screening ("non screening areas"), to women who lived in the "screening areas" where women were invited by the National screening program to be screened. Unfortunately, the authors actually had no idea who actually participated in screening in the "screening areas". They also had no idea whether or not, and how many women were being screened outside the national program in the, supposedly, "non-screening areas". This is a fundamental flaw, but in addition the paper relied on the claim that the rate of cancers and types of cancers would have been the same in the "non-screening areas" and the "screening areas" so that the women in the two areas could be compared. They claimed that women would develop the same types of cancers at the same time so that they could compare women who were invited to be screened (with no data on who was actually screened) with those who were not invited (without knowing if these women were being screened outside the program). In fact their own data show that the populations were not comparable and that the groups were not comparable. In their Figure 1 (the first graph) they show the rate of advanced cancers in the two areas, for women under the age of 50. Since women were not being offered screening before the age of 50, none of these women were, theoretically, ever screened. If the areas were identical, as the authors claim, then the curves should have been identical over all the years. Anyone can see that from 1980 to 2000, the group in the "screening areas" had much higher rates of advanced cancers than the group in the "non screened area" and these fell over time, while the rate in the "non screening areas" was the opposite starting low and rising rapidly over time. The two groups could not have been more incomparable. This means that their analysis and conclusions are, fundamentally unreliable.

Figure 1. 3-y moving averages of advanced breast tumors (>20 mm) in women aged <50 y, 50 to 69 y, and 70 to 84 y.



The second graph (below), representing women who were invited to be screened (ages 50-69), not only shows that the rates are completely different in the time period before screening was offered (raising major questions about the comparability of the two populations), but the data contradict the claim by the authors that advanced cancers were not reduced. Clearly the rate of advanced cancers in the "non screening areas" steadily increased while there are fewer advanced cancers among women in the "screening areas" after screening was offered.



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Unfortunately, this recent paper is just another example of "alternative facts" that have made their way past poor peer review to be published in even the most prestigious journals ([xxv]) over many years. Since there is no ethical oversight at these journals, the editors are free to publish whatever they want. Several have undeclared biases against breast cancer screening, particularly for women ages 40-49 ([xxvi],[xxvii]). As a result, the pseudo "debate" about breast cancer screening has been allowed to go on and on based on "alternative facts".

In the 1960's it was falsely claimed that finding breast cancer earlier would not save lives. This was disproven by the randomized, controlled trials.

In the 1970's it was falsely claimed we could not possibly screen large numbers of women which was disproven by the Breast Cancer Detection Demonstration Project.

In the 1970's it was falsely claimed that the radiation from mammograms would cause more cancers than they would cure. The data clearly show that the risk to the breast from radiation drops rapidly with increasing age so that

by the age of 40 there is no measurable risk and even the extrapolated risk is well below even the smallest benefit ([xxviii],[xxix]).

In the 1990's it was falsely claimed that mammography screening was leading to earlier deaths among screened women in their forties. This was shown to be completely false ([xxx],[xxxi]).

In the 1990's it was falsely claimed that screening didn't start working until the age of 50 ([xxxii]).

Even the American Cancer Society and the US Preventive Services Task Force now agree that the most lives are saved by annual screening starting at the age of 40 ([xxxiii],[xxxiv]). In fact there are no data to show that any of the parameters of screening changes suddenly at the age of 50 or any other age ([xxxv]). Age 40 is the only science based threshold.

Over the past 10 years the concept of "overdiagnosis" is the latest "alternative fact". Those seeking to reduce access to screening claim that each year, thousands of mammographically detected invasive breast cancers would regress or disappear if left undetected by mammography ([xxxvi]). They point to a handful of large, palpable cancers that have been reported to have disappeared on their own (some of these women still died from their "disappearing" breast cancers). They have used these reports that amount to "miracles" rather than common events, to argue against screening. This makes no sense if, for no other reason, than the fact that these were large palpable cancers yet they are not suggesting that these should be ignored. In fact there is not a single report of a mammographically detected invasive breast cancer disappearing on its own. They claim tens of thousands each year yet no one has ever seen this happen!

Overdiagnosis of invasive breast cancers is based on other flawed studies. Those who have been promulgating "fake" breast cancers have done so by "guessing" what the incidence of breast cancer would have been over a period of time had women not had access to screening (once again they have no data on who was actually being screened and no data on which cancers were found by screening) ([xxxvii]). Using their "guesses" and not actual, scientifically supported, data, they claimed that, since the actual number of cancers over the same period was higher than their "guesses" would have predicted, the difference must have been cancers that would have never become clinically important ("real"). The problem is that respected journals have allowed these "studies" based on "guesses". Had the authors used actual figures that show that long before screening the rate of invasive cancers had been going up steadily for at least 40 years, they would have found no evidence of "overdiagnosis" ([xxxviii]).

There are legitimate questions about the management of lesions called “Ductal Carcinoma in Situ (DCIS)”, but invasive breast cancers found by mammography are “real” cancers with lethal potential. There is no way of predicting with certainty what will happen with any woman with breast cancer, regardless of its size, but early detection is the main reason that the death rate from breast cancer has declined dramatically in the U.S.

We all hope for a universal cure, or a safe way to prevent breast cancer, but none is even on the horizon. Mammography is not the ultimate answer to breast cancer. Not all cancers are visible on mammograms, and mammography does not find all breast cancers early enough to result in a cure, but all of the science based data show that early detection saves lives. All of the major groups agree that the most lives are saved by annual screening beginning at the age of 40 and women should be encouraged to participate. Women and their physicians should demand an end to “alternative facts” and a return to evidence based medical care.

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