The Great Mammography Debate
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• Well, here we go again.....
But first, a news flash

- Researchers report that chest x-rays are worthless. Long term follow-up study shows no value in detecting lung cancer, pneumonia, pneumothorax or 329 other thoracic conditions.

Investigator with study subject #45. testing for vocal fremitus found to be superior to CXR.
Twenty five year follow-up for breast cancer incidence and mortality of the Canadian National Breast Screening Study: randomised screening trial
Vast Study Casts Doubts on Value of Mammograms

By GINA KOLATA  FEB. 11, 2014

Nearly 75 percent of American women 40 and over say they had a mammogram in the past year.

Damian Dovarganes/Associated Press

One of the largest and most meticulous studies of mammography ever done,
Do mammograms really work? Mixed messages on screening for breast cancer

By Beth Greenfield, Shine Staff | Healthy Living

Are mammograms useless? That's just one of the turn-your-world-upside-down questions raised in a provocative and personal New York Times Magazine piece about the fight against breast cancer, published online Thursday and set to hit newsstands this weekend.

More on Shine: Strangers Donate to Dream Wedding for Bride with Cancer
A Mammogram Killed My Dog

A woman from Topeka, Kansas has reportedly lost her beloved mixed breed dog to the mammography controversy. It seems that CUDDLES tried to stop her owner from leaving the driveway to get her annual mamm and slid under an oncoming mail truck and was killed. Experts, including Gina Kolata stated “this is yet another example of the dangers of mammos.” The American Cancer Society declined comment but the American Kennel Club has now joined forces with the anti-mammography group.

Related

Deaths from breast cancer have declined substantially in most
Popular Girl Refuses to go on Prom Date Because Boyfriend’s Mom Got a Screening Mammogram
Canadian National Breast Screening Study

• **Goal**: compare breast cancer incidence and mortality in women aged 40-59 who did or did not undergo screening mammography
  
  – Prior trials of screening mammography showed a down-staging of cancers but were not designed to demonstrate a survival benefit in the 40-49 subset.

• **Accrual 1980 – 1985**

• Everyone had a clinical breast examination by trained doctors or nurses

• Allocation to screen or control arm allowed for discretion

• Women allocated to the screen arm could continue to get mammograms in their community
### Canadian National Breast Screening Study

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“From this we infer that if there is a benefit from a mammography only screening program it is derived through cancers detectable by a thorough breast physical examination.”

The Authors, Canadian National Breast Screening Study
Canadian National Breast Screening Study

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“...our data show that annual mammography does NOT result in a reduction in breast cancer specific mortality for women aged 40-59 beyond that of physical examination alone...the value of mammography screening should be reassessed”

The Authors, Canadian National Breast Screening Study
Study Limitations

• Fails the ‘common sense’ test
• Fails to explain the reduction in breast cancer specific mortality that has been documented since 1990 attributable to screening
• Fails to explain larger, superior trials that demonstrate substantial reductions in mortality
• Fails to acknowledge patient allocation bias, limitations in technology (1980 mammo equipment), limitations in technologist training and experience, significant under-powered study.
Reviewers and reporters have focused SOLELY ON THE RESULTS of the study without critically reviewing the design and performance of the trial.
Lack of Statistical Power to Prove Benefit

- It was expected that the trial would have an 80% power to show a 40% reduction or greater benefit 5 years into the study period.
- Based upon the original HIP study from NY at 25% reduction would have been more realistic; proving a 25% reduction would have required 250,000 women if the control arm had an 80% 5 year survival rate.
- The observed survival rate was far HIGHER than historical controls in Canada; ‘volunteer effect’.
- The Canadian National Breast Screening Study had one-tenth the requisite number of patients it required to show a significant reduction.
- Furthermore, 26% of women in the control arm got mammograms themselves in their community.
Patient Allocation Rather Than Randomization

- After volunteering for participation in the trial the patient had a clinical breast examination and was then assigned to either the study group or the control group.
  - Women in the study group had both clinical breast exam and mammograms; control group had neither
  - Were women with palpable cancers placed into the screening arm selectively?
  - The authors deny that this practice occurred in the patient allocation process;
• In a screening trial, symptomatic patients MUST be excluded from the trial altogether; that did not occur in the CNBSS.

• In fact, patients with advanced, lymph node positive breast cancer were randomized significantly more often to the screening arm
  – Women ages 40-49: 33 patients with positive axillary nodes were placed in the screening arm while only 21 similar women were placed in the control arm
  – In patients with four or more positive nodes the ratio was 19:5 in favor of the screening arm and 17/19 had palpable cancers and were placed in the screening arm.
  – 91% of the cancers that had spread to lymph nodes among women assigned to the screening arm were PALPABLE (everyone had a breast exam) raises serious doubts that this happened by chance; moreover, the excess of higher stage cancers in the screening arm INCREASED in years 2 and 3 of the trial: **there was never equilibration in number of advanced cancers between the two arms.**
A Test of Poor Quality Mammography

• Apparently a decision was made at the outset that the **quality of mammography** was not important.
A Test of Poor Quality Mammography

• Centers were allowed to use whatever equipment that they had on hand (no funding for modern equipment); no special training for technologists; two views taken were different that state of the art views today; no effort was undertaken to improve the quality of images or their interpretation over time.

• Two advisors to the trial – Wende Logan and Stephen Feig resigned in protest;

• External review of mammo quality over years 1-4 revealed that 50% were POOR or worse – not interpretable.

• Two published reviews of year 5 found that poor quality mammos were common in 75% of screening centers; overall, only 33% of mammos were technically acceptable; this figure dropped to 15% in a subsequent external review;

• Sensitivity during 5 year period never exceeded 30% (70% false negative rate)
“In my work as reference physicist to the CNBSS, I identified many concerns regarding the quality of the mammography carried out...which was far below the state of the art, even for that time (early 1980s). Problems...arose from inadequate equipment, image technique and training for technologists and radiologists.”

CONCLUSIONS
Is there ANY technology from 1980 that you consider benchmark today?
Mammography Then and Now
HOW IS IT POSSIBLE THAT THE MAJOR MEDIA OUTLETS DID NOT MENTION THE EXISTENCE OF MULTIPLE OTHER, LARGER, BETTER CONTROLLED TRIALS OF SCREENING MAMMOGRAPHY?
<table>
<thead>
<tr>
<th>Trial</th>
<th>Enrollment (years/age)</th>
<th>Intervention (invitations to screening)</th>
<th>Population x 1000 (screened/control)</th>
<th>Breast cancer mortality per 100 000 person-years (number) (screened/control)</th>
<th>RR (95% CI)</th>
</tr>
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<tr>
<td>Malmö I, Sweden</td>
<td>1976–78/50–69</td>
<td>4 in 8 years</td>
<td>16.8/16.8</td>
<td>47 (134)/57 (162)</td>
<td>0.84 (0.68–1.04)</td>
</tr>
<tr>
<td>Kopparberg, Swedish</td>
<td>1976–78/50–69</td>
<td>3 in 6 years</td>
<td>23.3/10.7</td>
<td>20 (93)/39 (83)</td>
<td>0.52 (0.39–0.70)</td>
</tr>
<tr>
<td>Östergötland, Swedish</td>
<td>1978–81/50–69</td>
<td>4 in 8 years</td>
<td>23.6/22.4</td>
<td>33 (117)/40 (137)</td>
<td>0.81 (0.64–1.03)</td>
</tr>
<tr>
<td>Stockholm, Sweden</td>
<td>1981–83/50–64</td>
<td>2 in 4 years</td>
<td>24.8/13.0</td>
<td>14 (48)/21 (37)</td>
<td>0.68 (0.44–1.04)</td>
</tr>
<tr>
<td>Göteborg, Sweden</td>
<td>1982–84/50–59</td>
<td>3 in 5 years</td>
<td>10.1/16.0</td>
<td>31 (40)/33 (67)</td>
<td>0.94 (0.62–1.43)</td>
</tr>
<tr>
<td>Finland</td>
<td>1987–89/50–64</td>
<td>2 in 4 years</td>
<td>89.9/68.9</td>
<td>16 (64)/21 (63)</td>
<td>0.76 (0.53–1.09)</td>
</tr>
<tr>
<td>All trials</td>
<td></td>
<td></td>
<td>188.5/147.8</td>
<td>25 (496)/36 (549)</td>
<td>0.75 (0.67–0.85)</td>
</tr>
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Tests for heterogeneity between trials $\chi^2_5 = 8.83; p > 0.1$; not significant

Summary of the randomised trials in women aged 50-69 without the HIP or Canadian trials RRR 25%
International Agency for Research on Cancer Handbook of Cancer Prevention volume 7 2002
Fig. 3  Breast cancer mortality trends 1989–1990 to 2007, according to age group

Trends in breast cancer specific mortality by age group

>50 years Mortality Begins Falling
**Figure 3.** Screen Detection Capability Based on Tumor Biology and Growth Rates

Growth rates of 4 tumors are displayed from the time the first tumor cells appear while the tumor is not yet detectable (microscopic); when it can be detected as localized (confined to the organ) and most likely to be curable; regional (after the tumor spreads beyond the organ) where it may not be curable; and to the point when metastases and death occur. Tumor A remains undetectable and without morbidity during the patient’s lifetime. Tumor B grows until it becomes detectable but never causes symptoms or leads to death. Both tumors A and B represent low-risk indolent or IDLE (indolent lesions of epithelial origin) tumors. Tumor C is destined to become metastatic and fatal but can be detected while still curable. Tumor D is destined to become metastatic but grows so quickly that by the time it can be detected, it may no longer be curable. Among these 4 tumors, only the patient with tumor C benefits from screening.
Tobacco Enema

- A rectal tube inserted into the anus was connected to a fumigator and bellows that forced the smoke towards the rectum. The warmth of the smoke was thought to promote respiration.
- Doubts about the credibility of tobacco smoke enemas lead to the popular phrase “blowing smoke up your …...”
- This old tool seems to be repeatedly reintroduced in modern times by opponents of screening mammography.
• “It is now as it was then and as it may ever be, concepts from the past blind us to facts that slap us in the face.”