

Failure to Screen for Cancer: Medical Malpractice in the New Millennium

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Background

- Current malpractice crisis makes rest of this discussion all the more urgent:
 - Some malpractice carriers going bankrupt or not writing new insurance forcing doctors to change carriers
 - Premiums increasing dramatically for doctors with no prior claims
 - Doctors who have had prior claims against them are finding it difficult and/or very expensive to remain insured – in some cases even if victorious in court
 - The Florida solution (at least 20% of doctors in Miami have no malpractice insurance) is not practical under Virginia law

Cancer and Medical Malpractice

- Historically the missed diagnosis of cancer amounts to a large percentage of medical malpractice claims; single biggest cause of lawsuits against doctors from 1985 to 1996
- Can affect primary-care physicians and specialists
- Examples (breast cancer):
 - Failure to interpret mammogram correctly (radiologist) or...
 - Failure to act on abnormal mammogram report (PCP)
 - Assumption that normal mammogram excludes cancer (PCP)

Further examples – lung cancer

- Failure to read chest xray correctly (radiologist) or....
- Failure to act on abnormal report, either by failing to see report before it is filed or by failing to realize significance of abnormal report (PCP)
- Failure to follow up pneumonia in adults to the point of radiographic clearing (PCP or pulmonologist)

Another Example: Prostate Cancer

- Failure to notice abnormal PSA before put in chart
- Failure to act on elevated PSA
- Failure to notice rapidly rising PSA even if still in the normal range (Senator Kerry)

The latest wrinkle: failure to screen for cancer in asymptomatic individuals

■ Example #1:

- 58 y.o. man enters the hospital via the ED with crampy abdominal pain
- Anemic: H/H 8/30 MCV 72 platelets 585,000
 - Ferritin 8; Fe/TIBC 15/400
 - Stool hemoccult positive
- Picture of bowel obstruction on x-rays
- Further work-up reveals obstructing cancer of hepatic flexure
- Semi-urgent cecostomy performed to decompress bowel
- Several days later definitive surgery done...

Example #1, continued

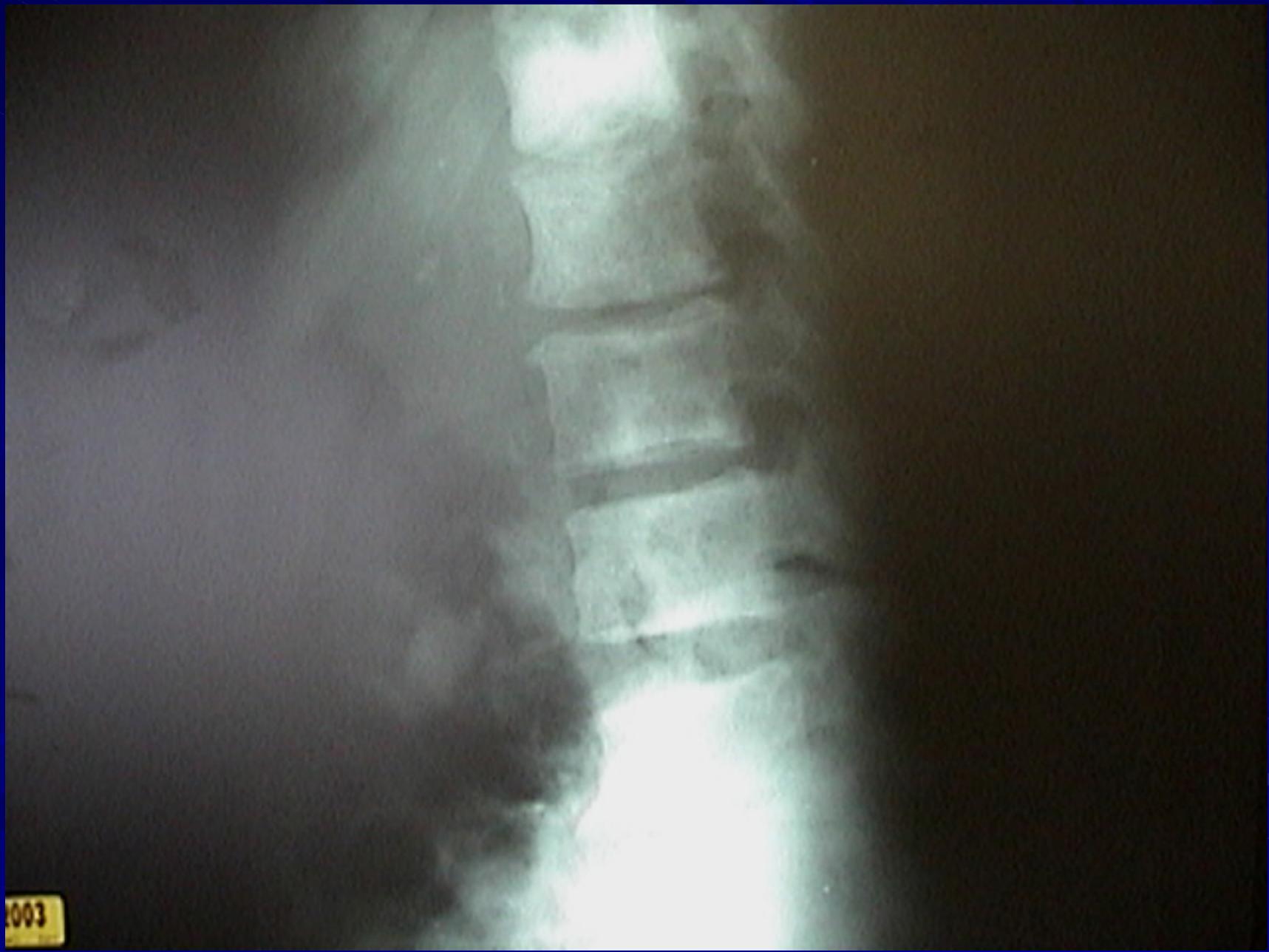
- At laparotomy large cancer of hepatic flexure is encountered with impending perforation
- Numerous metastatic lesions in liver and omentum discovered
- Palliative resection performed
- Post-operatively patient started on chemotherapy; lives for 22 months, dies of metastatic disease
- Before death, patient sues PCP for failing to initiate colorectal screening at age 50; estate carries on with suit after his death

The claim, continued

- Claim states that if screening had been initiated at age 50 tumor would have been found while it was still polyp or at a stage when much smaller cancer and metastases would have been prevented
- Issues to discuss in analyzing physician's potential responsibility and whether earlier diagnosis would have made a difference:
 - Frequency of screening of asymptomatic individuals in general population
 - Likelihood of finding lesion beyond reach of flexible sigmoidoscope even if appropriate guidelines had been followed
 - Value of the early detection of colorectal cancer in the prevention of excess mortality

Example # 2

- 62 year old man goes to PCP complaining of back pain
- Examination: enlarged nodular prostate
- PSA 52
- Bone scan diffusely positive; plain films done...





Example #2, continued

- Prostate biopsy + in all quadrants for poorly differentiated adenocarcinoma
 - Gleason's score $4+5=9$ in worst biopsy
 - Most biopsies $3+4=7$
- Started on depo-lupron with prompt relief of back ache, reduction of PSA to 0.5
- Initiates lawsuit against PCP for failing to obtain annual prostate cancer screening (PSA and DRE) starting at age 50

Issues in evaluating physician's responsibility and relation of delay to outcome

- Evaluate evidence that PSA screening saves lives
- Try to estimate what PSA would have been years earlier (i.e., when he was 50)
- Incorporate unfavorable Gleason's score into overall prognosis

Basics of cancer screening

- Disease must be common
- Patient must be asymptomatic for disease being screened or event is not true “screening”
- Screening test must be safe, cost-effective (defined in societal terms: cost/life saved; what society will bear as burden) and have high sensitivity (few false negatives; false positive rate may increase with enhanced sensitivity)
- Outcome of disease screened must be altered by early detection

Screening basics, cont.

- Above considerations rule out screening for such things as ca pancreas, brain tumors and, probably, ca lung
- With colon cancer, slow growth rate and long premalignant (i.e., adenomatous polyp) phase make argument for screening most compelling among all diseases commonly screened (along with cancer of cervix)

Guidelines for Colorectal Screening

- Everyone over the age of 50
- People at high risk should be started at earlier age (e.g. FAP, other familial syndromes)
- Screening itself involves at least:
 - Episodic flexible sigmoidoscopy
 - Annual stool hemoccults X 3 on meat-free high residue diet
 - Guidelines do vary a bit among various bodies that set the standards (e.g., American College of Surgeons vs. American Cancer Society vs. American College of Physicians)

Current ACS guidelines: probably represent minimum

- fecal occult blood test (FOBT) every year*, or
- flexible sigmoidoscopy every 5 years, or a fecal occult blood test every year plus flexible sigmoidoscopy every 5 years, or
- double-contrast barium enema every 5 years, or colonoscopy every 10 years

*For FOBT, the take-home multiple sample method should be used

Colorectal screening

- PCP should articulate in the chart plan for CRS when patient becomes eligible
- If patient declines to participate this should be explicitly documented
- Issue of comprehensive care vs. episodic care unresolved, but if PCP does annual visit with H&P and PE presumption of comprehensiveness probably prevails
- Overall compliance rate in US 25-50% (including people with no regular physician); may not matter whether patient has on-going comprehensive-care relationship with PCP;
hasn't mattered in recent law suits

Evidence to Support CRC Screening

- Fecal occult blood testing: Several large studies show altered outcome for patients screened versus general population
- The Swedish experience....

The Göteborg Study

- 68,308 inhabitants born between 1918-31 subjects; randomized to hemoccult screening versus no screening
- Compliance about 60%
- 4.4% + initial test:
 - 47 cancers
 - 129 adenomas ≥ 1 cm

Göteborg, continued

Colon cancers found during screening period

Dukes Stage	Screened	Refused Screening	Controls	p value
A	29	1	4	<0.03
B	22	3	33	
C	23	5	14	
D	7	6	11	<0.04
Total	81	15	62	

The English FOB trial

- 26,975 asymptomatic individuals
- 10,253 active intervention group
 - 3,613 were compliant
- 2.1% compliant group were hemoccult +
 - 13 cancers
 - 9 Dukes A
- Control group: 10,272
 - 17 cancers
 - 0 Dukes A
- False negative rate for Hemoccult 24%

English FOB results

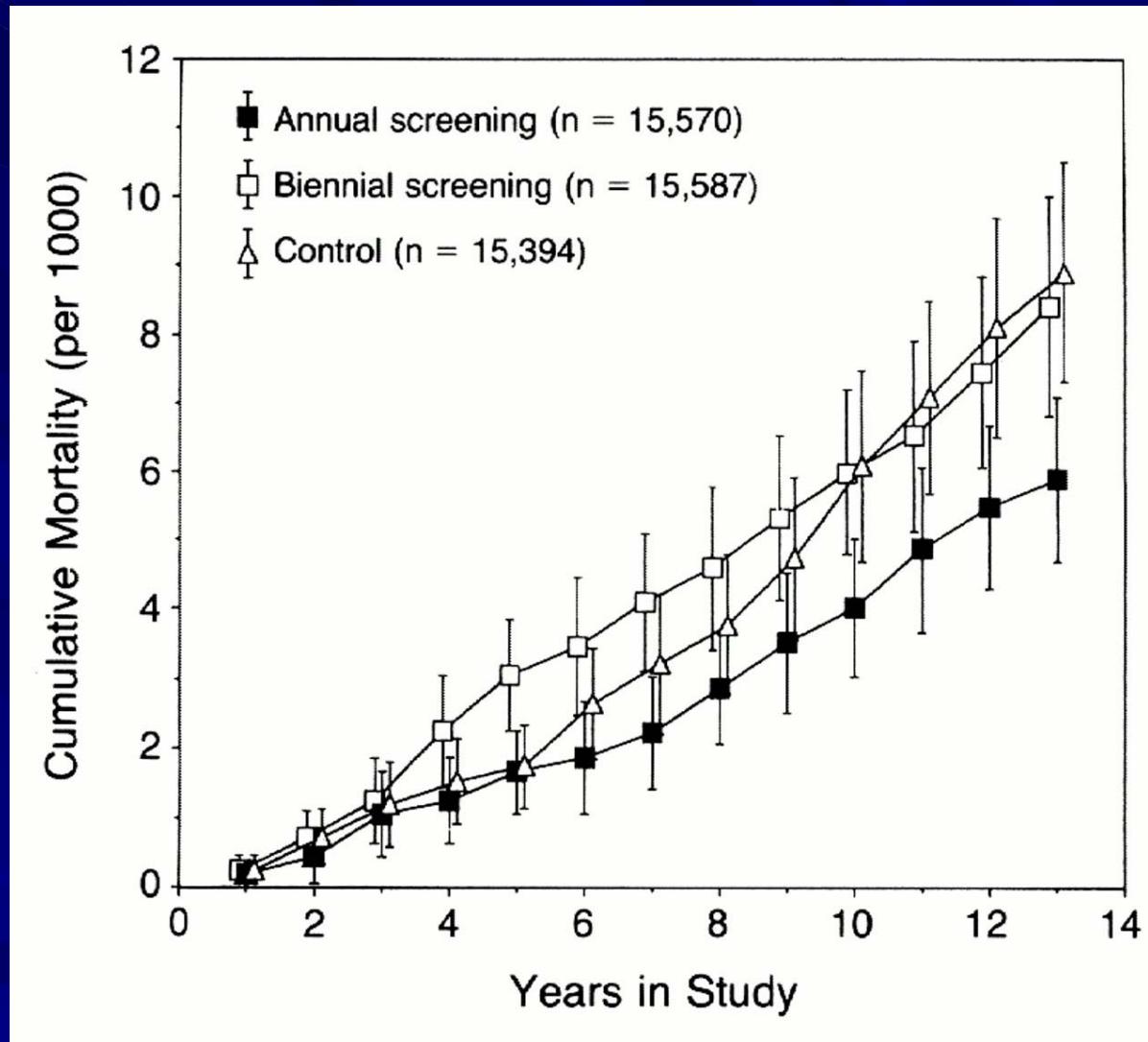
Colon cancers found during screening period

Dukes Stage	Screened n=3,613	Refused Screening n=6640	Controls n=10,272
A	12	2	0
B	4	7	8
C	2	1	6
D	2	4	3
Total	20	14	17

Mortality reduction from FOB screening

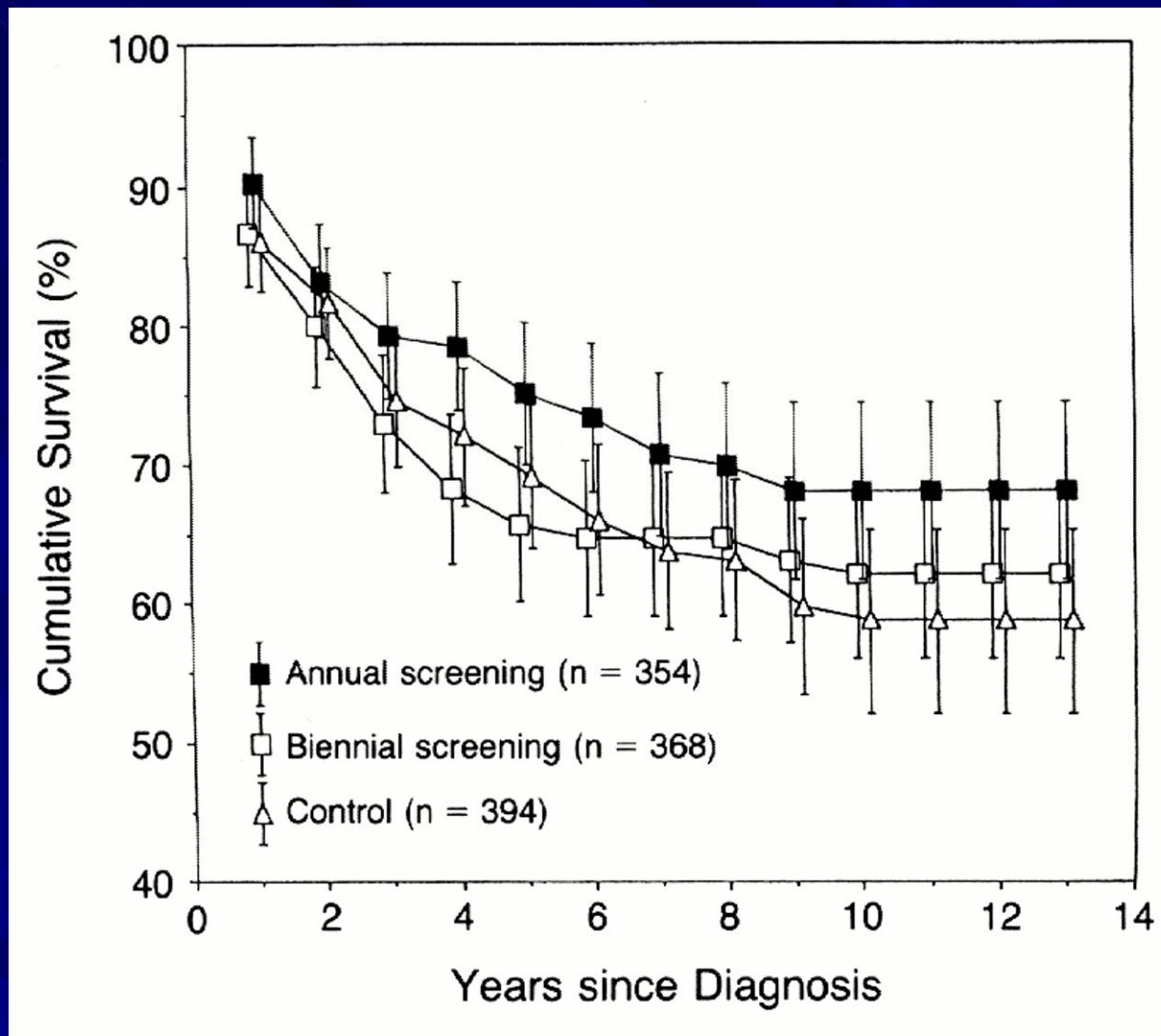
- Mandel study in *NEJM* shows dramatic reduction in mortality as a result of FOB testing
- 46,551 participants
- Screenings annual, or once every two years, or no screening
- Long follow-up....

Cumulative Mortality from Colorectal Cancer, According to Study Group



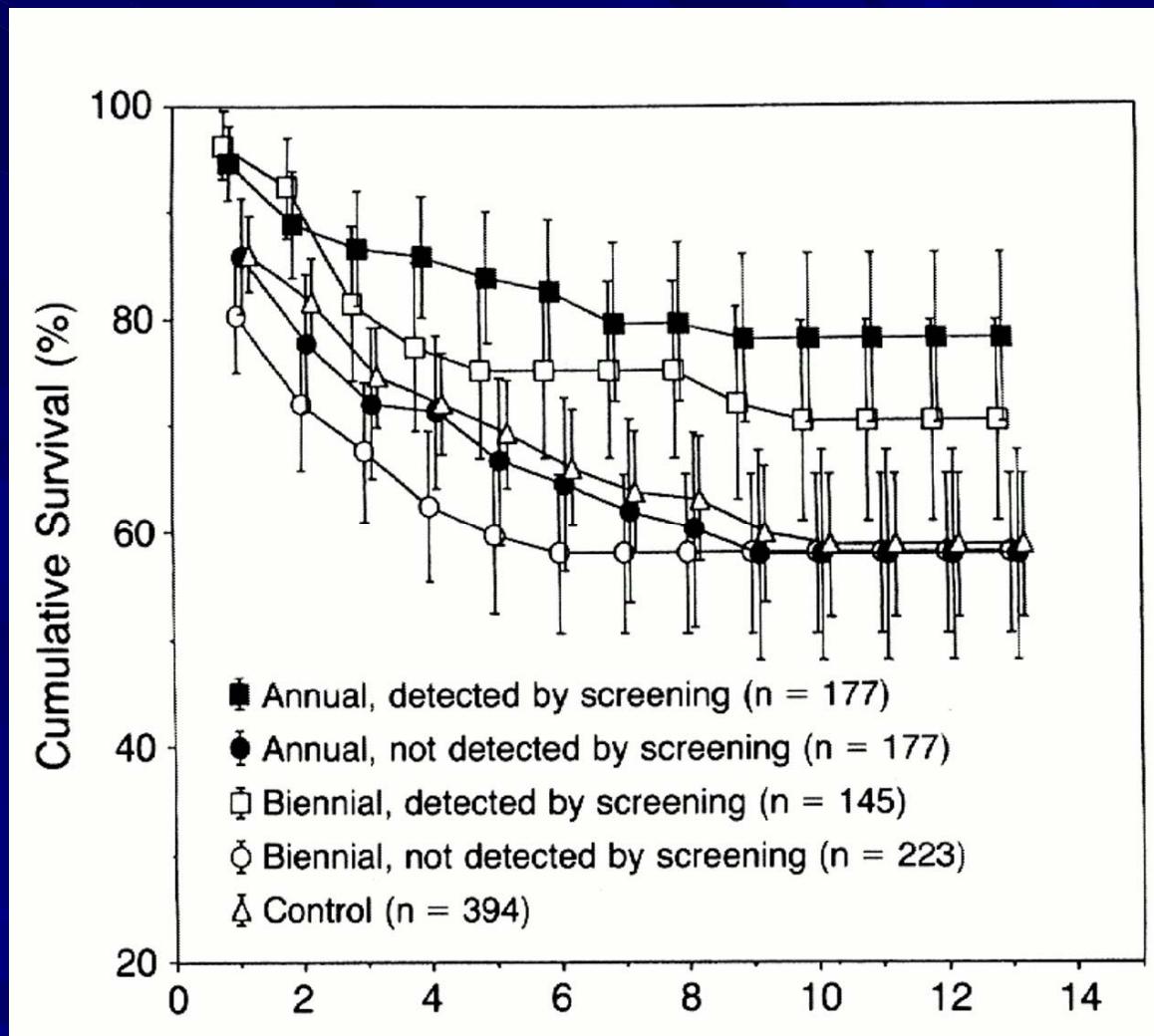
Mandel, J. S. et. al. N Engl J Med 1993;328:1365-1371

Cumulative Survival of Participants with Colorectal Cancer, According to Study Group



Mandel, J. S. et. al. N Engl J Med 1993;328:1365-1371

Cumulative Survival of Participants with Colorectal Cancer, According to Method of Detection and Study Group



Mandel, J. S. et. al. N Engl J Med 1993;328:1365-1371

CRC Screening: flexible sigmoidoscopy (SS)

- Best data from case-control study*
 - Not true randomization; compares screening in affected group vs. general population
- Looked at records of 261 Kaiser Permanente Medical Care Program in SF Bay area who died of colon cancer between 1971 and 1988
- 8.8% of the 261 had undergone SS in 10 years prior to diagnosis of cancer
- 868 age- and sex-matched non-cancer controls selected from their database (didn't use cancer survivors (!))
- 24.2% of Kaiser control enrollees had undergone SS in same period of time

*Selby NEJM 323: 653, 1992

Kaiser, continued

- Next looked at 268 patients dead of CRC with tumors beyond reach of SS
- Looked at 268 controls from Kaiser database
- No difference in frequency of SS between groups
- Conclusion: SS reduces mortality from CRC in that portion of colon seen with scope ($p<0.0001$); absence of change in mortality in proximal colon validates model

Role of colonoscopy

- Basically undefined; no randomized trials; theoretically should be best; question is how much gain of information versus cost/morbidity
- VA Study* studied 17,732 patients; 97% men
- 3121 agreed to colonoscopy
- 37.5% had some sort of neoplasm – often tiny polyp
- Significant polyps in 9.5%
- Invasive cancer in 1%
- 1765 had negative exams as far as flex sig would have reached
 - 2.7 % of these had large polyps or cancer more proximally
 - 52% of patients with proximal lesions had no distal lesions
- Authors concluded that colonoscopy added value above and beyond flexible sigmoidoscopy

Colorectal screening: conclusions

- All patients over age 50 should be screened
 - Data strongly support role of FOB testing
 - Sigmoidoscopy data less compelling
 - Colonoscopy data exist; makes sense but minimal population-based data to support routine use; has become *de facto* standard of care in absence of large database
 - Current guidelines support use of FOB plus endoscopy of some sort
- PCP should have plan for each patient
- Key to avoiding accusation after the fact that screening was ignored and led to incurable cancer

What about our patient?

- In case #1 it is difficult to construct a defense that screening
 - a: isn't the standard of care
 - b: doesn't affect the outcome
- Data on outcome with screening and slow growth rate of colon cancer with long premalignant (polyp) phase make argument for screening compelling

Performance of PSA screening by age of patient and specialty

What is the real-world standard of care? How does this relate to our patient (case #2)?

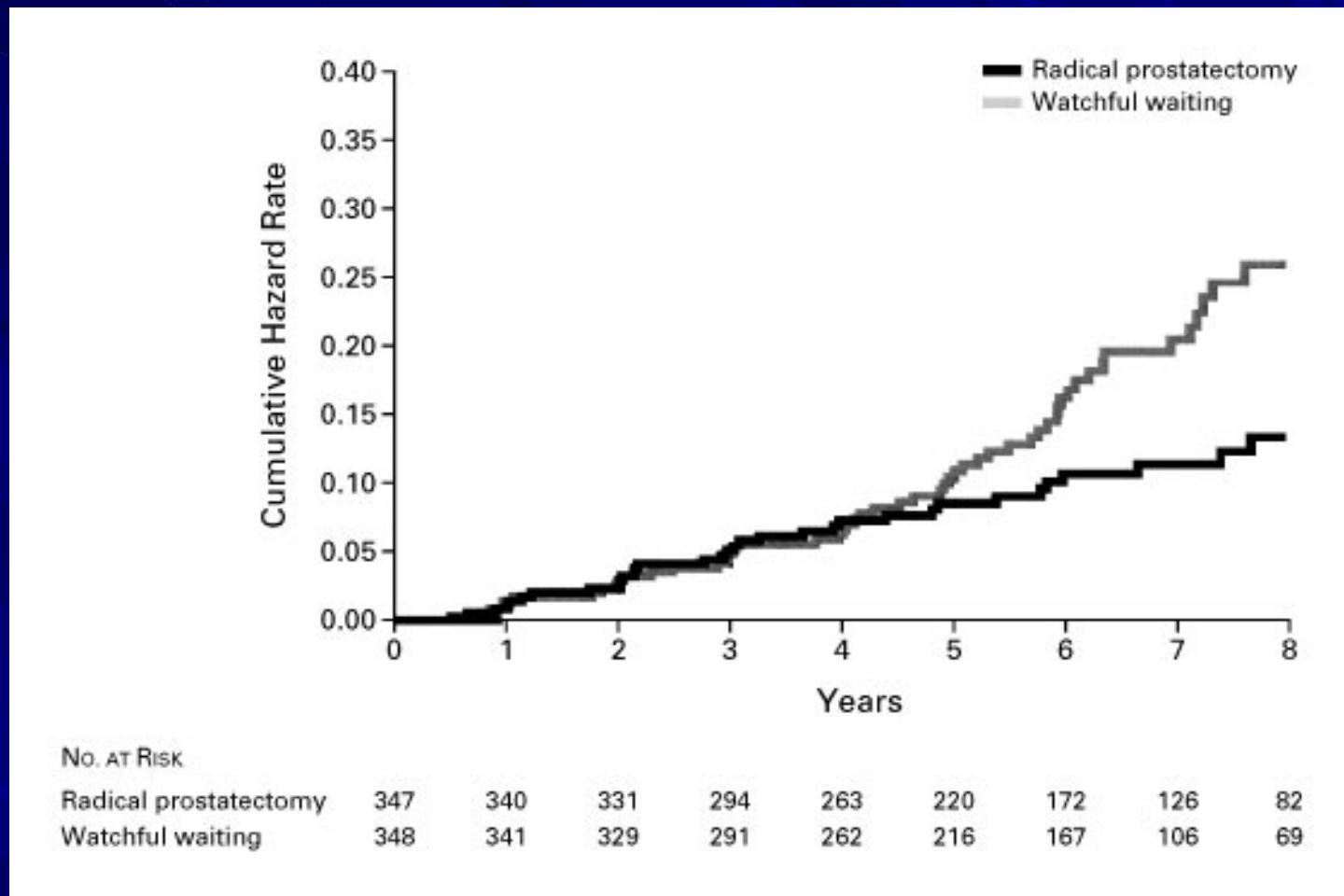
PCP's perform PSA (%)	age range of patients				
	50-59	60-69	70-74	75-79	80+
Almost always	55	66	65	58	53
> 1/2 time	16	14	11	14	13
≤ 1/2 time	29	20	24	28	34

Urologists recommend PSA	Yes	97	98	88	50	25
No		3	2	12	50	75

Do screening and early intervention matter? The Scandinavian Prostatic Cancer Group Study Number 4

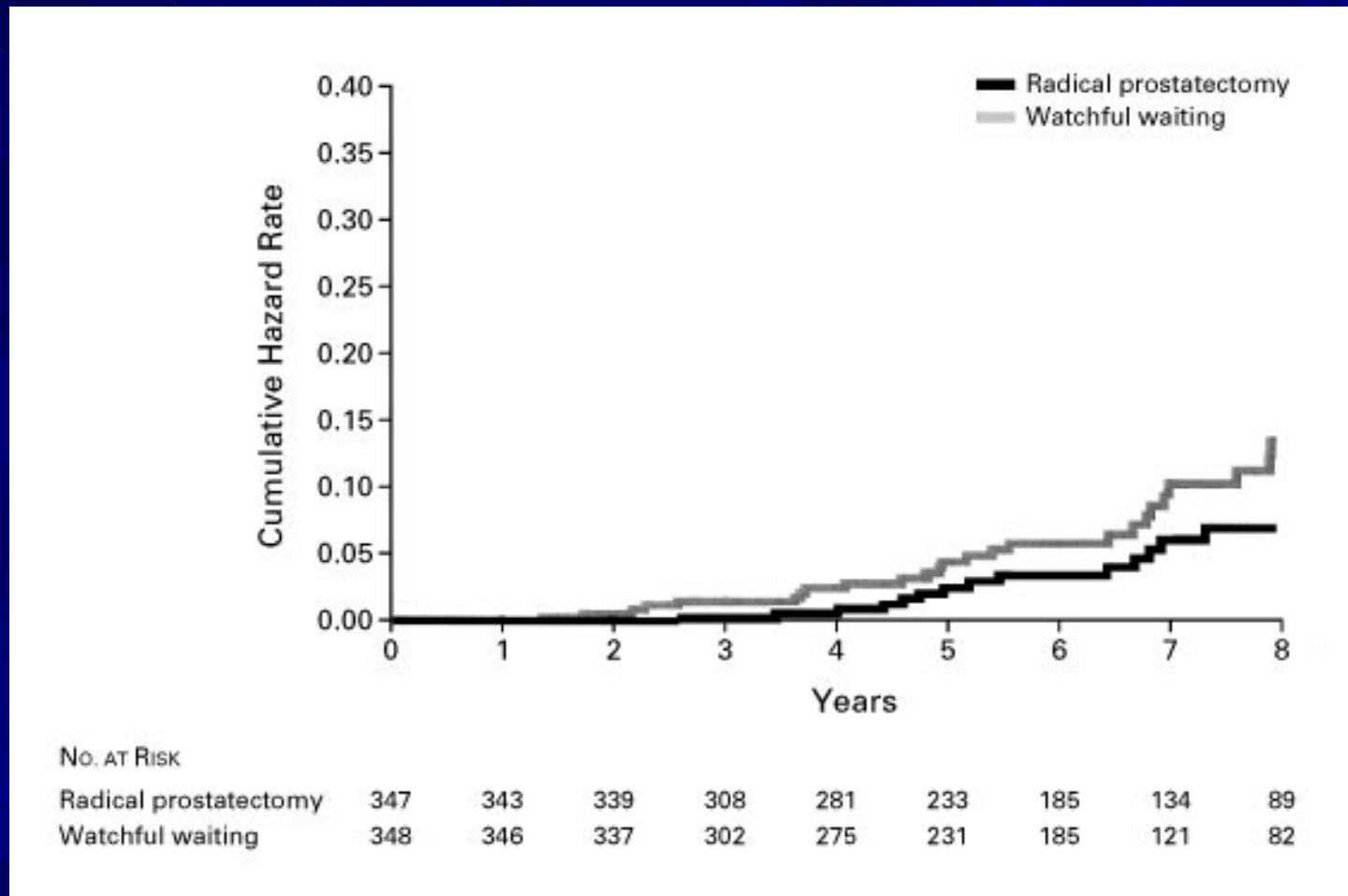
- Only truly prospective randomized trial; all other studies were retrospective analyses and are tainted by heavy selection bias
- 695 men with newly diagnosed CaP randomized to radical prostatectomy vs. watchful waiting
- All had T1b, T1c or T2 tumors
- Some in each group (about 6%) wound up with the other treatment
- Median follow-up 6.2 years...

Cumulative Hazard Rate of Development of Distant Metastasis



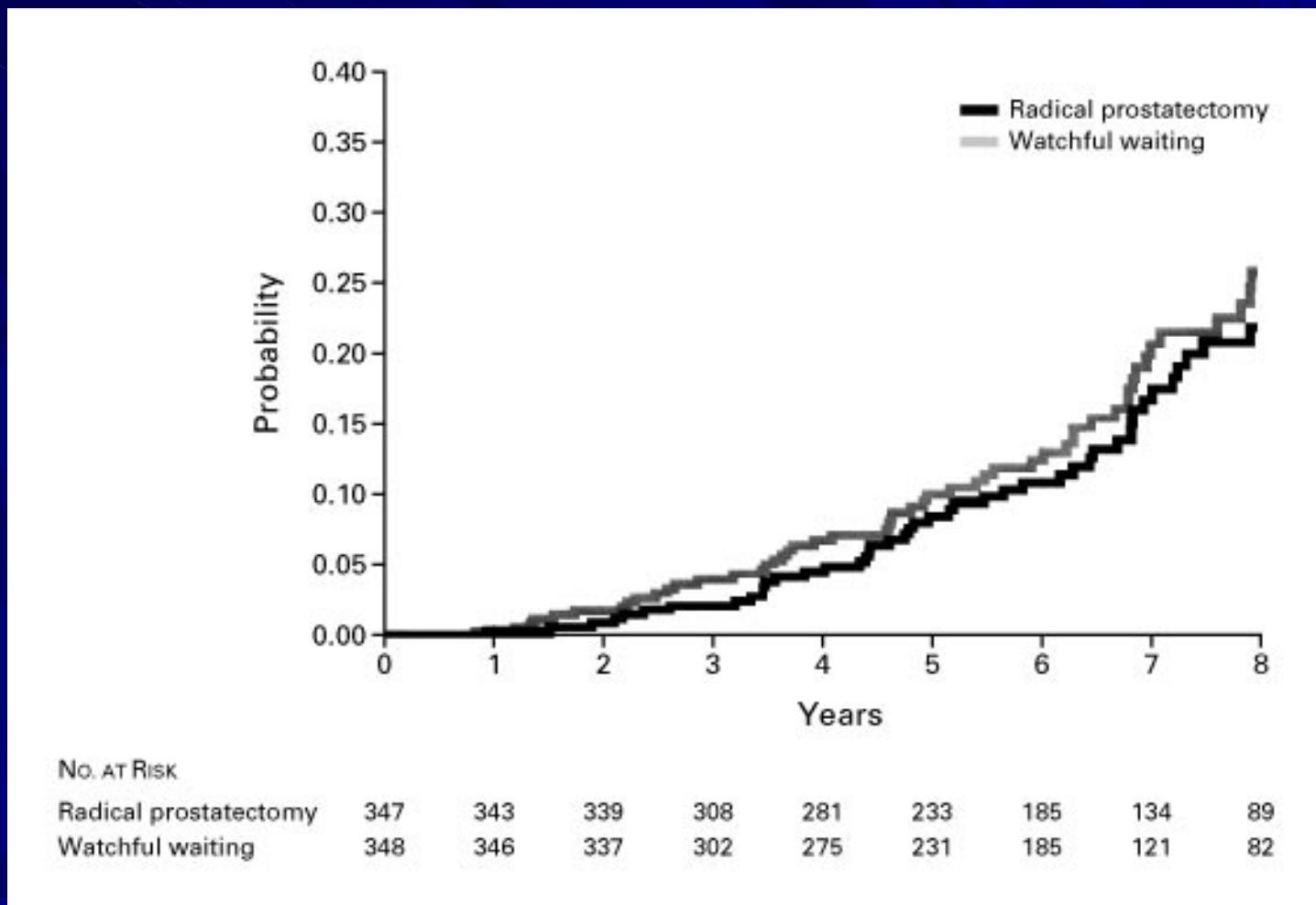
Holmberg, L. et. al. N Engl J Med 2002;347:781-789

Cumulative Hazard Rate of Death from Prostate Cancer



Holmberg, L. et. al. N Engl J Med 2002;347:781-789

Cumulative Probability of Death



Holmberg, L. et. al. N Engl J Med 2002;347:781-789

TABLE 2. CAUSE OF DEATH ACCORDING TO THE FINAL CONSENSUS MEETING OF THE END-POINT COMMITTEE.

CAUSE OF DEATH	WATCHFUL WAITING (N=348)	RADICAL PROSTATECTOMY (N=347)
	number	
Prostate cancer	31	16
Other causes	31	37
Other main cause with metastases	3*	1†
Other main cause without metastases but with local progression or recurrence	8*	6†
Other main cause with no evidence of metastases or local progression or recurrence	19‡	29§
Other main cause within first mo after randomization	1	1
All causes	62	53

*Of these 11 men, 3 died from another cancer.

†Of these 7 men, 3 died from another cancer.

‡Of these 19 men, 5 died from another cancer.

§Of these 29 men, 12 died from another cancer.

Prostate Cancer, continued

- Scandinavian study is best study thus far regarding value of intervention but results show modest improvement and have not been corroborated
- Study results create problems for nihilistic approach to screening
- Nonetheless ACP still refuses to endorse screening
- The screening/litigation dilemma:
 - Fear of litigation is pushing more doctors into screening
 - The “Standard of Care” is thus tilting in direction of screening because more and more doctors are doing it
 - Litigation thus drives the standard rather than the reverse!
 - No way out of dilemma at the moment

Back to our patient: Issue of PSA rate of increase

- Had the man in case #2 been screened starting at age 50 when would his PSA have become abnormal?
- Data such as it is suggests a PSA doubling time on the average of about 4 years for the several years prior to the diagnosis of cancer
- What does this mean in practical terms?

Looking backward on PSA:

- Using 4 years as average DT of PSA over life of cancer, PSA was:
 - 26 when he was 58
 - 13 when he was 54
 - 6.5 when he was 50
- By this analysis his outlook (for better or worse for the defendant physician) would have been much better when he was 50, at a time when screening arguably should have been started

What about Gleason's score?

- Score of worst biopsy at time of diagnosis was 9; associated with bad outcome no matter what PSA is at time of diagnosis
- Did Gleason's score worsen over time, i.e., does CaP de-differentiate over time?
- If so, then defendant is in even worse trouble, for PSA at 50 would have been 6.5 and Gleason's score would have been more favorable

Does Gleason's score worsen over time?

- Answer requires serial prostate biopsies over time; only two studies done
- Results are in conflict; one suggests random Gleason drift; the other suggests a worsening over time
- Situation unresolved

Conclusions

- Data for value of colorectal screening are solid; clearly lives are saved
- Data for altered outcome with prostate screening much less compelling
- Current litigation climate requires physician to have a plan for screening, articulate that plan in the record, and, hopefully, put that plan into action if the patient agrees....see example

