

Expenditures

- Prostate- 8 billion 11.2%
- Lung- 9.6 billion 13.3%
- Breast 8.1 billion 11.2%

Presentation Outline

- Study Design
- Research Objectives
- Results
- Next Steps

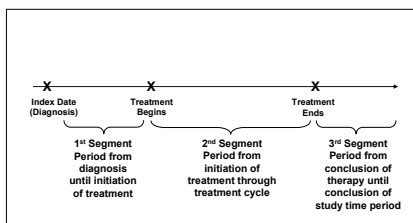
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Selection Criteria

- **Inclusion Criteria**
 - Men ≥ 40 years of age
 - Index date occurs during the enrollment period
 - Continuously eligible for at least 18 months (6-month pre-period and a minimum 12-month post-period)
- **Exclusion Criteria**
 - Members with ICD-9 claims for any other cancer

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Measurement Segments



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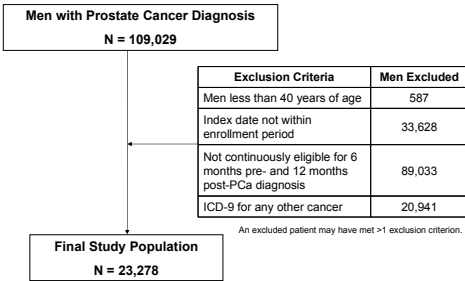
Data Sources

- PharMetrics
 - Data from over 85 health plans and 45 million lives
 - Mostly a commercial population (80%)
 - Timeframe of the dataset is 1995 to present (approximately a 6-month lag)



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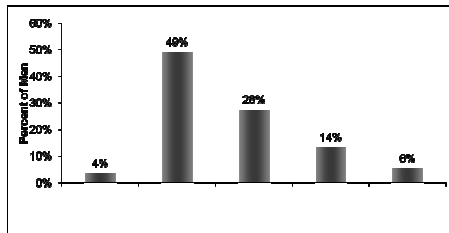
Patient Selection



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Age

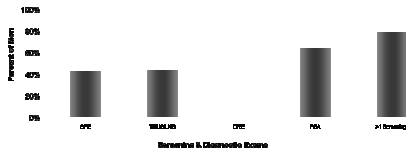
Mean age = 61.2 years



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Screening & Diagnostics

80% of men had screening/diagnostic exam(s) in the 6-month pre-period through the cancer index date. Men had PSA most often.

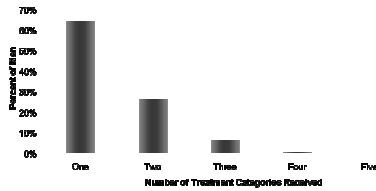


*35% had 1, 16% had 2, and 30% had ≥3 screening or diagnostic exams
DRE - Digital Rectal Exam, PSA - Prostate Specific Antigen, SPE - Surgical Pathological Exam, TRUS - Transrectal Ultrasound, LNB - Lymph Node Biopsy

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Number of Treatments

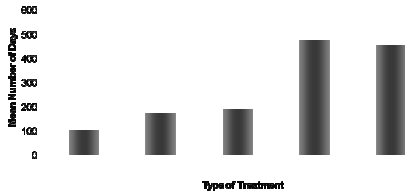
Of men that were treated, the majority received one type of treatment.



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Time to Treatment

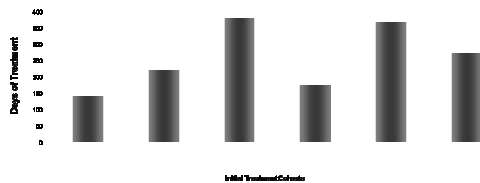
Of all men that received treatment, surgery occurred closest to diagnosis, and miscellaneous treatments occurred furthest from diagnosis (1.31 years).



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Average Duration of Treatment

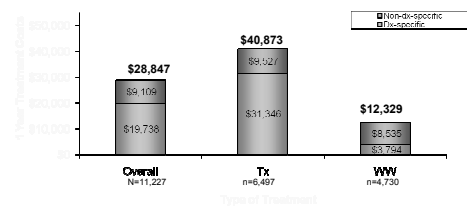
Mean days from first to last treatment ranged from 141 days for surgery cohort to 381 days for hormone therapy cohort.



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Average Annual Cost per Patient

Patients with prostate cancer cost \$28,847 in the 1 year following diagnosis. Those who received any treatment were more costly.

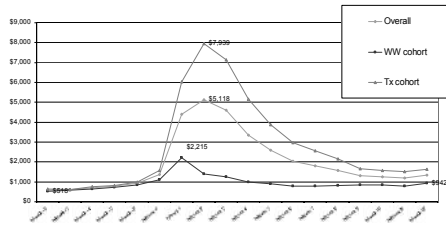


Costs were calculated from diagnosis through 1 year
WW - Watchful Waiting

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Average Total Monthly Medical Costs

Costs peak in the month following diagnosis and are highest for patients who receive treatment

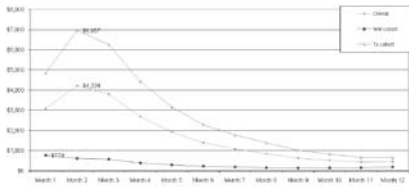


WW – Watchful Waiting

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Average Prostate Cancer-specific Monthly Medical Costs

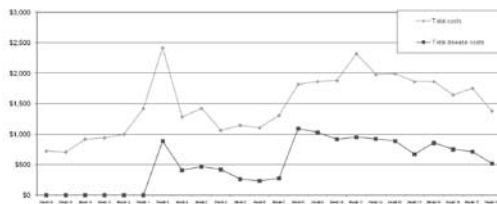
Disease-specific costs account for a high proportion of total costs



WW – Watchful Waiting

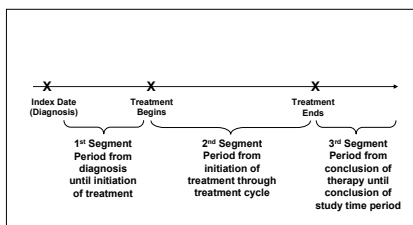
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Average Monthly Medical Costs: Patients Starting Therapy at ≥8 Months



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Measurement Segments



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Summary

- The majority of men receive one type of treatment.
- Surgery was the most common treatment. It was received by the youngest men and resulted in the highest costs and most clinical events.
- Annual costs, regardless of treatment pattern, were \$30K per patient in the year following diagnosis.
- Costs peaked in the month following diagnosis.
- The watchful waiting cohort had the lowest costs and fewest clinical events.

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Why Prostate Cancer Prevention?

- Significant public health risk
 - 186,000 new cases and 26,000 deaths yearly (2008)
- Risk factors (age, race, genes) are not modifiable
- Benefit of screening on mortality is unproven
- Therapy is associated with morbidity
 - That Leaves Prevention

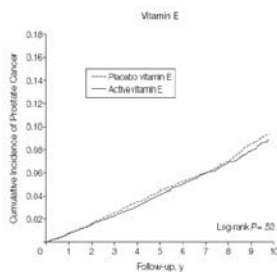
Prostate Cancer Diet & Exercise Risk Factors

- May **Increase** Risk
 - Fat / Red Meat
 - Cooking methods
 - Dairy/Calcium
 - Smoking
 - Total Calories, Body size
- May **Decrease** Risk
 - Plant-based Foods/ Vegetables
 - Tomatoes
 - Cruciferous
 - Soy/Legumes
 - Specific Nutrients
 - Selenium
 - Vitamin E
 - Carotenoids/Lycopene
 - Total Antioxidants
 - Fish / Marine Omega 3 Fatty acids
 - Moderate to Vigorous Exercise



Courtesy J. Chan, UCSF

Vitamin E and Prostate Cancer Physicians Health Study II



N = 14,641

Gaziano et al, JAMA (in press)

Effect of Dutasteride on Cancer in BPH Trials

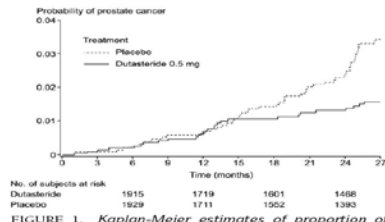
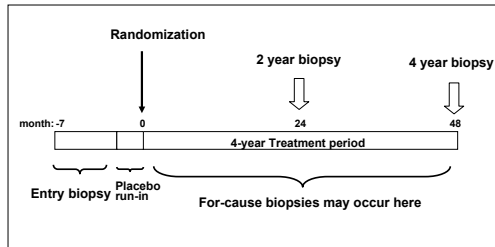


FIGURE 1. Kaplan-Meier estimates of proportion of subjects experiencing a prostate cancer adverse event with onset after randomization (study population).

Andriole et al, Urology 64: 537, 2004

REDUCE Schema



Andriole et al, J Urol 172:1314, 2004

REDUCE and PCPT Study Design Differences

Parameter	REDUCE	PCPT
Study drug	AVODART 0.5 mg daily	Finasteride 5 mg daily
Study duration	4 years	7 years
Number of patients	8,250	18,882
Age (years)	50 to 75	≥ 55
Baseline biopsies	Yes (1 negative biopsy)	No
Follow up (planned) biopsies	Year 2 and Year 4 (mandatory)	Year 7 (recommended)
PSA entry criteria	2.5 - 10 ng/mL if 50-60 years; 3 - 10 ng/mL if > 60	≤ 3 ng/mL
Location	International	United States

Note: Due to the differences in study design and patient population, comparisons of the results from REDUCE and PCPT cannot be made.

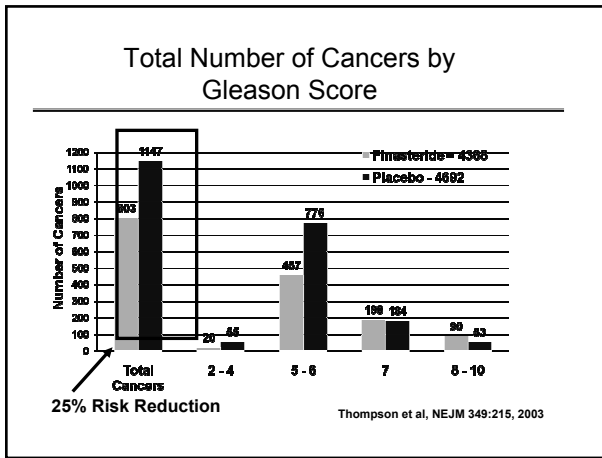
1. Thompson M et al. NEJM 2003;349(3):215-224. 2. Andriole G et al for the REDUCE Study Group. J Urol 2004;172:1314-1317. 3. Ciorella L.G. Curr Opin Uro 2005;15:2932. 4. Musquera M et al. Expert Reviews 2008;8(7):1079-1079.

REDUCE: Primary endpoint (analysis ongoing)

Dutasteride reduced the risk of prostate cancer over 4 years by **23%**
 $p < 0.0001$
 (857 placebo vs 659 dutasteride)

Note: Analysis of data from the REDUCE trial is ongoing. Once the analysis is complete, the results will be published.

Data on file, GlaxoSmithKline (ARI40006)



Statins and Prostate Cancer Risk

Risk Group	Risk Ratio
Any Px Cancer	1.09
Advanced Px Cancer	
Any use	0.51
Use < 5 yrs	0.60
Use > 5 yrs	0.26

Health Professionals Follow-up Study, N = 34,989
Platz et al, JNCI 98:1819-25, 2006

Prevention: What to Tell Patients

Historical Imperative for Prevention

- Superior doctors prevent the disease.
- Mediocre doctors treat the disease before evident.
- Inferior doctors treat the full blown disease.

Nai-Ching (2600 B.C. 1st Chinese Medical Text)

