



Widespread Mammogram Screening does not withstand Scrutiny



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Background

The benefits of screening for the early detection of several diseases, including breast cancers, have been widely promoted over the last 20 years. Recently, a growing body of research systematically questions screening benefits by asserting that "overtreatment of overdiagnosed conditions" is actually doing substantial harm.

Patients can be harmed, as well as economies, as mammography diverts resources into unjustified testing and treatments that cannot withstand scrutiny. <http://www.preventingoverdiagnosis.net> Accurately determining the probability of freedom from invasive breast cancer (IBC) is particularly important given the recently identified long term harms of mammogram screening.

These 10 empirically substantiated harms include an associated 20-fold increase in ductal carcinoma in situ (DCIS), a doubling of the rate of invasive breast cancer (IBC) diagnoses, the failure of early detection to reduce mortality, screening induced breast cancer, and six other harms to patient health and well-being.

Methods and Criteria

Our systematic review* identified 19 published studies of 2,305,427 peri/postmenopausal women meeting 5 stringent criteria: Each study

1. Enrolled only women with no prior history of invasive breast cancer
2. Reported number of women enrolled
3. Reported the length of follow-up [we avoided subsequent subsets studies]
4. Identified the number of first-time IBC cases during follow-up
5. No woman could be counted more than one time

Linear regression was used to estimate

1. incidence of first invasive breast cancer based on follow up duration¹. and
2. incidence of freedom from diagnosis in all 19 studies and in 2 subset groups.

* <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0128895>

Results

1. The expected percent who will remain disease free after 25 years of follow-up is 94.55% (95% CI: 93.97, 95.13).
2. For every additional year of study follow-up, the % of enrolled women who are expected to remain free from an IBC diagnosis decreases by 0.20% (95% CI: 0.23, 0.17; p<.01).
3. For peri/postmenopausal women with no prior diagnosis, continued freedom from IBC has a long-term baseline probability of ~95% over their next 25 years of life.

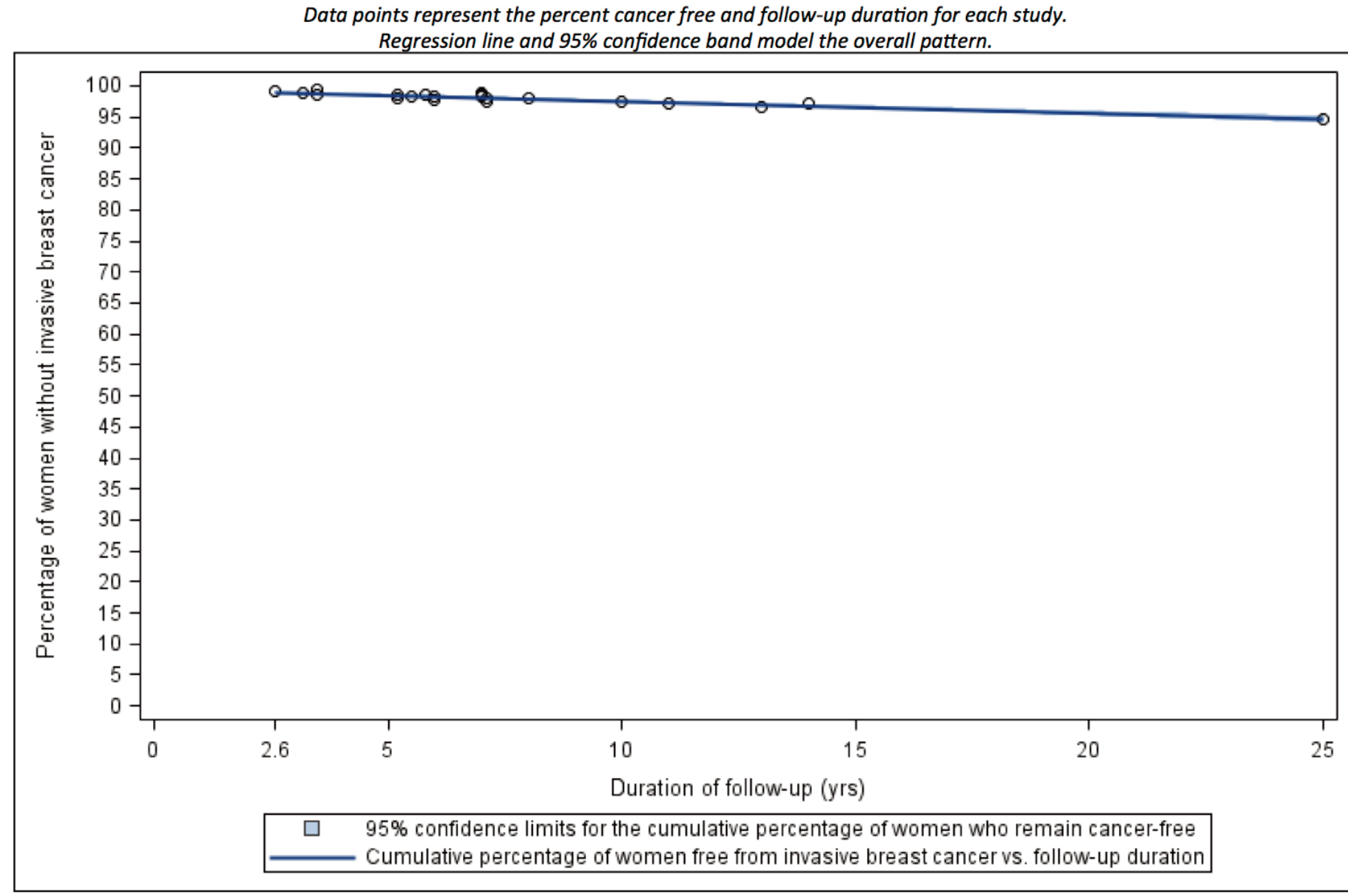
Is Screening Worth it?

3 perspectives to consider

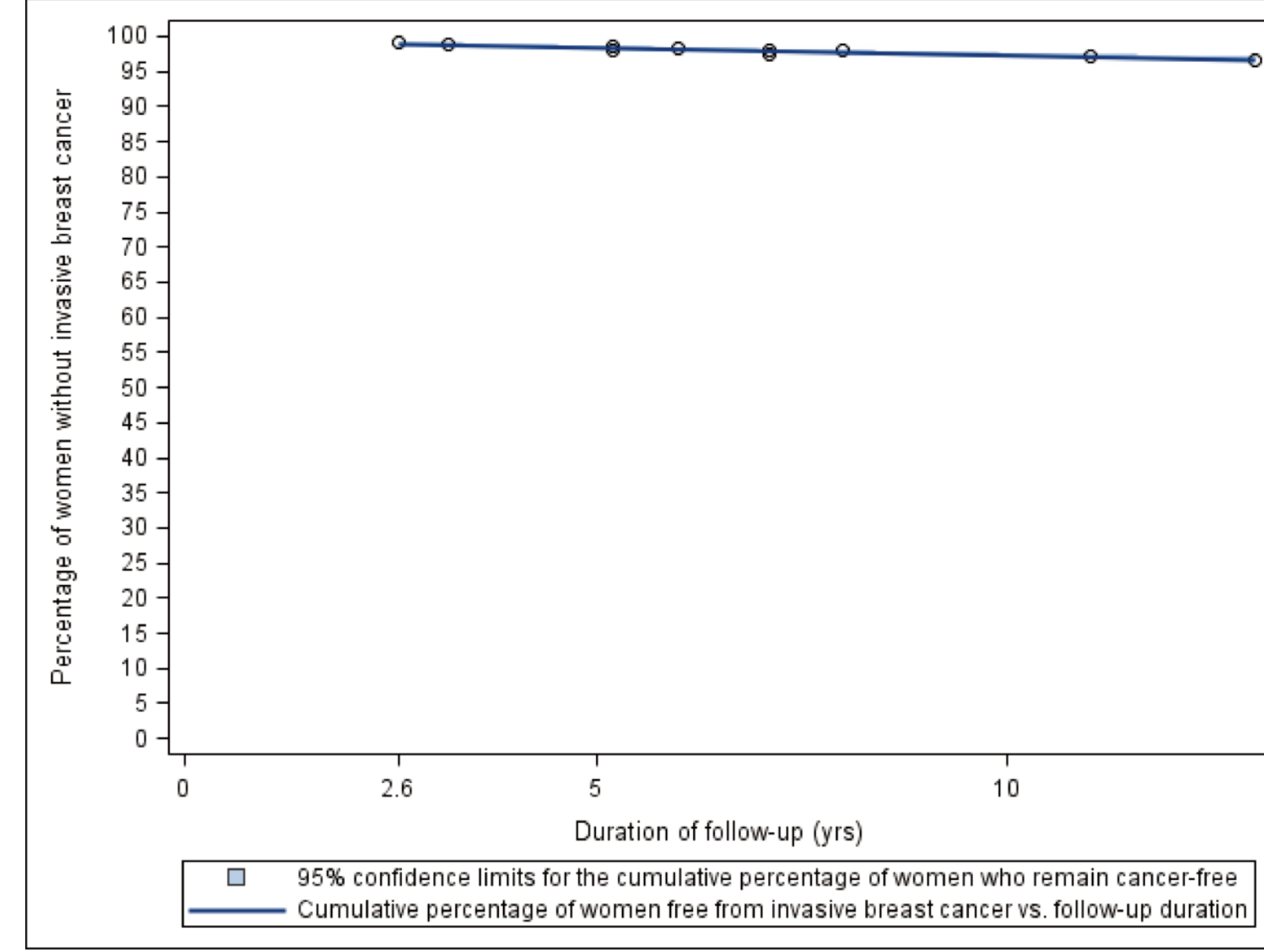
For women without a prior IBC diagnosis

- Does early detection actually save lives?
- Harms of mammograms
- 7 behavioral practices to reduce IBC incidence

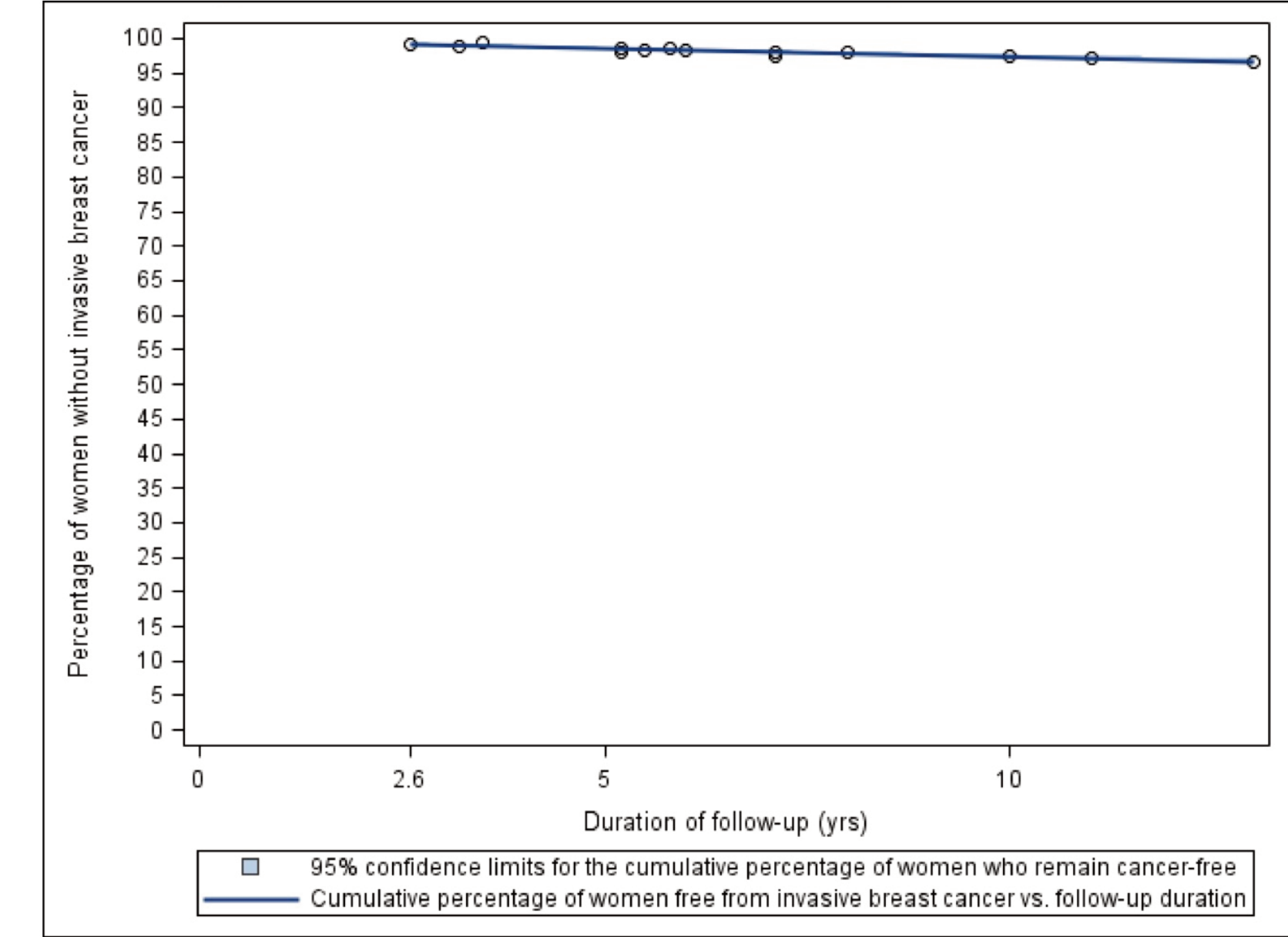
Percentage of Women Free from a Diagnosis of Invasive Breast Cancer among All 19 Studies



Percentage Free from a Diagnosis of Invasive Breast Cancer among Studies of Women > 50 Years at Enrollment



Percentage of Women Free from a Diagnosis of Invasive Breast Cancer among Studies of Women Post-Ovariectomy or > 50 Years at Enrollment



Does Mammogram Screening Save Lives?

In terms of Total Lives Lost

1. Screening does not actually save lives.¹⁶
2. Screening has not reduced total mortality.¹
3. Total mortality from breast cancer has been less than 1.2% regardless of screening.¹

In terms of Breast Cancer Cases

1. Long term follow up showed no mortality benefit of repeated screening of women.¹
2. Short term studies inflated by overdiagnosis appear to reduce mortality.

16. Autier P, Boniol M, Gavin A, Vatten L, J. Breast cancer mortality in neighboring European countries with different levels of screening but similar access to treatment: trend analysis of WHO mortality database. *BMJ* 2011;343:d4411. <http://dx.doi.org/10.1136/bmj.d4411>

1. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0128895>

Overdiagnosis Reduces/Distorts Case Mortality Rate

Both institutions diagnose 100 cases of IBC and find mortality at 10 year follow up = 30 women

30d/100 cases = 30% case mortality rate



Institution B then initiates screening. Now 150 cases/year are diagnosed including 50 that are overdiagnosed. 50/150 = 33% overdiagnosed that year. 30d/150 cases = 20% case mortality rate

33% overdiagnosis, then = 33% ↓ in case mortality rate; 50% overdiagnosis = 50% ↓ in case mortality rate

Distorted mortality rates foster an illusion of treatment progress, selling more screening, yielding further distortion.

The Harms of Mammogram Screenings

1. **Overdiagnosis:** Overdiagnosis 45%³⁻⁶ → 50%¹⁸ by 2018 adding digital mm
2. **Substantial False Positive Rate** >42%⁷ in 8 yrs; 11%¹⁵ @ 1 yr
3. **Overtreatment** w. toxic effects of surgery, radiation, chemo or HT ^{9,10}
4. **Radiation induced Breast Cancer** 125 cases per 100K screens¹²
Digital (tomosynthesis) screens double this rate
Radiation induced increase in breast cancer is cumulative!
5. **Loss of Income** for patient, time away from work: & i.e. brain fog
6. **Chronic Psychological + Physical Distress** persists¹³ yrs post +/- biopsy
7. **Substantial side effects common** genitourinary syndrome ¹⁴
8. **Treatment Costs** >\$4B/year in US: [\$850/tp,\$12K/DCIS, \$51.8K/IBC]¹⁵
9. **Conflicts of Interest** and rarely disclosed¹⁶
10. **Failure to Warn Informed Consent** is biased, not understandable, and directive instead of neutral¹⁷

USA Costs of False-Positives and Overdiagnoses

per case
False Positives—Invasive Breast Cancer—DCIS

702,154 Health Insurance women Participants [USA Provider] age 40-59, 1 base line year for entry data (2012) with 1 yr. follow up to the diagnosis

Diagnosis	Average Expenditures
False-Positive Mammograms	\$ 852.00
Invasive Breast cancer	\$ 51,837.00
Ductal Carcinoma in situ	\$ 12,369.00

Total USA excess cost in 2013 was \$4,000,000,000.00



[medscape.com/viewarticle/842820](http://www.medscape.com/viewarticle/842820)

healthaffairs.org/doi/abs/10.1377/hlthaff.2014.1087

USA Costs of False-Positives and Overdiagnoses

False Positives—Invasive Breast Cancer—DCIS
Per year using 2013 – USA wide estimates in women – age 40-59

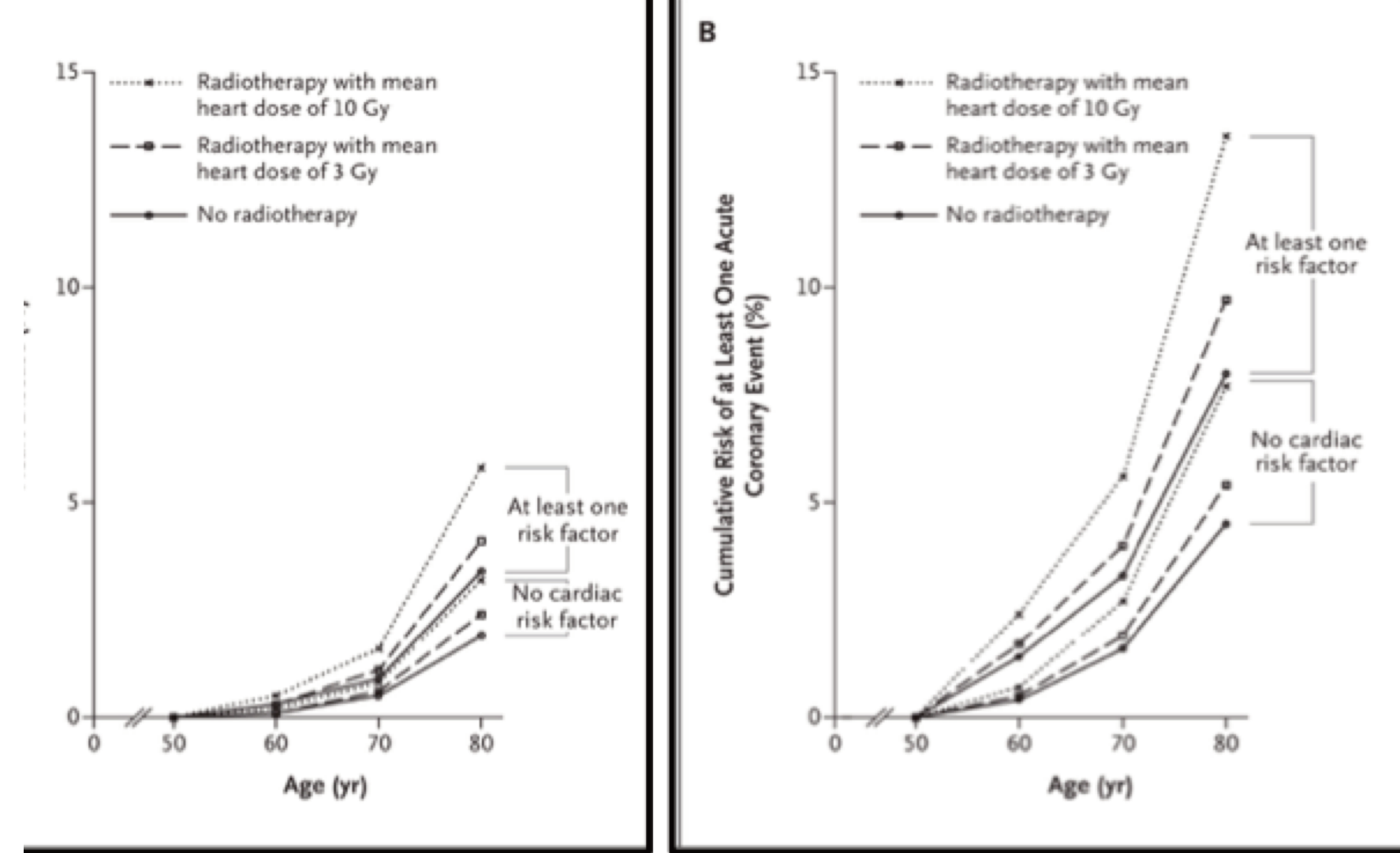
Diagnosis	National Expenditures 2012
False-Positive Mammograms @ 11% of screened women	\$ 2,800,000,000.00 (@3.2m cases/year)
Invasive Breast Cancer @ 22% of Cases	\$ 1,000,000,000.00 (@20,116 cases/year)
Ductal Carcinoma in Situ @ 86% of Cases	\$ 243,000,000.00 (@19,600 cases/year)

Total USA excess cost in 2013 was \$4,200,000,000.00 (@29.5m screened of 43.6m age 40-59)

<http://www.medscape.com/viewarticle/842820>
<https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2014.1087>

Death from Ischemic Heart Disease and Major Coronary Event are proportional to mean radiation dose to the heart. [7.4% per Gy].

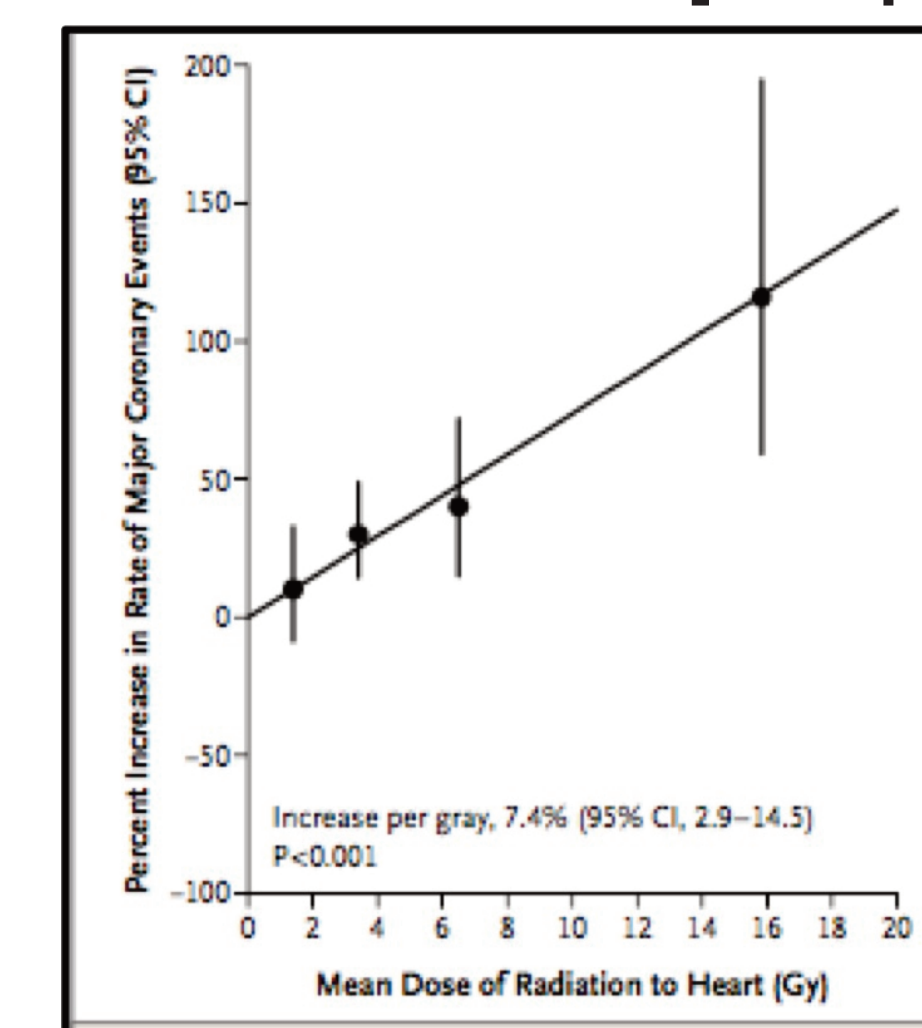
Risk starts within 5 years accumulating for >20 years



Darby SC et al. (2013) *N Engl J Med.* 2013 Mar 14;368(11):987-98. doi: 10.1056/NEJMoa1209825.

Increased Rate of Major Coronary Events: MI or Coronary Revascularization

Is directly proportional to mean radiation dose to the heart. [7.4% per Gy].



2168 women who underwent Radiotherapy for breast cancer 1958-2001 Sweden/Denmark without recurrence of IBC

1958-2001 Sweden/Denmark 963 with major coronary events 1205 without "

Risk starts within 5 years accumulating for >20, years

Major Outcomes* of the NSABP B-24 Trial: DCIS RCT after Lumpectomy and Radiation:

1804 women, 5 yrs placebo vs. Tamoxifen 20 mgs/day.

- Mortality:**
No significant difference
Both at 7* [and 15** years]
- The benefit: Placebo vs. drug**
[@84 mos]*
74 vs 44 cases IBC
- The Harms: Placebo vs drug**
[@ 97mos]*
11 vs 31 harms
4 vs 8 Endometrial Ca
0 vs 1 Uterine Sarcoma
2 vs 7 strokes
5 vs 15 Thrombotic events
DVT, PE

Type of Event	902 Women Placebo No. of Events	Rate per 1000/yr	902 women Tamoxifen No. of Events	Rate per 1000/yr	RR	95% CI limits
Invasive breast cancer (Primary endpoint)	74	16.73	44	9.60	0.57	0.39 to 0.84
- Ipsilateral	47	10.61	27	5.90	0.56	0.33 to 0.91
- Contralateral	25	5.64	17	3.71	0.66	0.33 to 1.27
Side undetermined	2	0.44	0	0	—	—
Secondary Endpoints						
DCIS	56	12.66	41	8.95	0.71	0.46 to 1.08
- Ipsilateral	46	10.40	38	8.29	0.88	0.51 to 1.25
- Contralateral	10	2.26	3	0.65	0.29	0.05 to 1.13
All Breast Cancer Events	129	29.16	84	18.34	0.63	0.47 to 0.83
- All ipsilateral events	96	21.70	65	14.19	0.65	0.47 to 0.91
- All contralateral events	37	8.36	20	4.37	0.52	0.29 to 0.92
Deaths	32	7.14	28	6.11	0.86	0.53 to 1.39
Uterine Malignancies ¹	4	0.89	9	1.96	2.20	0.53 to 8.81
Endometrial Adenocarcinoma ¹	4	0.89	8	1.74	1.93	0.53 to 6.81
Uterine Sarcoma ¹	0	0.00	1	0.22	—	—
Second primary malignancies (other than endometrial and breast)	30	6.68	29	6.33	0.95	0.66 to 1.37
Stroke	2	0.44	7	1.53	3.45	0.53 to 22.10
Thromboembolic events (DVT, PE)	5	1.11	15	3.25	2.92	0.83 to 10.10

Refs: ¹https://www.accessdata.fda.gov/drug-satfda_docs/label/2005/17970s053tbl.pdf

²<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3107729>

*Table 1: from the 2018 link to full prescribing information approved in the new drug application for tamoxifen (updated)

Survival was similar in the placebo and NOLVADEX groups. At 5 years from study end survival was 97% for both groups.

Seven Behavioral Practices that Increase Freedom from Breast Cancer and Reduce Overall Mortality

The greatest magnitude in risk reduction is attributable to 7 behaviors:

1. **Prevent weight gain:** Develop a healthful dietary practice (e.g. The Mediterranean Diet) and lose weight if overweight.
2. **Exercise daily:** At least 30 minutes a day, ideally in fresh air; mini breaks during the day are very good.
3. **Enjoy wine in moderation, but avoid excess:** ~6 ounces per day for a 140 pound woman = moderate.
4. **Get daily sunshine:** Expose on skin of whole body for about 15 minutes or take 2000 mg of Vitamin D3.
5. **Prevent the plunging progesterone and estrogen levels of peri and post menopause that trigger the increased incidence of breast cancer:** Learn about and engage in the best individualized options.
6. **Discover the demonstrated benefits of sequential bioidentical MHT and the dangers of continuous combined and/or synthetic forms of MHT.**
7. **If asymptomatic, refuse mammogram screening:** Instead, submit to professional breast exams from an experienced health care provider

Conclusion

The widely marketed statement that early detection saves lives has not withstood scrutiny according to published research by others.

In light of the high likelihood of an asymptomatic woman's remaining cancer free and the harms of mammogram screening, omitting mammogram screening makes sense for many peri and post-menopausal women without prior breast cancer history or excessive risk factors.

Women should not be made to feel guilty for refusing mammogram screening.

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