Prostate Cancer: Incidence, Risk Factors and Prevention

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Kansas City, Kansas
## New Cases of Cancer - 2007

### Estimated New Cases*

<table>
<thead>
<tr>
<th>Tissue Type</th>
<th>Males</th>
<th>%</th>
<th>Females</th>
<th></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>218,890</td>
<td>29%</td>
<td>Breast</td>
<td>178,480</td>
<td>26%</td>
</tr>
<tr>
<td>Lung &amp; bronchus</td>
<td>114,760</td>
<td>15%</td>
<td>Lung &amp; bronchus</td>
<td>98,620</td>
<td>15%</td>
</tr>
<tr>
<td>Colon &amp; rectum</td>
<td>79,130</td>
<td>10%</td>
<td>Colon &amp; rectum</td>
<td>74,630</td>
<td>11%</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>50,040</td>
<td>7%</td>
<td>Uterine corpus</td>
<td>39,080</td>
<td>6%</td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>34,200</td>
<td>4%</td>
<td>Non-Hodgkin lymphoma</td>
<td>28,990</td>
<td>4%</td>
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<tr>
<td>Melanoma of the skin</td>
<td>33,910</td>
<td>4%</td>
<td>Melanoma of the skin</td>
<td>26,030</td>
<td>4%</td>
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<tr>
<td>Kidney &amp; renal pelvis</td>
<td>31,590</td>
<td>4%</td>
<td>Thyroid</td>
<td>25,480</td>
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</tr>
<tr>
<td>Leukemia</td>
<td>24,800</td>
<td>3%</td>
<td>Ovary</td>
<td>22,430</td>
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<tr>
<td>Oral cavity &amp; pharynx</td>
<td>24,180</td>
<td>3%</td>
<td>Kidney &amp; renal pelvis</td>
<td>19,600</td>
<td>3%</td>
</tr>
<tr>
<td>Pancreas</td>
<td>18,830</td>
<td>2%</td>
<td>Leukemia</td>
<td>19,440</td>
<td>3%</td>
</tr>
<tr>
<td><strong>All Sites</strong></td>
<td><strong>766,860</strong></td>
<td><strong>100%</strong></td>
<td><strong>All Sites</strong></td>
<td><strong>678,060</strong></td>
<td><strong>100%</strong></td>
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</table>
### Estimated Cancer Deaths - 2007

<table>
<thead>
<tr>
<th>Location</th>
<th>Males</th>
<th>Females</th>
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<tbody>
<tr>
<td>Lung &amp; bronchus</td>
<td>89,510</td>
<td>70,880</td>
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<tr>
<td>Prostate</td>
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<td>40,460</td>
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<td>Pancreas</td>
<td>16,840</td>
<td>16,530</td>
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<tr>
<td>Leukemia</td>
<td>12,320</td>
<td>15,280</td>
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<tr>
<td>Liver &amp; intrahepatic bile duct</td>
<td>11,280</td>
<td>9,470</td>
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<tr>
<td>Esophagus</td>
<td>10,900</td>
<td>9,060</td>
</tr>
<tr>
<td>Urinary bladder</td>
<td>9,630</td>
<td>7,400</td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>9,600</td>
<td>5,590</td>
</tr>
<tr>
<td>Kidney &amp; renal pelvis</td>
<td>8,080</td>
<td>5,500</td>
</tr>
<tr>
<td><strong>All Sites</strong></td>
<td><strong>289,550</strong></td>
<td><strong>270,100</strong></td>
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</tbody>
</table>

Percentage by Location:

- **Lung & bronchus**: 31% for Males, 26% for Females
- **Prostate**: 9% for Males, 15% for Females
- **Colon & rectum**: 9% for Males, 10% for Females
- **Pancreas**: 6% for Males, 6% for Females
- **Leukemia**: 4% for Males, 6% for Females
- **Liver & intrahepatic bile duct**: 4% for Males, 4% for Females
- **Esophagus**: 4% for Males, 3% for Females
- **Urinary bladder**: 3% for Males, 3% for Females
- **Non-Hodgkin lymphoma**: 3% for Males, 3% for Females
- **Kidney & renal pelvis**: 3% for Males, 2% for Females

**All Sites**: 100% for Males, 100% for Females
Cancer Incidence Rates
Cancer Death Rates
Evidence of the Effectiveness of Screening

• We are not finding “autopsy” tumors
• Dugan and colleagues analyzed 337 men undergoing radical prostatectomy and looked at tumor size, back-calculating, based on doubling time, risks that tumors were insignificant
• Worst case analysis—less than 1 tumor in 7 was insignificant

Results of Dugan’s Analysis

## Results of Cost Analysis of Screening

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Cost per QALY Gained</th>
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<tbody>
<tr>
<td>Liver transplantation</td>
<td>$237,000</td>
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<tr>
<td>Screening mammography (&lt; age 50)</td>
<td>$232,000</td>
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<tr>
<td><strong>Worst case—CaP Screening</strong></td>
<td><strong>$145,600</strong></td>
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<tr>
<td>CABG—2 vessel/angina</td>
<td>$106,000</td>
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<tr>
<td>Captopril for hypertension</td>
<td>$82,600</td>
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<td>Hydrochlorothiazide for hypertension</td>
<td>$23,500</td>
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<tr>
<td><strong>Best case—CaP Screening</strong></td>
<td><strong>$8,700</strong></td>
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<tr>
<td>Stop smoking MD message</td>
<td>$1,300</td>
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</table>

QALY=quality-adjusted life years; CaP=prostate cancer; CABG=coronary artery bypass graft
Thompson IM, Optenberg SA. *Oncology (Huntingt)*. 1995;9:141-145.
Evidence That Complications Are Falling

• AUA Prostate Cancer Panel: 12,501 papers published on management of localized prostate cancer
• 1999 reanalysis found that complication rates fell significantly*

Evidence That Screening Is Associated with a Fall in Mortality

• Fall in mortality now seen
  – SEER*
  – Olmsted County, MN†
  – Canada/Quebec‡
  – US Department of Defense (DoD)
  – Tyrol, Austria

• Mortality fall *not seen* (where PSA screening not or less-commonly performed)
  – Mexico
  – Europe

SEER=Surveillance, Epidemiology and End Results
Death Rates From CA and Heart Dz
## Incidence and Death Rates by Race

<table>
<thead>
<tr>
<th></th>
<th>All Races</th>
<th>White</th>
<th>African American</th>
<th>Asian American/Pacific Islander</th>
<th>American Indian/Alaska Native†</th>
<th>Hispanic-Latino‡</th>
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<tr>
<td>Male</td>
<td>562.1</td>
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<td>385.5</td>
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<td>415.3</td>
<td>421.1</td>
<td>383.8</td>
<td>303.3</td>
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<td>128.2</td>
<td>130.8</td>
<td>111.5</td>
<td>91.2</td>
<td>74.4</td>
<td>92.6</td>
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<td>63.7</td>
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<td>45.9</td>
<td>53.5</td>
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<td>41.9</td>
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<tr>
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<td>9.3</td>
<td>9.5</td>
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<td>9.4</td>
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<tr>
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<td>8.2</td>
<td>7.2</td>
<td>11.1</td>
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<td>3.6</td>
<td>8.3</td>
<td>6.5</td>
<td>5.8</td>
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<tr>
<td>Male</td>
<td>10.7</td>
<td>9.7</td>
<td>17.4</td>
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<td>21.6</td>
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<tr>
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<tr>
<td>Male</td>
<td>243.7</td>
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<td>166.4</td>
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<td>164.3</td>
<td>163.4</td>
<td>192.4</td>
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<td>111.6</td>
<td>108.8</td>
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<tr>
<td><strong>Breast (female)</strong></td>
<td>28.0</td>
<td>25.4</td>
<td>34.4</td>
<td>12.6</td>
<td>13.8</td>
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<tr>
<td>Male</td>
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<td>10.5</td>
<td>11.1</td>
<td>11.4</td>
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<tr>
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<tr>
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<td></td>
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<tr>
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<tr>
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<tr>
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<td>5.1</td>
<td>2.5</td>
<td>2.6</td>
<td>3.4</td>
</tr>
</tbody>
</table>
Age-Adjusted Rates of Prostate Cancer Per 100,000 Standardized to the World Population

- US, SEER: black
- US, SEER: white
- Iceland
- Canada
- Sweden
- Norway
- Australia, NSW
- Finland
- Denmark
- France, Bas-Rhin
- Germany, Searland
- Neth., Eindhoven
- Italy, Varese
- Czech., Slovakia
- UK, England & Wales
- Spain, Basque Country
- Estonia
- Japan, Nagasaki
- Singapore, Chinese
- India, Bombay
- Hong-Kong
- China, Shanghai

Rate/100,000 Men

Relationship of Dietary Fat Intake and Death Rate from Prostate Cancer

Muir Study

Prostate Cancer Migratory Trends

Incidence per 100,000

Japanese

Chinese

White

Homeland

San Francisco

Complementary Medicine Use in Men with CAP

- 1,400 pts from 6 academic institutions
- All men with CAP were eligible regardless of age or stage
- All surveys were 30 multiple-choice questions on demographics and use of CAM
- Given to pts in clinic and mailed back to one of the institutions

Complementary Medicine Use in Men with CAP

- Overall response rate 78.5% (1,099)
- CAM had previously been used by 23.5%
- CAM was being used by 18.2%
- Higher income, education and more advanced stage was associated with greater use
- 90% expected use to prolong life and improve QOL, 60% relieve symptoms and 47% cure

<table>
<thead>
<tr>
<th>Do you currently use?</th>
<th>Have you ever do you use?</th>
<th>How Much using this product?</th>
<th>Where did you hear of using this product?</th>
<th>Why do you use this product?</th>
<th>How long have you used this product?</th>
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<td>Soy Products</td>
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<td>a. Prostate Cancer ☐</td>
<td>a. Prostate Cancer ☐</td>
<td>a. Prostate Cancer ☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. family ☐</td>
<td>b. Prostate Health ☐</td>
<td>b. Prostate Health ☐</td>
<td>b. Prostate Health ☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. friend ☐</td>
<td>c. Other ☐ (specify)</td>
<td>c. Other ☐ (specify)</td>
<td>c. Other ☐ (specify)</td>
</tr>
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<td>a. Prostate Cancer ☐</td>
<td>a. Prostate Cancer ☐</td>
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<td>b. family ☐</td>
<td>b. Prostate Health ☐</td>
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</tr>
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<td>b. Prostate Health ☐</td>
<td>b. Prostate Health ☐</td>
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<tr>
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<td>c. friend ☐</td>
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<td>c. Other ☐ (specify)</td>
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<td>c. Other ☐ (specify)</td>
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<td>c. friend ☐</td>
<td>c. Other ☐ (specify)</td>
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<td>a. Prostate Cancer ☐</td>
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<td>c. Other ☐ (specify)</td>
<td>c. Other ☐ (specify)</td>
</tr>
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</table>
University of Kansas CAM Survey
Demographics

- 302 men completed questionnaire
- Mean age 55, range 17-91
- Education level:
  - 23% high school
  - 39% college
  - 37% post-graduate
- 177 men (55%) used supplements
Distribution of Supplement Use

- Vitamin E
- Vitamin D
- Zinc
- Soy Products
- Saw Palmetto
- Multi-Vitamins
- Selenium
- Shark Cartilage
- Lycopenes
- PC-SPES
Reasons For Using Supplements

- Prostate health: 43%
- General health: 41%
- Cardiovascular health: 8.6%
Information Sources

- Literature
- Family
- Health Care Worker
- Friend
- Television
- Internet
Age and Supplement Use

Percent

<30  31-40  41-50  51-60  61-70  >70

Age
An eyeful a day keeps the doctor away

By JONATHAN HAYTER

STARING at women’s breasts is good for men’s health and makes them live longer, a new survey reveals.

Researchers have discovered that a 10-minute ogle at women’s breasts is as healthy as half-an-hour in the gym.

A five-year study of 200 men found that those who enjoyed a longing look at busty beauties had lower blood pressure, less heart disease and slower pulse rates compared to those who did not get their daily eyeful.

Dr Karen Weatherby, who carried out the German study, wrote in the New England Journal of Medicine: “Just 10 minutes of staring at the charms of a well endowed female is roughly equivalent to a 30-minute aerobics workout.

“Sexual excitement gets the heart pumping and improves blood circulation.

“There is no question that gazing at breasts makes men healthier.

“Our study indicates that engaging in this activity a few minutes daily cuts the risk of a stroke and heart attack in half.

“We believe that by doing so consistently, the average man can extend his life four to five years.”
<table>
<thead>
<tr>
<th>Medication</th>
<th>Indication</th>
<th>Placebo Response</th>
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<td>Paxil</td>
<td>Antidepressant</td>
<td>42%</td>
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<tr>
<td>Propecia</td>
<td>Hair loss</td>
<td>42%</td>
</tr>
<tr>
<td>Rogaine</td>
<td>Hair loss</td>
<td>40%</td>
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<tr>
<td>Uprima</td>
<td>ED</td>
<td>25%</td>
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<tr>
<td>Viagra</td>
<td>ED</td>
<td>25%</td>
</tr>
<tr>
<td>Xenical</td>
<td>Weight loss</td>
<td>6 lbs</td>
</tr>
</tbody>
</table>

Nonexistent’ to ‘excessive’ dosages
Study finds wide variation in branded supplements

Range of supplements’ active ingredients

Above recommended dosage (%)

Recommended dosage

Below recommended dosage (%)

Vitamin E  Selenium  Vitamin D  Saw palmetto  Lycopene

SOURCE: NEIL FLESHNER, MD, MPH
Prostate Cancer

Lifestyle Changes and Dietary Supplements

- Obesity
- Fat intake
- Statins
- Antioxidants
- Calcium
- Soy products
- ASA/ NSAIDs
Cancer Prevention Study II
n=900,000

- 404,576 men and 495,477 women free of cancer at enrollment in 1982
- Examined BMI and risk of developing any cancer over 16 year follow-up
- Controlled for other variables using a multivariate proportional hazards model

Calle EE et al. NEJM 2003; 348:1625-38
Cancer Prevention Study II
Results

• BMI $\geq 40$ CSDR 52% higher for men and 62% higher for women than normal weight
• BMI was associated with higher death rates due to cancer of esophagus, colorectal, liver, pancreas and kidney
• Trend of higher risk of death from CaP with increasing BMI
• Obesity could account for 14% of deaths from cancer in men and 20% in women

Calle EE et al. NEJM 2003; 348:1625-38
Obesity and Outcomes Following Radical Prostatectomy

n=1,250

• Examined PSA recurrence after RP in 5 medical centers
• Age, race, stage, PSA, Gleason sum and BMI were examined using Cox-proportional hazards model
• Determined if BMI was a significant independent predictor of PSA recurrence

Obesity and Outcomes Following Radical Prostatectomy

Results

• Black men more likely to be obese
• BMI > 35 kg/m² predicted 4x increase in PSA failure
• After controlling for all preoperative clinical parameters and higher pGleason, BMI remained an independent predictor of PSA recurrence following RP

Obesity and the Risk of Prostate Cancer Metastasis and Death
n=752

- Case-control study of men newly diagnosed with CAP and BMI available from previous yr
- Obesity defined as BMI $\geq 30$ kg/m$^2$
- Controlled for confounders of age, race, smoking status, Gleason sum, stage at diagnosis, PSA and treatment

Obesity and the Risk of Prostate Cancer Metastasis and Death

Results

• Obesity was associated with a 2.6-fold increased risk of prostate cancer-specific mortality
• Obesity was associated with a 3.6-fold increased risk of metastasis
• The association remained across strata defined by Gleason sum, stage and treatment

Dietary Fat and LNCaP: Tumor Volume with Time

- Yellow: 40% fat
- Orange: 30% fat
- Blue: 20% fat
- Green: 10% fat
- Pink: 2.3% fat

Tumor Volume (cm³)

Weeks

0 0.05 0.1 0.15 0.2 0.25 0.3 0.35
0 1 2 3 4
Dietary Fat and Hormone Levels

- Decreasing fat from 40% to 25% and increasing polyunsaturated fat led to 40% reduction in serum test within 6 weeks
- Urinary testosterone and estrogen levels lowered 30% by decreasing dietary fat from 40% to 30%

Fat Intake and CaP

- Increased risk of CaP in men with high dietary fat intake from red meat
- Increased risk in those with high linolenic fatty acid (red meat) intake
- No correlation with linoleic fatty acid (fish) intake

Case-Control Studies: Prostate Cancer and Dietary Fat

Number of studies 23
Cases/controls 8917/10,399
Positive association with dietary fat 17
Odds ratio 1.3-3.4

Kolonel, LN. Epidemiologic Reviews 23: 72, 2001
### Cohort Studies: Prostate Cancer and Dietary Fat

<table>
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<th>Parameter</th>
<th>Value</th>
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<td>Number of studies</td>
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<tr>
<td>Number of patients</td>
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<tr>
<td>Person-years observed</td>
<td>612,002</td>
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<tr>
<td>Positive association</td>
<td>4</td>
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<tr>
<td>Relative risk</td>
<td>1.8-2.4</td>
</tr>
</tbody>
</table>

Kolonel, LN. Epidemiologic Reviews 23: 72, 2001
Fat Intake and IGF-1

- Men with high levels of serum IGF-1 had a 4-fold increase in CaP
- Serum levels of IGF-1 positively associated with high fat intake

Statin Use and Cancer
n=3,129

- Case-control study to compare risk of cancer between users and non-users of CV drugs including statins
- Matched 3,129 cancer cases and 16,976 control subjects
- Matched subjects on basis of sex, age, geographic region, duration of FU and index date

Statin Use and Cancer
Results

- Use of statin drugs reduced the overall risk of cancer by 20%
- Use of statins for > 4 years reduced the overall risk by 36%
- Reduction in prostate cancer was 63% although this was not statistically significant

Statin Use and Advanced CAP: Health Professionals F/U Study

- Analyzed data from 34,989 patients who were cancer free in 1990/ followed until 2002
- Total of 2,579 prostate cancers diagnosed and 316 of these were advanced
- Adjusted findings based on PSA-screening history

Statin Use and Advanced CAP: Results

- No overall difference in the risk of prostate cancer between users and non-users
- Men currently using statins had 50% reduction in metastatic or fatal CAP
- Longer use of statin drugs led to a continual drop in the risk of advanced or fatal disease

Diet and Exercise Effects on LNCaP Cell Growth

- 13 obese men (42-73yrs) enrolled in 11 day intervention of low-fat (<10%), high-fiber (35-40g/cal/d) diet + exercise
- Walk 30-60min 4-5x/wk ; 40-60min 1-2x/wk
- Mixed the pts serum pre- and post- w/ LNCaP cells (androgen-dependent)
- 30% reduction in growth post-intervention

Diet and Stress Reduction Effects on PSAV

- 10 men with PSA recurrence after RRP
- Enrolled in 4-mon low sat. fat, hi-fiber diet
- Combined with MBSR program
- Median doubling time of PSA increased from 6.5 to 17.7 months in 8 of 10 men
- 3 men had an absolute decrease in PSA

Low-Fat Diet

Recommendations:

- Modest evidence exists for a protective effect of a low-fat diet
- Unknown if reducing dietary fat will change the course of existing prostate cancer.
- May slow recurrence
- More studies are currently underway
Statin Use and CaP

- Retrospective review of men enrolled in diet and CaP study
- 72 w/ CaP, 150 w/ - bx, and 208 w/ nl. PSA
- Men ranged in age from 49-90 years
- Reviewed total days on statins, cumulative dose, average daily dose and total statin use

Shannon J et al ASCO 40th Annual Meeting
Statin Use and CaP Results

- 58% decreased risk of CaP and 55% lower risk of elevated PSA in users after adjusting for age and BMI
- Men using >19g for >3yrs and average daily dose of >40mg had 65% lower risk of CaP
- Statins appear to be protective but needs confirmation

Shannon J et al. ASCO 40th Annual Meeting
Saturated Fat

- Only type of fat clearly linked to heart disease
- Only type of fat strongly linked to cancer
- Cholesterol reduction
- Favorable hormonal effects? IGF-1?

## Selenium In Vitro Studies

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>Selenite</th>
<th>Se-Met</th>
<th>MSC</th>
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<tbody>
<tr>
<td>Membrane damage</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Cell growth inhibition</td>
<td>+++</td>
<td>++</td>
<td>++++</td>
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<tr>
<td>DNA synthesis inhibition</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Cell cycle block</td>
<td>S/G₂M</td>
<td>?</td>
<td>S</td>
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<tr>
<td>Cell death</td>
<td>Necrosis</td>
<td>Apoptosis and aberrant mitosis</td>
<td>Apoptosis</td>
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</tbody>
</table>

Natural Selenium Distribution
Selenium

• Clark reported on effects of selenium on skin cancer – 63% lower incidence of CaP
• Men with increased selenium in their toenails had significantly lower incidence of CaP
• Selenium deficiency may predispose to CaP

Selenium Problems - Clark Trial

- Prostate ca was secondary endpoint
- Majority of pts were selenium deficient
- Only 14% of pts with elevated PSA had a bx
- Bladder ca, breast ca, lymphoma were higher in the selenium group
- Incidence of lung ca was lower in the original study but was changed after further followup
Selenium

• 9345 Jap-Am men studied 1971-1977
• Surveillance of 20 yrs with 249 cases of ca.
• Deleted cases diagnosed in first 5 yrs
• Found 50% lower risk in pts in highest quartile of serum selenium vs. lowest (p=.02)
• No reduced risk in intermediate quartiles

Selenium

- Baltimore Longitudinal Study of Aging
- 52 pts w/ CaP vs 96 age- matched controls
- Measured levels 3.83 \( \pm \) 1.85 yrs prior to dx
- Lowest quartile (107ng/ml) had 4-fold higher risk of CaP
- Serum levels decreased with age

Selenium Tissue Levels

- 6 prostate specimens snap-frozen in OR
- All normal peripheral zone tissue
- Selenium levels measured with atomic fluorescence spectroscopy
- Compared to published reports from other organs

Arnold WN and Thrasher JB. Biol Trace Element Res. 91:277, 2003
Selenium Tissue Levels

• Dry weight conc. – 1.24-1.42 µg Se/gm
• Mean conc. – 1.32 µg Se/gm
• Highest known organ levels in autopsy studies are from kidney- 0.74-1.40 µg Se/gm
• Prostate appears well-endowed with Se

Arnold WN and Thrasher JB. Biol Trace Element Res. 91:277, 2003
Vitamin E
In Vitro Studies

- Moyad found that γ-tocopherol 1,000x more potent than α- in LNCaP cells
- Venkateswaran noted PC-3 and LNCaP cells exposed to physiological conc. of vit. E exhibit cell cycle arrest
- Gamma-tocopherol may be stronger antioxidant and higher cellular uptake

Moyad MA et al. Semin Urol Oncol. 17:85, 1999
Vitamin E: Finnish Cancer Prevention Study

- Followed 29,133 male smokers on beta-carotene (20mg), vitamin E (50mg), both or placebo for 6 years
- Incidence of CaP 32% lower in men on vit. E and ds-mortality was 41% lower
- No evidence of an effect due to beta-carotene

The ATBC Study Group. NEJM 330:1029, 1994
SELECT (Selenium and Vitamin E Chemoprevention Trial)

4 Arms (32,400 men over 5 years):
1. Selenium (200 µg/day)
2. Vitamin E (400 mg/day)
3. Selenium (200 µg/day) + vitamin E (400 mg/day)
4. Placebo

Antioxidants for Cancer Prevention: Meta-analysis of 68 Trials

- Reviewed trials of antioxidants for cancer prevention
- Beta-carotene, vitamin E and vitamin A increased overall mortality
- Vitamin C and selenium had no significant effect on mortality

Antioxidants for Cancer Prevention: Meta-analysis of 68 Trials

- Reviewed trials of antioxidants for cancer prevention
- Beta-carotene, vitamin E and vitamin A increased overall mortality
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Calcium Supplementation and CAP

- Approximately $\frac{1}{2}$ of studies show association between dairy and CAP
- CPS-II Nutritional Cohort and HPFS both found high calcium intake (> 2,000mg from food or supp.) increased risk
- Only 1% of pop. consumed that amount
- More moderate intake did not effect risk

Sonn, GA, et al. PCPD 8: 304, 2005
SELECT

- Men age >55 and nil DRE and PSA
- Endpoint: biopsy-detected CaP
- Biopsy recommended for abnormal DRE or PSA during 7-12 yr followup
- Results expected in 2013

Soy Products

- Average Asian diet contains 10 times the amount of soy products
- Isoflavones are present in up to 3mg/gm soy protein
- Average intake of isoflavones in Taiwan is 100mg/day
- Average intake of isoflavones in U.S. is 2-3mg/day

Genistein & Diadzein

• Inhibit both androgen dependent and independent CaP cell lines in vitro
• Inhibit CaP development in Lobund-Wistar rats
• LNCaP xenografts undergo apoptosis and reduced microvessel density when mice fed different diets of soy phytochemicals
• Inhibition through G2/M cell cycle arrest, downreg. cyclin B and upreg. p21

Peterson G et al. Prostate 22: 335-345, 1993
Pollard M et al. Prostate 45:101-105, 1999
LNCaP Growth in SCID Mice

Fred Hutchinson Soy RCT
n=81

• Double-blind, RCT comparing 83mg/d isoflavones (soy protein powder) to placebo
• Measured serum PSA at baseline and 12 months in healthy men age 50-80 years
• Mean PSA increased 0.5% more in study arm (p=.94)
• No difference in PSA velocity

In Vivo Effect on Human Prostate Tissue

- 12 pts enrolled in a dose-escalation study of soy extract 4 weeks prior to RRP
- Flav-ein capsules (3B’S Limited) with 28mg total isoflavones
- Four pts.-112mg/d, 4 pts.- 168mg/d and 4 pts.- 224mg/d
- Serum PSA, testosterone, DHEA and total estrogen done baseline and prior to RRP

In Vivo Effect on Human Prostate Tissue

- No consistent effect on PSA
- Testosterone level mean $\Delta$: pre-soy-5.004ng/ml to 3.175ng/ml post-soy
- Estrogen level mean $\Delta$: pre-soy-171.1pg/ml to 139.8pg/ml post-soy
- Downregulation of ER$\alpha$ and upregulation of cdc-2 and p-cdc-2 in Ca and nl tissue

Cdc-2 Protein Expression
pcdc-2 Protein Expression
Soy Consumption and CAP in Japanese Men

• Population-based prospective dietary questionnaire in 43,509 men
• All were Japanese men ages 45-74
• Questionnaire had 147 food item questions
• In 9 year follow-up 307 diagnosed with CAP-74 advanced and 220 localized

Soy Consumption and CAP

Results

• Total prostate cancer risk was not changed
• In men over 60 yrs there was a dose-dependent decrease in risk of localized prostate cancer
• Slight increase in the risk of advanced prostate cancer

Ongoing Phase 2 Trial

Histologically Confirmed Adenocarcinoma of the Prostate

Scheduled to Undergo Prostatectomy for Curative Therapy

Randomize

Legume 30pts
Soy Extract 30pts
Genistein 30pts
Lithium Carbonate
n=609

• Pts with psych disorders treated ≥1yr with lithium in 3 mental health centers
• 2396 age-, time- and center-matched controls
• Dose range 300-1800mg/d (modal 900mg)
• All pts matched against Nationwide Central Cancer Registry for malignancy
• No statistical diff. but significant inverse correlation with dose

Cohen Y et al. Medical Oncology 15: 32, 1998
Lithium Chloride Effect on Prostate Cell Lines

- PC-3, DU145 and LNCaP cells - proliferation, invasion and apoptosis (6-12mM LiCl)
- Proliferation - 5x10⁴ cells seeded in 12-well plates overnight then LiCl or KCl added
- Clonogenic survival - 10³ cell in 35-mm dish cultured with LiCl and counted daily x14d
- Cell invasion assay - 3D collagen gel

Liao X et al. FEBS Letters (accepted for publication)
Cell Proliferation

PC-3
- 0
- 3 mM
- 10 mM

* $P < 0.05$

Viable Cells (x 10^4)

day 0     day 1   day 2    day 3

DU145
- 0
- 3 mM
- 10 mM

* $P < 0.05$

Viable Cells (x 10^4)

day 0     day 1   day 2    day 3

Liao X, et al. FEBS Letters (accepted for publication)
Cell Proliferation

Liao X, et al. FEBS Letters (accepted for publication)
Colony Formation

Liao X, et al. FEBS Letters (accepted for publication)
β-Catenin Nuclear Translocation

Liao, X et al. FEBS Letters (accepted for publication)
Cell Cycle Distribution

Control

G1: 64.64%
S: 20.45%
G2/M: 14.91%

SB216763 (25 µM)

G1: 53.12%
S: 27.54%
G2/M: 19.34%

LiCl (10 mM)

G1: 26.46%
S: 53.20%
G2/M: 20.34%

S-Phase Cells (%)

Time Point

0h 6h 12h 18h 24h

Liao X, et al. FEBS Letters (accepted for publication)
Cell Invasion

Liao X, et al. FEBS Letters (accepted for publication)
Apoptosis

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<td>PARP</td>
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<tr>
<td>Caspase Inhibitor</td>
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<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

Liao X, et al. FEBS Letters (accepted for publication)
NSAIDs

- Prostaglandins and other eicosanoids synthesized from arachidonic acid via cyclooxygenase (COX) pathway
- Eicosanoids modulate DNA/RNA synthesis, cell communication, proliferation, invasive potential and immune surveillance
- NSAIDs inhibit eicosanoid biosynthesis through binding to COX protein
Aspirin and NSAIDs
Baltimore Longitudinal Study

• 887 men studied from 1980-95
• Adjusted for age, education and year
• 96 had CaP: 64% used ASA; 34% other NSAID and 26% acetaminophen
• Reduction in risk: 24% NSAID; 15% ASA; and none for acetaminophen

Aspirin and NSAIDs
Olmsted County Study

- 1362 men aged 50-79 years
- 589 used NSAIDs and 793 did not
- 4% of users and 9% of non-users dev. CaP (p= 0.001)
- Protective effect increased with age

NSAIDs in Prostate Cancer
Ohio State Case-Control Study

- 417 newly diagnosed CaP pts. compared to 420 group-matched controls
- Adjusted OR based on age and other confounders
- Regular daily intake of NSAIDs reduced risk of CaP by 66% (OR=0.34, 95% CI = 0.22-0.66, p<0.01)

Nelson JE and Harris RE Oncology Rep 7: 169, 2000
Long-term Adult-strength ASA and Cancer Incidence

• Reviewed cancer incidence in the Cancer Prevention Study II Nutrition Cohort
• A total of 69,810 men and 76,303 women
• Specifically addressed no use of ASA vs 5 years or greater daily use

Long-term Adult-strength ASA and Cancer Incidence

- During 10 yr follow-up 10,931 men were diagnosed with cancer
- Daily use of ASA for ≥5 yrs associated with 15% reduction in overall incidence
- Incidence of colorectal cancer reduced by 30%
- Incidence of CAP reduced by 20%

Dietary Supplements with Possible Prostate Cancer Effects

• Lycopenes and cruciferous vegetables—weak if any (PLCO Trial)
• Green tea polyphenols – *in vitro* only
• Pomegranate juice – *in vitro* and PSA doubling time effect
• Smoking – weak if any association

Wolk, A Acta Oncologica 44: 277, 2005
Vitamins, disease link reported

High-dose multivitamins may increase men's risk of dying from prostate cancer, study suggests.

The Associated Press
WASHINGTON | There is more worrisome news about vitamins: Taking too many may increase men's risk of dying from prostate cancer.

The study, being published today, doesn't settle the issue. But it is the biggest yet to suggest that high-dose multivitamins may harm the prostate, and is the latest chapter in the confusing quest to tell whether taking various vitamins really helps a variety of conditions or is a waste of money, or worse.

Government scientists turned to a study tracking the diet and health of almost 300,000 men.

About a third reported taking a daily multivitamin, and 5 percent were heavy users, swallowing the pills more than seven times a week.

Within five years of the study's start, 10,241 men had been diagnosed with prostate cancer. Some 1,476 had advanced cancer; 179 died.

Heavy multivitamin users were almost twice as likely to get fatal prostate cancer as men who never took the pills, concludes the study, in *Journal of the National Cancer Institute*.

Here is the twist: Overall, the researchers found no link between multivitamin use and early stage prostate cancer.

The researchers speculate that perhaps high-dose vitamins had little effect until a tumor appeared, and then could spur its growth.

Although similar but smaller studies have suggested a link, too, more rigorous research is needed, the National Cancer Institute scientists say.

This newest study involves men who voluntarily took vitamins.

Those most at risk — perhaps because they had a family history of the disease — may have been more likely to take the pills in hopes of avoiding their fate.
Night Shift and Cancer

Working at night to be listed as ‘probable’ cause of cancer

By Maria Cheng
The Associated Press

LONDON — Like UV rays and diesel exhaust fumes, working the graveyard shift will soon be listed as a “probable” cause of cancer.

It is a surprising step, validating a concept once considered wacky. And it’s based on research that finds higher rates of breast and prostate cancer among people whose workday starts after dark.

Next month, the International Agency for Research on Cancer, the cancer arm of the World Health Organization, will add overnight shift work as a probable carcinogen.

The higher cancer rates don’t prove working overnight causes cancer. There may be other factors common among graveyard shift workers that raise their risk. However, scientists suspect that overnight work is dangerous because it disrupts the body’s biological clock. The hormone melatonin, which can suppress tumor development, is normally produced at night.

If the graveyard shift theory proves correct, millions of people worldwide could be affected. Experts estimate that nearly 20% of workers in developed countries work night shifts.

Among the first to spot the night shift/cancer connection was Richard Stevens, a cancer epidemiologist and professor at the University of Connecticut Health Center. In 1987, Stevens published a paper suggesting a link between light at night and breast cancer.

He was trying to figure out why breast cancer incidence suddenly shot up starting in the 1930s in industrialized societies, where night work was considered a hallmark of progress. Most scientists were bewildered by his proposal.

But in recent years, several studies have found that women working at night over many years were more prone to breast cancer. Also, animals that have their light-dark schedules switched develop more cancerous tumors and die earlier. Some research also suggests that men working at night may have a higher rate of prostate cancer.

Because these studies mostly focused on nurses and airline crews, bigger studies in different populations are needed to confirm or disprove the findings.

There are still plenty of skeptics. And the “probable carcinogen” tag means merely that the link between overnight work and cancer is plausible.

The American Cancer Society website notes that carcinogens do not always cause cancer.

Still, many doubters of the night shift link may be won over by the IARC’s analysis to be published in the December issue of the journal Lancet Oncology.

“The indications are positive,” said Vincent Cogliano, who heads the agency’s carcinogen classifications unit. “There was enough of a pattern in people who do shift work to recognize that there’s an increase in cancer, but we can’t rule out the possibility of other factors.”

Scientists believe lower melatonin levels can raise the risk of developing cancer. Light shuts down melatonin production, so people working in artificial light at night may have lower melatonin levels.

Sleep deprivation may be another factor in cancer risk. People who work at night often are awake much of the day, too. Not getting enough sleep makes your immune system vulnerable to attack and less able to fight off potentially cancerous cells.

Even worse is flipping between daytime and overnight work.
Conclusions

• Decreasing wt, lowering fat intake and daily exercise may reduce the risk of CaP
• Selenium and Vit. E (SELECT Trial)
• Calcium and antioxidants in moderation-multivitamin correctly taken
• Soy products require further study
• Statins, ASA / NSAIDs require further study but may be beneficial for CA and heart
still safer here than at Michael Jackson’s!