Ruolo del PSA nello screening

Giovanni L. PAPPAGALLO

G.L. Pappagallo: relazioni con l'Industria farmaceutica e potenziali conflitti di interesse

Azienda	Relazione	Patologia
Sanofi	training area medica, consulenza clinico-epidemiologia	ca. prostata, m. diabetica, m. cardiovascolari, sclerosi multipla
Janssen	partecipazione advisory board, produzione *value dossier*	ca. prostata
Takeda	partecipazione advisory board, training forza vendite	ca. prostata, ca.mammella
Astellas	partecipazione advisory board, training area medica	ca. prostata
Pfizer	training area medica	ca. rene, artrite reumatoide, m. cardiovascolari
GSK	training area medica	ca. rene
Roche	training forza vendite,consulenza clinico-epidemiologica	ca. polmone, ca. ovaio
Novartis	training forza vendite	ca. rene, ca. mammella
UCB	training forza vendite, produzione *value dossier*	m. di Parkinson, m. epilettica, artrite reumatoide, artrite psoriasica, spondilite anchilosante
Pierre Fabre	training forza vendite	ca. vescica

The well-known actor says a PSA test detected prostate cancer and saved his life. Medical experts say the test is flawed and often unnecessary.

Despite actor Ben Stiller's recommendation, many medical professionals are still skeptical about men undergoing a once common screening for prostate cancer.


Con il Patrocinio di
AIOM
RAO
SIU
AIRO
IL TEAM MULTIDISCIPLINARE NEL
CARCINOMA DELLA PROSTATA
NEGRAR | 24 novembre 2016
Ospedale Sacro Cuore - Don Calabria
Sala Perez

La Scienza…

PRINCIPLES AND PRACTICE OF SCREENING FOR DISEASE

J. M. G. WILSON
Principal Medical Officer, Ministry of Health, London, England

G. JUNGNER
Chief, Clinical Chemistry Department, Sahlgren's Hospital, Gothenburg, Sweden

WORLD HEALTH ORGANIZATION
GENEVA
1968

(1) The condition sought should be an important health problem.
(2) There should be an accepted treatment for patients with recognized disease.
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(8) Th[illegible] tients.
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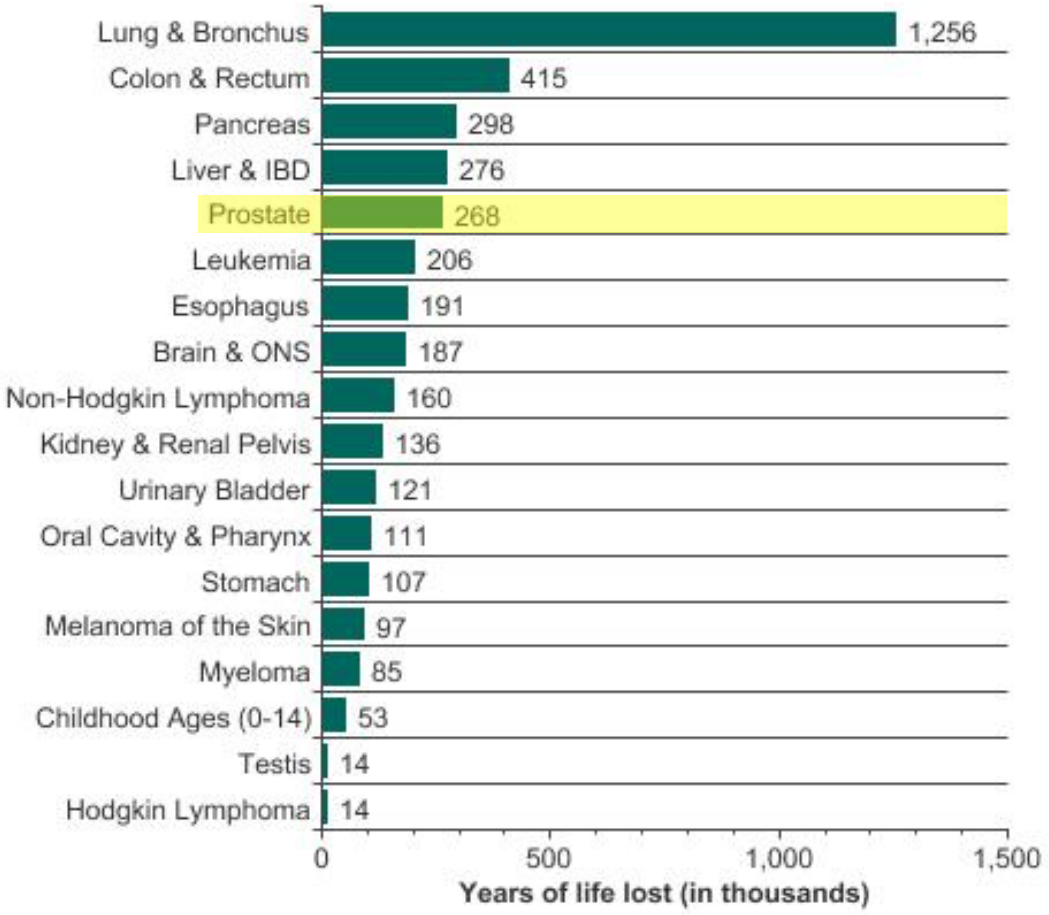
Rilevanza del problema per la salute pubblica

NATIONAL CANCER INSTITUTE

Cancer Trends Progress Report

Person-years of life lost in 2012 due to cancer, total U.S., all races, males



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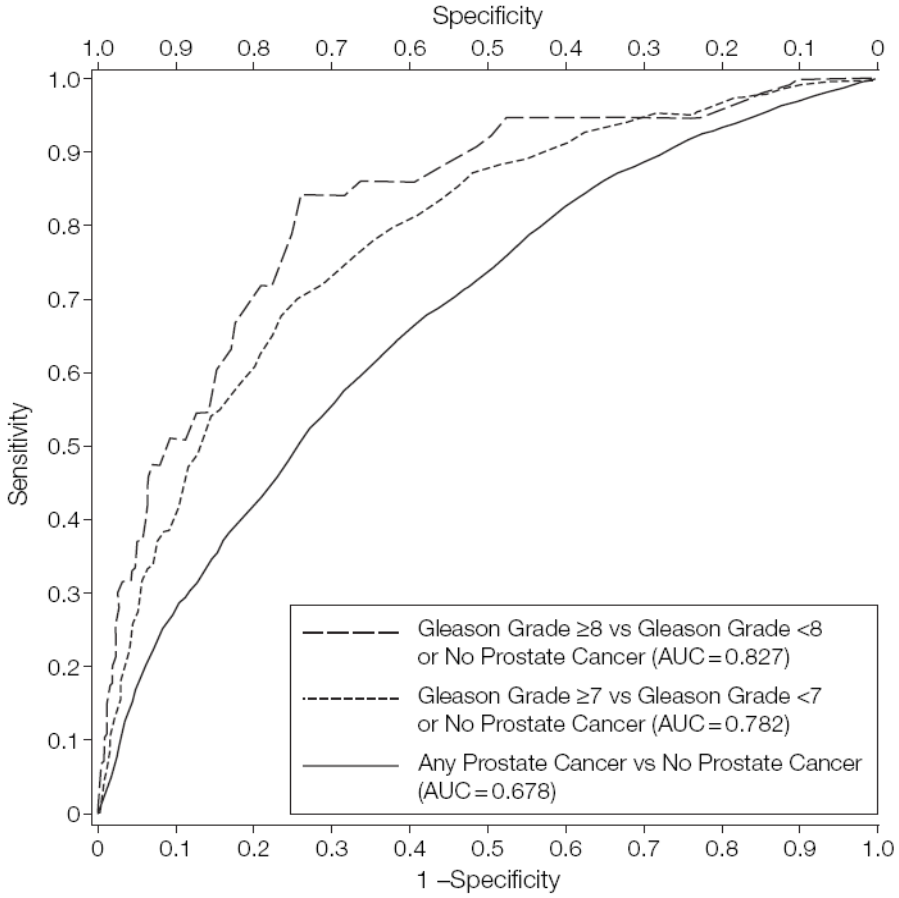
Disponibilità di un test diagnostico attendibile

Operating Characteristics of Prostate-Specific Antigen in Men With an Initial PSA Level of 3.0 ng/mL or Lower

Ian M. Thompson, MD	Phyllis J. Goodman, MS
Donna Pauler Ankerst, PhD	John J. Crowley, PhD
Chen Chi, MS	Howard L. Parnes, MD
M. Scott Lucia, MD	Charles A. Coltman, Jr, MD

JAMA, July 6, 2005—Vol 294, No. 1



There is no cutpoint of PSA with simultaneous high sensitivity and high specificity for monitoring healthy men for prostate cancer, but rather a *continuum* of prostate cancer risk at all values of PSA

Prostate specific antigen for early detection of prostate cancer: longitudinal study

Benny Holmström, urologist,[1,2] Mattias Johansson, postdoctoral fellow,[2,3] Anders Bergh, professor of pathology,[4] Ulf-Håkan Stenman, professor of clinical chemistry,[5] Göran Hallmans, professor of nutritional

positive likelihood ratio above 10
strong evidence to "rule in" disease

negative likelihood ratio below 0.1
sufficient evidence to "rule out" disease

predicti

PSA cut-off	Sensitivity*	Positive likelihood ratio†	Specificity§	Negative likelihood ratio¶
0.5	0.99	1.15	0.13	0.04
1	0.96	1.73	0.44	0.08
2	0.78	3.15	0.75	0.30
3	0.59	4.51	0.87	0.47
4	0.44	5.45	0.92	0.61
5	0.33	6.35	0.95	0.70
10	0.13	12.34	0.99	0.88
20	0.05	28.11	1.00	0.95

No cut-off value for prostate specific antigen attains the likelihood ratios formally required for a screening test.

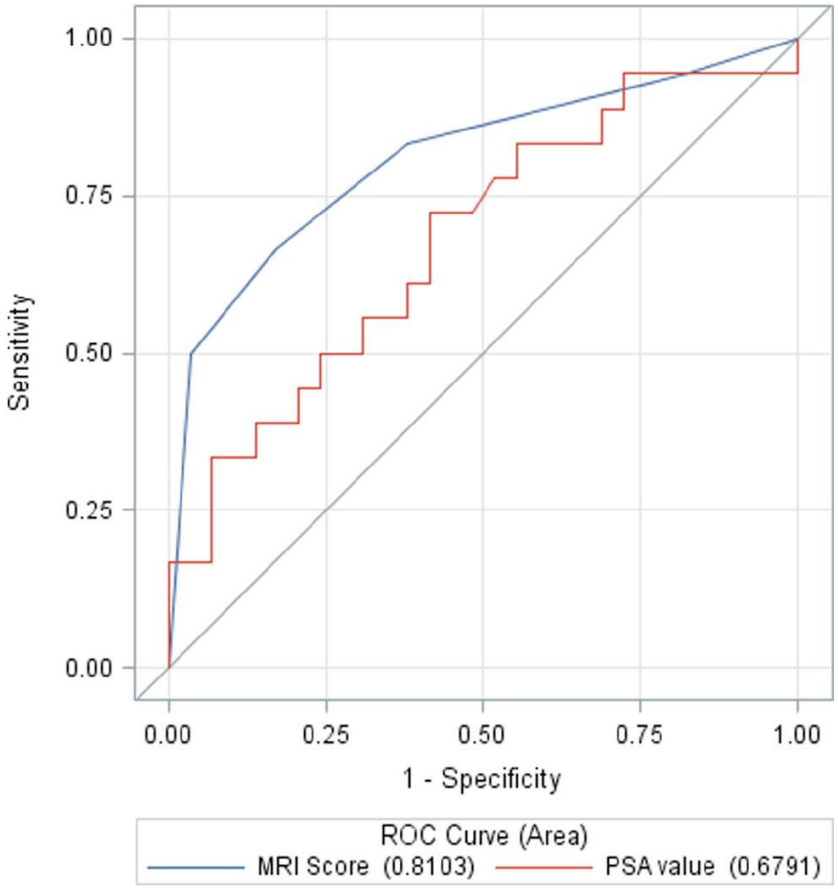
A Pilot Study to Evaluate the Role of Magnetic Resonance Imaging for Prostate Cancer Screening in the General Population

Robert K. Nam,* Christopher J. D. Wallis, Jessica Stojcic-Bendavid, Laurent Milot, Christopher Sherman, Linda Sugar and Masoom A. Haider

THE JOURNAL OF UROLOGY® Vol. 196, 361-366, August 2016

Table 1. *Multivariate logistic regression analysis of effect of PSA and MRI to predict prostate cancer*

Covariate	Adjusted OR (95% CI)	p Value
Age	1.1 (1.0—1.2)	0.07
DRE:		
Normal	1.0	
Nodule	4.2 (0.1—10.0)	0.43
PSA/1 ng/ml	1.1 (0.9—1.4)	0.21
MRI score/U	2.7 (1.4—5.4)	0.004



Randomized ongoing study NCT02799303

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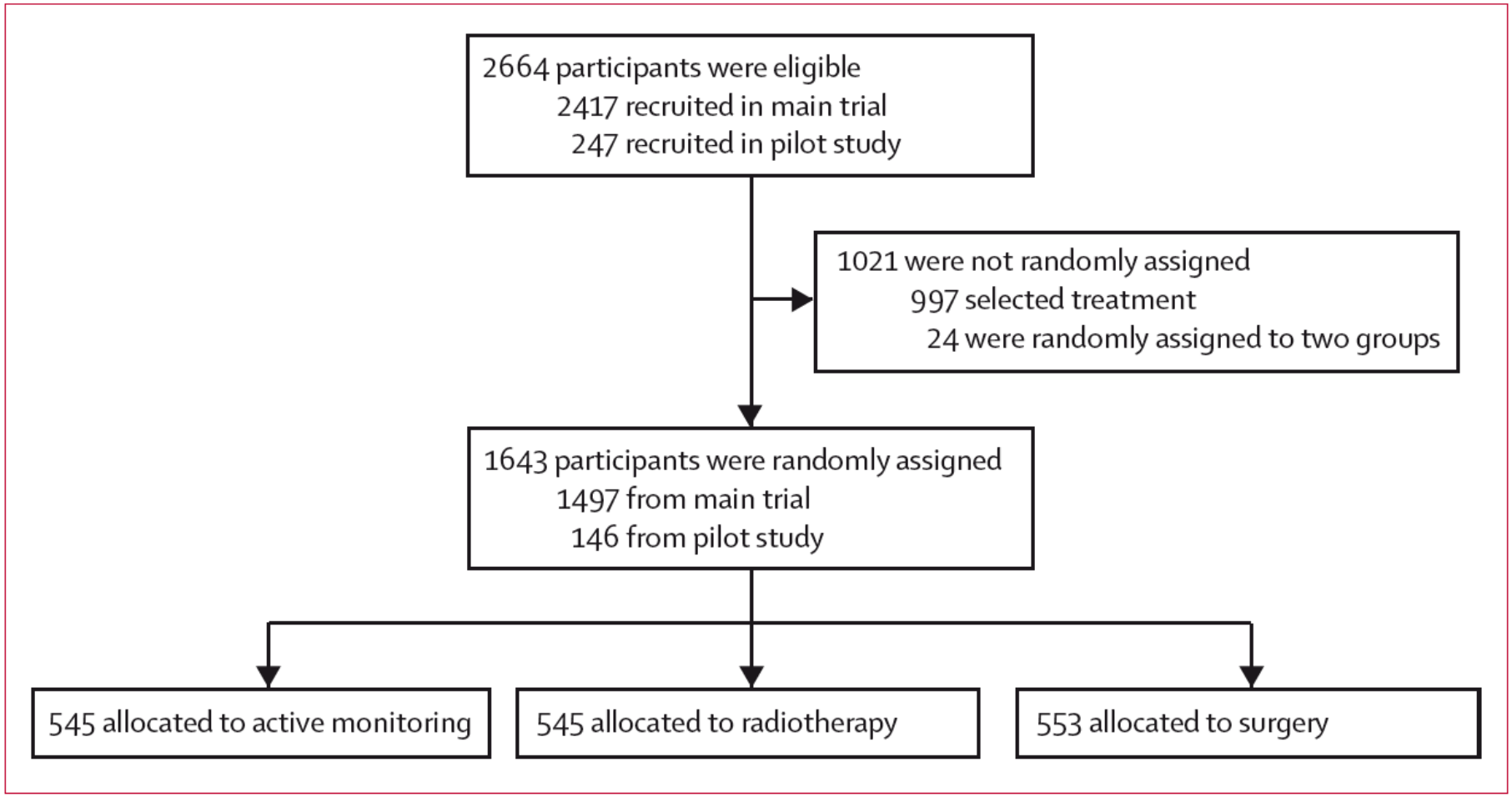
Esistenza di un trattamento di provata efficacia per la malattia oggetto di screening

Active monitoring, radical prostatectomy, or radiotherapy for localised prostate cancer: study design and diagnostic and baseline results of the ProtecT randomised phase 3 trial

J Athene Lane, Jenny L Donovan*, Michael Davis, Eleanor Walsh, Daniel Dedman, Liz Down, Emma L Turner, Malcolm D Mason, Chris Metcalfe, Tim J Peters, Richard M Martin, David E Neal*, Freddie C Hamdy*, for the ProtecT study group†*

Lancet Oncol **2014; 15: 1109–18**



10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer

F.C. Hamdy, J.L. Donovan, J.A. Lane, M. Mason, C. Metcalfe, P. Holding, M. Davis, T.J. Peters, E.L. Turner, R.M. Martin, J. Oxley, M. Robinson, J. Staffurth, E. Walsh, P. Bollina, J. Catto, A. Doble, A. Doherty, D. Gillatt, R. Kockelbergh, H. Kynaston, A. Paul, P. Powell, S. Prescott, D.J. Rosario, E. Rowe, and D.E. Neal, for the ProtecT Study Group*

DOI: 10.1056/NEJMoa1606220

Variable	Active Monitoring (N=545)	Surgery (N=553)	Radiotherapy (N=545)	P Value*
Incidence of metastatic disease				
Person-yr of follow-up free of metastatic disease	5268	5377	5286	
No. of men with metastatic disease	33	13	16	
Metastatic disease per 1000 person-yr (95% CI)	6.3 (4.5–8.8)	2.4 (1.4–4.2)	3.0 (1.9–4.9)	0.004
All-cause mortality				
Total person-yr in follow-up	5393	5422	5339	
No. of deaths due to any cause	59	55	55	
All-cause deaths per 1000 person-yr (95% CI)	10.9 (8.5–14.1)	10.1 (7.8–13.2)	10.3 (7.9–13.4)	0.87

Metastasis Free Survival (MFS) is a Surrogate for Overall Survival (OS) in Localized Prostate Cancer (CaP).

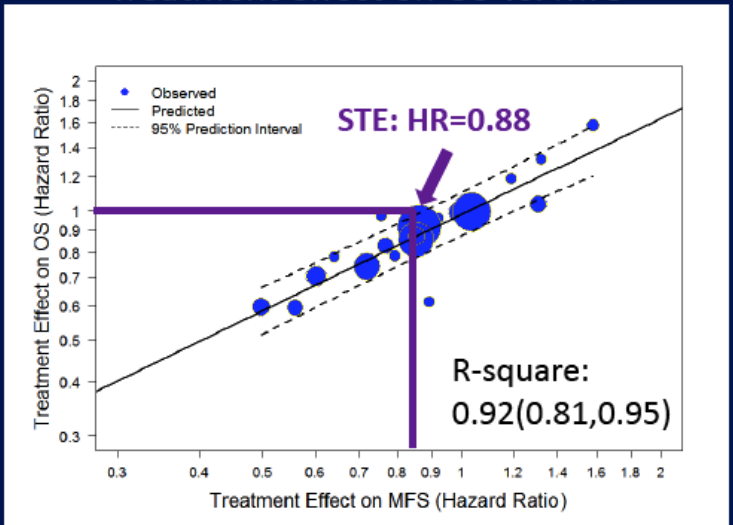
Wanling Xie, MS
(Dana Farber Cancer Institute, Boston)
On behalf of
The Intermediate Clinical Endpoints in CaP (ICECaP) Working Group

esmo.org

Surrogacy Threshold Effects (STE)

STE is defined as the min. treatment effect on the surrogate necessary to predict a non-zero effect on the true endpoint (Hazard ratio<1) in a future trial (Burzykowski and Buyse, 2006).

Treatment effect on OS vs. MFS

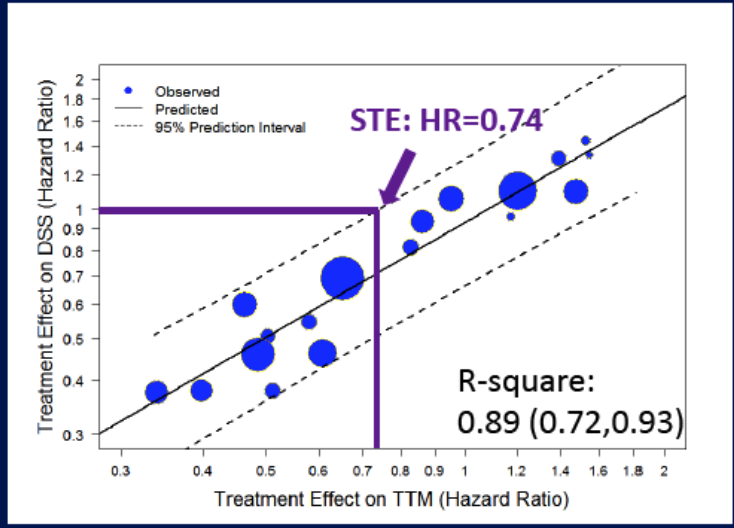


≥12% risk reduction in MFS

↓

>0 risk reduction in death

Treatment effect on DSS vs. TTM



≥26% risk reduction in TTM

↓

>0 risk reduction in CaP death

Presented by W. Xie

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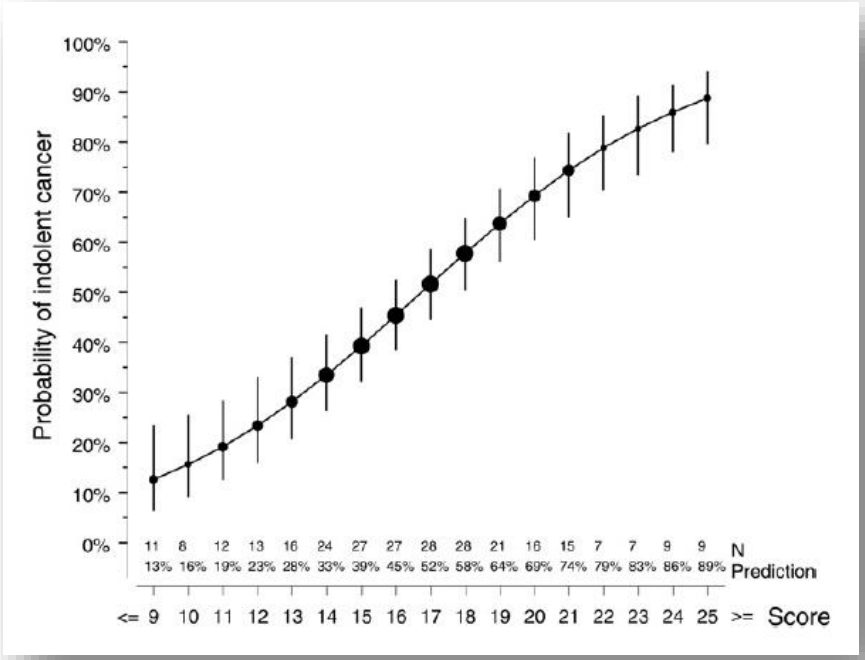
Accordo su quali pazienti sottoporre a trattamento attivo

Prediction of Indolent Prostate Cancer: Validation and Updating of a Prognostic Nomogram

E. W. Steyerberg,* M. J. Roobol, M. W. Kattan, T. H. van der Kwast, H. J. de Koning and F. H. Schröder

THE JOURNAL OF UROLOGY® Vol. 177, 107-112, January 2007



Validation of Pretreatment Nomograms for Predicting Indolent Prostate Cancer: Efficacy in Contemporary Urological Practice

Fei Dong, Michael W. Kattan, Ewout W. Steyerberg, J. Stephen Jones, Andrew J. Stephenson, Fritz H. Schröder and Eric A. Klein*

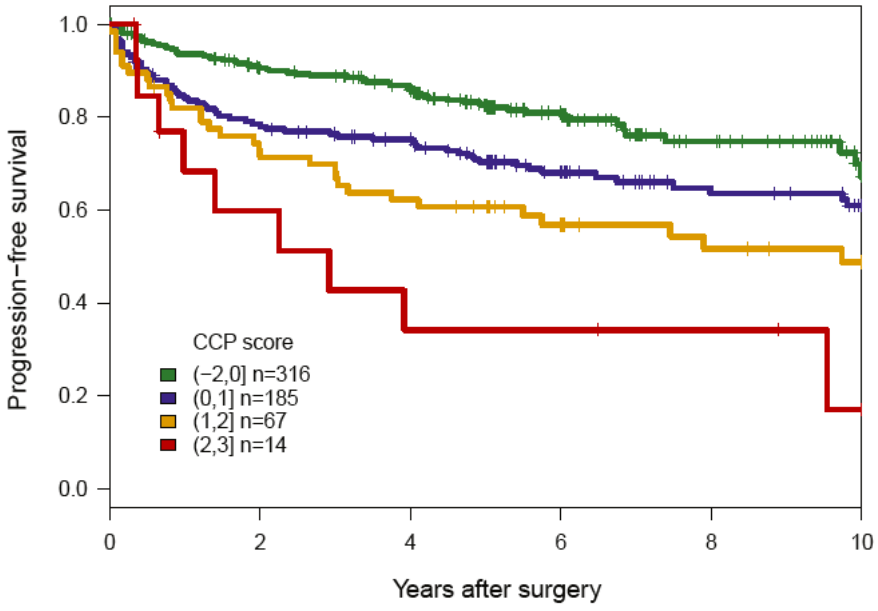
THE JOURNAL OF UROLOGY® Vol. 180, 150-154, July 2008

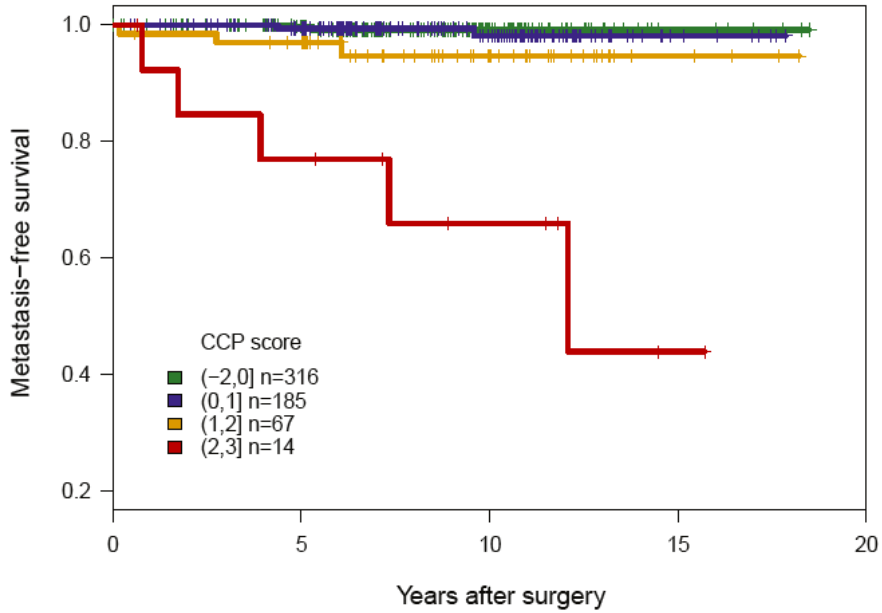
Prognostic Utility of the Cell Cycle Progression Score Generated from Biopsy in Men Treated with Prostatectomy

Jay T. Bishoff,*,†,‡ Stephen J. Freedland,†,§ Leah Gerber, Pierre Tennstedt, Julia Reid,‡ William Welbourn,‡ Markus Graefen, Zaina Sangale,‡ Eliso Tikishvili,‡ Jimmy Park,‡ Adib Younus,‡ Alexander Gutin,‡ Jerry S. Lanchbury,‡ Guido Sauter, Michael Brawer,‡ Steven Stone‡ and Thorsten Schlomm

THE JOURNAL OF UROLOGY® Vol. 192, 409-414, August 2014

Conclusions: The cell cycle progression score derived from a biopsy sample was associated with adverse outcomes after surgery. These results indicate that the score can be used at disease diagnosis to better define patient prognosis and enable more appropriate clinical care.

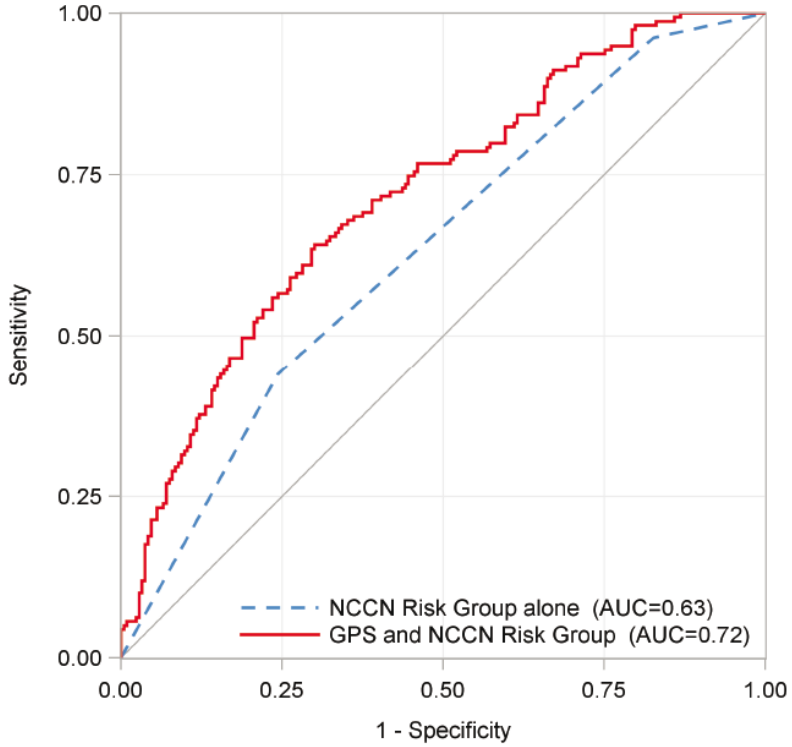




A Biopsy-based 17-gene Genomic Prostate Score Predicts Recurrence After Radical Prostatectomy and Adverse Surgical Pathology in a Racially Diverse Population of Men with Clinically Low- and Intermediate-risk Prostate Cancer

Jennifer Cullen[a,*], *Inger L. Rosner*[b], *Timothy C. Brand*[c], *Nan Zhang*[d], *Athanasios C. Tsiatis*[d], *Joel Moncur*[b], *Amina Ali*[a], *Yongmei Chen*[a], *Dejan Knezevic*[d], *Tara Maddala*[d], *H. Jeffrey Lawrence*[d], *Phillip G. Febbo*[d], *Shiv Srivastava*[a], *Isabell A. Sesterhenn*[e], *David G. McLeod*[b]

EUROPEAN UROLOGY XXX (2014) XXX–XXX



Receiver Operating Characteristic (ROC) curves for adverse pathology in patients with biopsy GS 3+3 and 3+4 and available NCCN risk groups.

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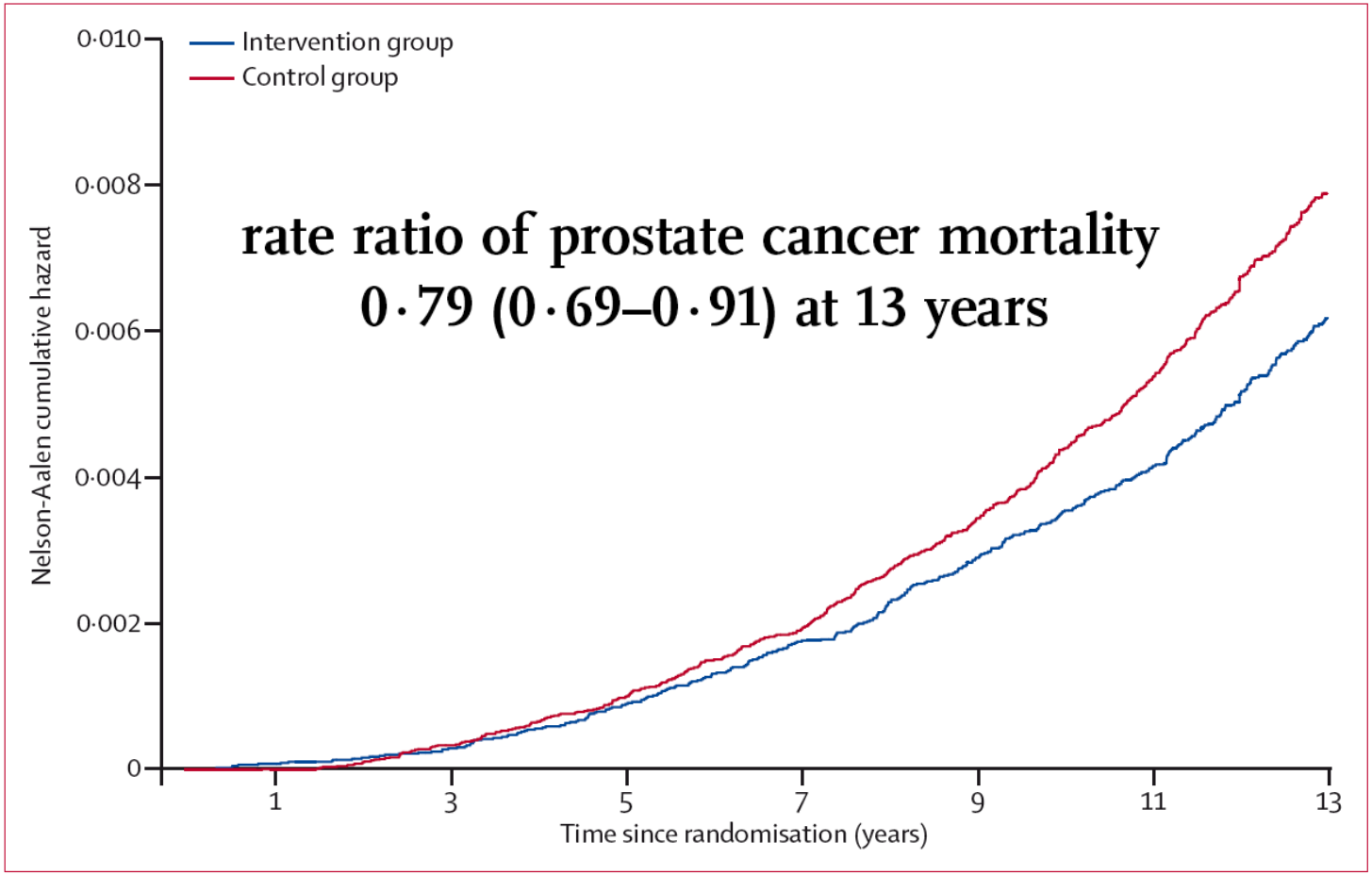
Bilancio positivo tra benefici e "danni"

Screening and prostate cancer mortality: results of the European Randomised Study of Screening for Prostate Cancer (ERSPC) at 13 years of follow-up

*Fritz H Schröder, Jonas Hugosson, Monique J Roobol, Teuvo L J Tammela, Marco Zappa, Vera Nelen, Maciej Kwiatkowski, Marcos Lujan, Liisa Määttänen, Hans Lilja, Louis J Denis, Franz Recker, Alvaro Paez, Chris H Bangma, Sigrid Carlsson, Donella Puliti, Arnauld Villers, Xavier Rebillard, Matti Hakama, Ulf-Hakan Stenman, Paula Kujala, Kimmo Taari, Gunnar Aus, Andreas Huber, Theo H van der Kwast, Ron H N van Schaik, Harry J de Koning, Sue M Moss, Anssi Auvinen, for the ERSPC Investigators**

www.thelancet.com **Published online August 7, 2014** **http://dx.doi.org/10.1016/S0140-6736(14)60525-0**

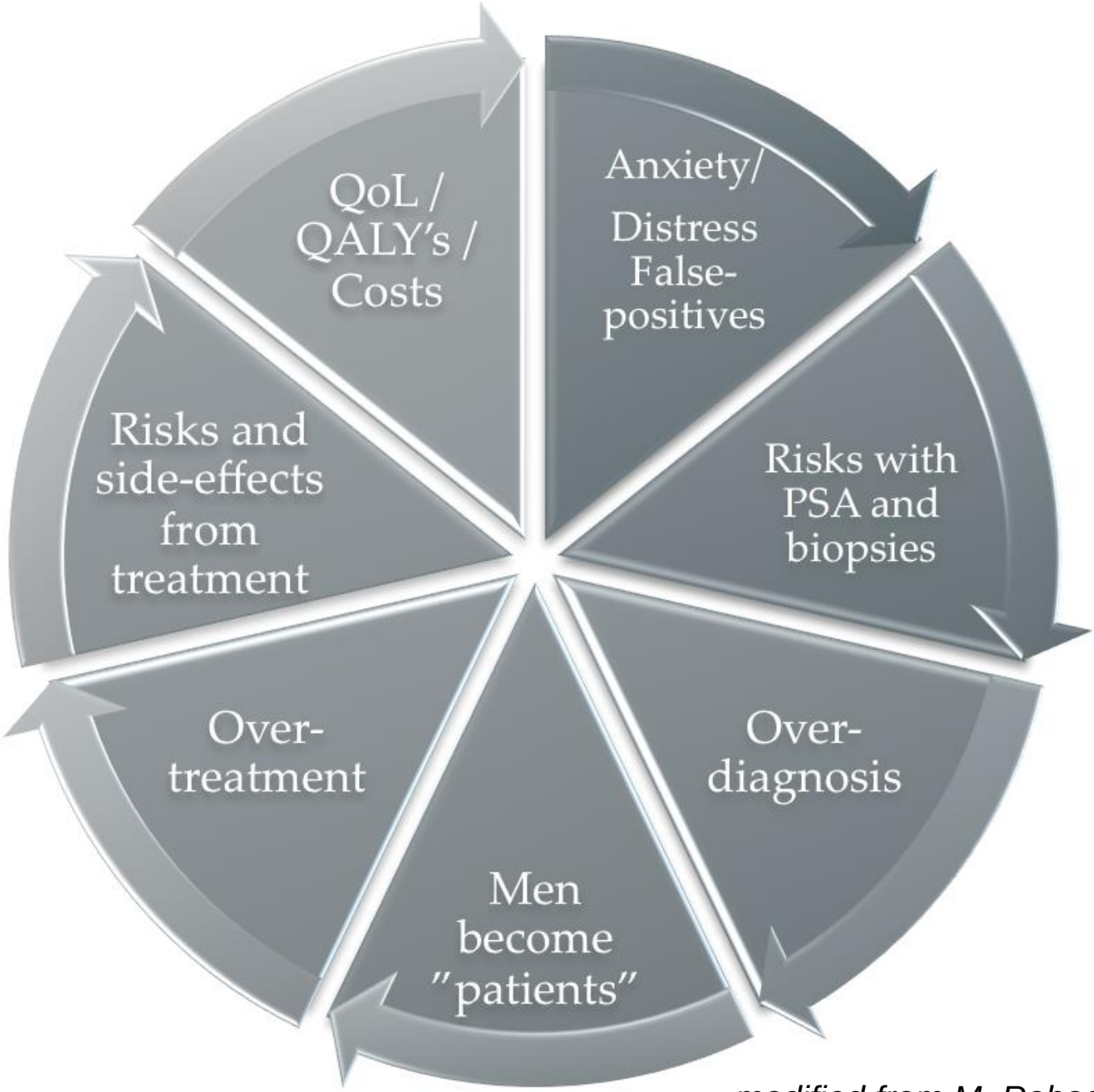


European randomised study of screening for prostate cancer (ERSPC), an up-date

Jonas Hugosson
Professor in Urology
Sahlgrenska Academy, University of Gothenburg, Sweden

Time-period	PC deaths in control group	PC deaths in screen group	RR (attenders)	95 % CI
1-9	278	193	0.85	0.70-1.03
1-11	415	265	0.78 (0.71)	0.66-0.91 (p=0.002)
1-13	545	355	0.79 (0.73)	0.69-0.91 (p=0.001)

	NNI	95 % CI	NND	95 % CI
1-11 years	979	594-2776	35	21-96
1-13 years	781	490-1929	27	17-66



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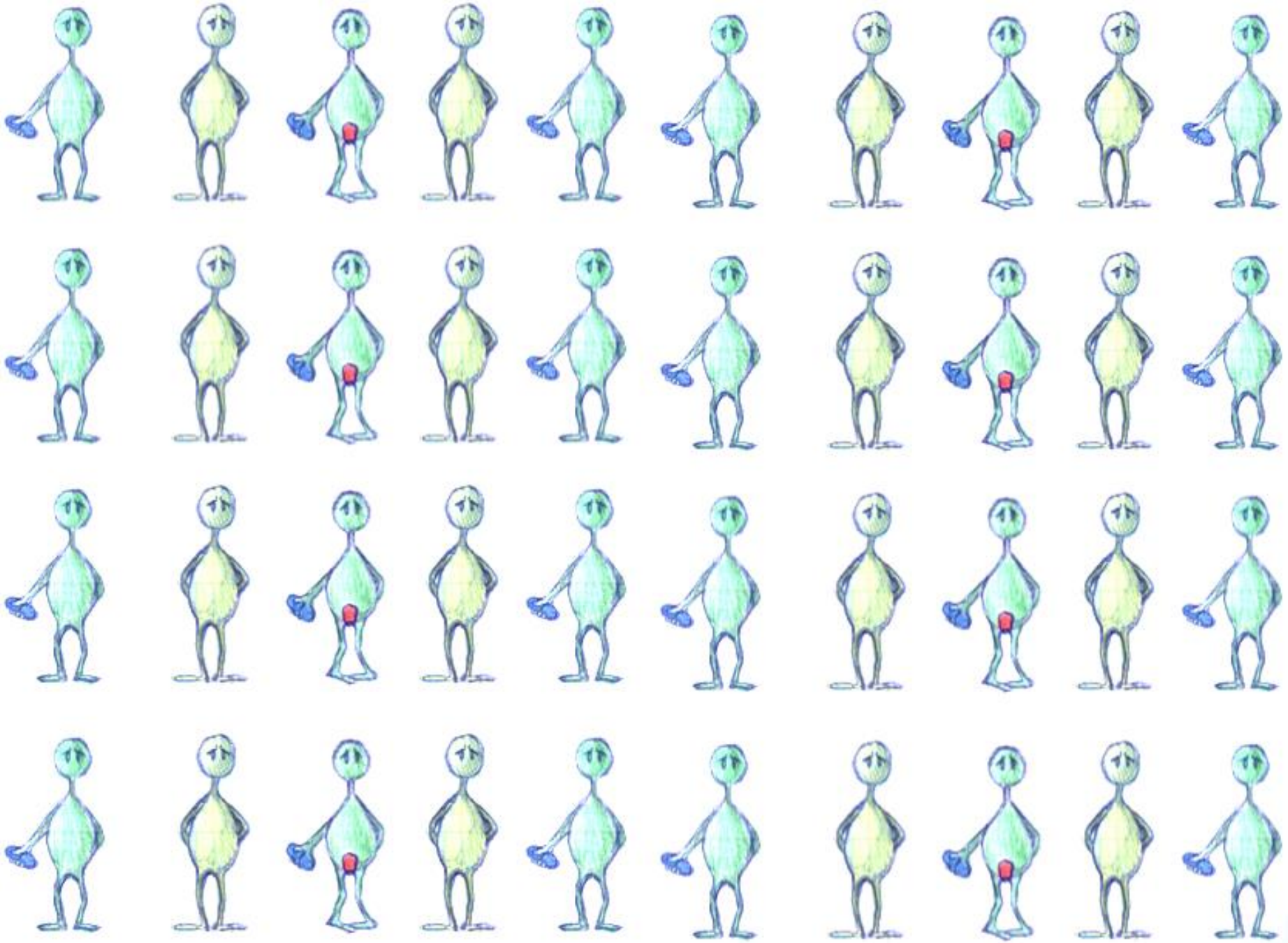

Screening and prostate cancer mortality: results of the European Randomised Study of Screening for Prostate Cancer (ERSPC) at 13 years of follow-up

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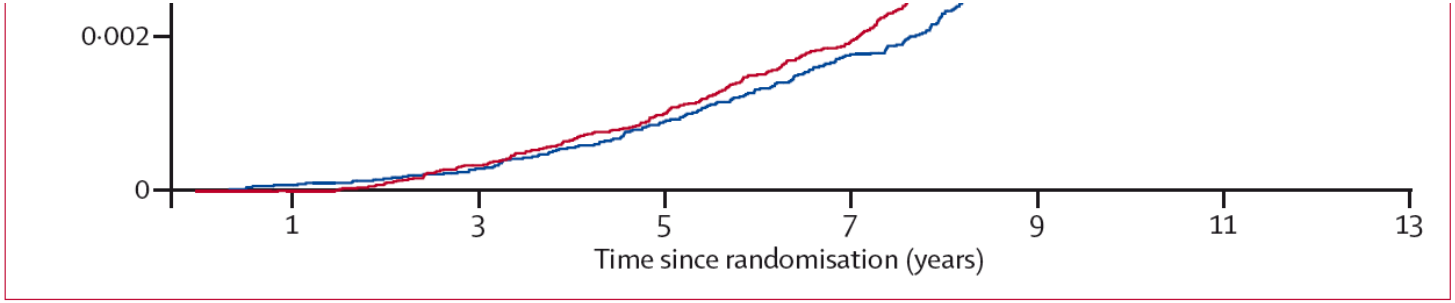
www.thelancet.com **Published online August 7, 2014** **http://dx.doi.org/10.1016/S0140-6736(14)60525-0**

Despite our findings, further quantification of harms and their reduction are still considered a prerequisite for the introduction of populated-based screening.



Nella pratica…

PSA Screening and Guidelines

- **USPSTF**: grade D recommendation against PSA screening for men of all ages

The New York Times

Why Was Warren Buffett Screened for Prostate Cancer?

CANCER | By TARA PARKER-POPE | April 18, 2012, 4:53 PM | 136 Comments

Ozier Muhammad/The New York Times

PSA Screening and Guidelines

- **USPSTF**: grade D recommendation against PSA screening for men of all ages

Abandoning screening altogether, would eliminate overdiagnosis but also would result in a doubling of patients presenting with metastatic disease and a 13% to 20% increase in prostate cancer deaths by 2025

Expected Population Impacts of Discontinued Prostate-Specific Antigen Screening

Roman Gulati, MS[1]; Alex Tsodikov, PhD[2]; Ruth Etzioni, PhD[1]; Rachel A. Hunter-Merrill, MA[1]; John L. Gore, MD[3]; Angela B. Mariotto, PhD[4]; and Matthew R. Cooperberg, MD[5]

Cancer 2014;000:000-000.

	Continued		Discontinued	
	FHCRC	UMICH	FHCRC	UMICH
Localized cases				
Screen detections				
Overdiagnoses	1,122,900	705,200	0	0
Early detections	1,763,600	2,071,400	0	0
Clinical detections	795,600	890,900	1,372,400	1,679,500
Metastatic cases	127,900	129,300	271,100	291,300
Prostate cancer deaths				
Base case PSA efficacy	283,500	284,600	319,400	342,000
Reduced PSA efficacy	284,300	285,400	301,800	320,700

FHCRC, Fred Hutchinson Cancer Research Center UMICH, University of Michigan

Prostate Needle Biopsy Outcomes in the Era of the U.S. Preventive Services Task Force Recommendation against Prostate Specific Antigen Based Screening

John S. Banerji, Erika M. Wolff, John D. Massman, III, Katherine Odem-Davis,* Christopher R. Porter and John M. Corman†

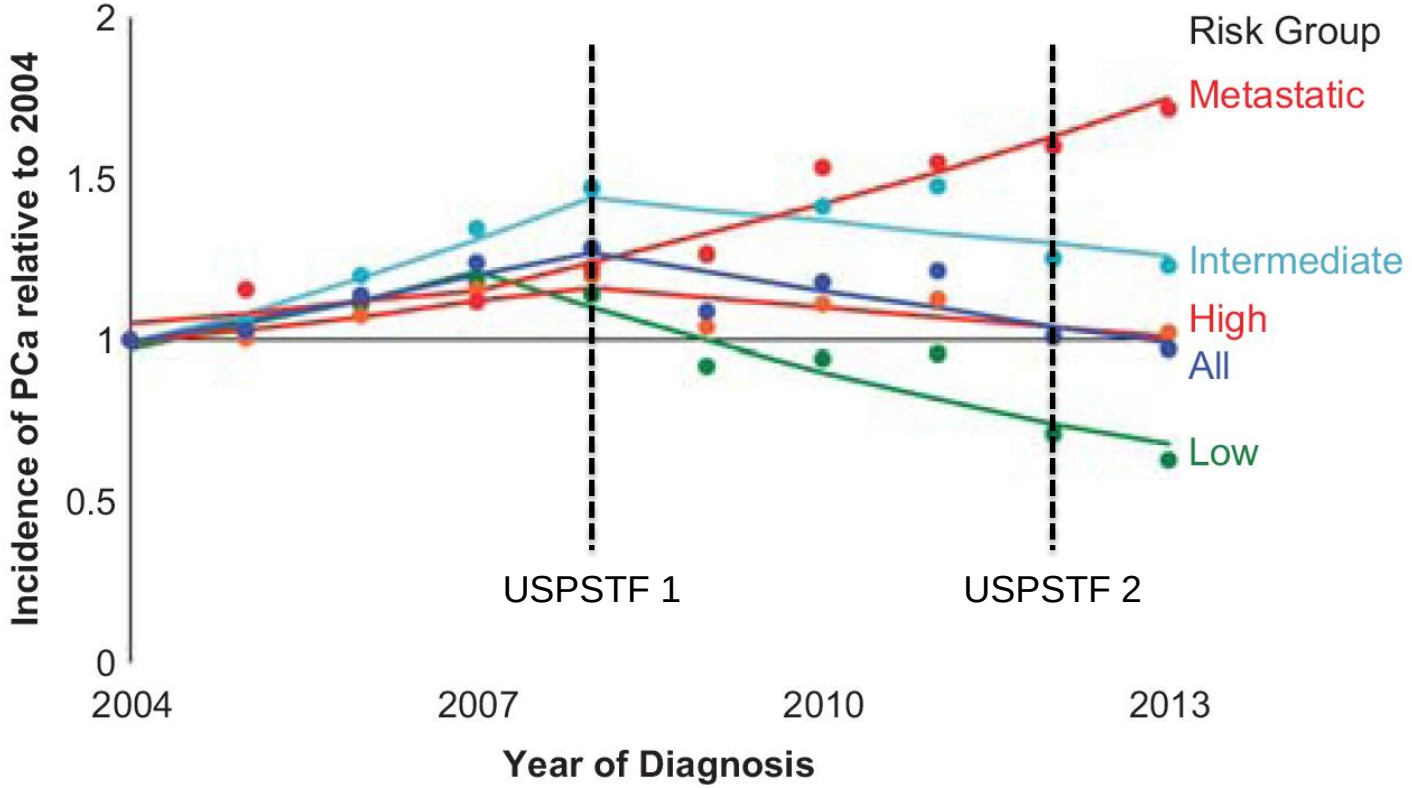
THE JOURNAL OF UROLOGY® Vol. 195, 66-73, January 2016

	Immediately Before USPSTF (30 mos) vs After USPSTF	
	% Absolute Risk Difference (CI)	Relative Risk (CI)
Ca	2.46 (−4.87, 9.80)	1.05 (0.91, 1.22)
Gleason 4+3 or greater	1.74 (−1.88, 5.37)	1.15 (0.86, 1.56)
D'Amico high risk*	11.55 (1.35, 21.75)	1.33 (1.03, 1.72)
CAPRA high risk*	7.24 (−1.21, 15.69)	1.42 (0.94, 2.15)

Increasing incidence of metastatic prostate cancer in the United States

AB Weiner[1], RS Matulewicz[1], SE Eggener[2] and EM Schaeffer[1]

Prostate Cancer and Prostatic Diseases (2016) 19, 395–397



PSA Screening and Guidelines

- **USPSTF**: grade D recommendation against PSA screening for men of all ages
- **AUA, ACS, NCCN, EAU**: shared decision-making approach

Disagreement between guidelines as to how screening should be implemented for men who opt to proceed, namely *how strictly they adhere to the protocols from randomized trials*

Evidence-Based Versus Personalized Prostate Cancer Screening: Using Baseline Prostate-Specific Antigen Measurements to Individualize Screening

Stacy Loeb, *New York University, New York, NY*

Journal of Clinical Oncology, Vol 34, No 23 (August 10), 2016: pp 2684-2686

Men with PSA levels >1 ng/mL in their 40s represent a high-risk population, for whom more frequent screening is justified.

Conversely, men with a baseline PSA below the age-specific median represent a low-risk group, for whom more extended screening intervals are reasonable.

EUROPEAN UROLOGY 61 (2012) 865–874

Prostate-Specific Antigen and Long-Term Prediction of Prostate Cancer Incidence and Mortality in the General Population

David D. Ørsted[a,b], *Børge G. Nordestgaard*[a,b,c], *Gorm B. Jensen*[c], *Peter Schnohr*[c], *Stig E. Bojesen*[a,b,c,*]

Strategy for detection of prostate cancer based on relation between prostate specific antigen at age 40-55 and long term risk of metastasis: case-control study

Andrew J Vickers *attending*[1], David Ulmert *research fellow*[2 3], Daniel D Sjoberg *research biostatistician*[1], Caroline J Bennette *PhD student*[4], Thomas Björk *associate professor*[3], Axel Gerdtsson *resident*[3], Jonas Manjer *associate professor*[5], Peter M Nilsson *professor*[6], Anders Dahlin *data manager*[7], Anders Bjartell *professor*[3], Peter T Scardino *chair*[2], Hans Lilja *attending clinical chemist, professor*[2 8 9 10 11]

BMJ 2013;346:f2023 doi: 10.1136/bmj.f2023 (Published 15 May 2013)

Baseline Prostate-Specific Antigen Levels in Midlife Predict Lethal Prostate Cancer

Mark A. Preston, Julie L. Batista, Kathryn M. Wilson, Sigrid V. Carlsson, Travis Gerke, Daniel D. Sjoberg, Douglas M. Dahl, Howard D. Sesso, Adam S. Feldman, Peter H. Gann, Adam S. Kibel, Andrew J. Vickers, and Lorelei A. Mucci

J Clin Oncol 34:2705-2711.

Evidence-Based Versus Personalized Prostate Cancer Screening: Using Baseline Prostate-Specific Antigen Measurements to Individualize Screening

Stacy Loeb, *New York University, New York, NY*

Journal of Clinical Oncology, Vol 34, No 23 (August 10), 2016: pp 2684-2686

Age at which screening is discontinued seems to have a larger impact on the rates of overdiagnosis than the age at which it is initiated.

PSA levels may also inform the optimal age to discontinue screening.

The Effect of Start and Stop Age at Screening on the Risk of Being Diagnosed with Prostate Cancer

Rebecka Arnsrud Godtman,* Sigrid Carlsson,† Erik Holmberg, Johan Stranne and Jonas Hugosson

THE JOURNAL OF UROLOGY® Vol. 195, 1390-1396, May 2016

Influence of blood prostate specific antigen levels at age 60 on benefits and harms of prostate cancer screening: population based cohort study

Sigrid Carlsson *research fellow*[1 2], Melissa Assel *assistant research biostatistician*[3], Daniel Sjoberg *research biostatistician*[3], David Ulmert *research fellow*[2], Jonas Hugosson *attending urologist, professor*[1], Hans Lilja *attending clinical chemist, professor*[2 4 5 6 7], Andrew Vickers *attending biostatistician*[3]

BMJ 2014;348:g2296 doi: 10.1136/bmj.g2296 (Published 28 March 2014)

Evidence-Based Versus Personalized Prostate Cancer Screening: Using Baseline Prostate-Specific Antigen Measurements to Individualize Screening

Stacy Loeb, *New York University, New York, NY*

Journal of Clinical Oncology, Vol 34, No 23 (August 10), 2016: pp 2684-2686

Modeling studies suggest that a risk adapted approach to prostate cancer screening can preserve benefits with fewer harms compared with fixed screening protocols.

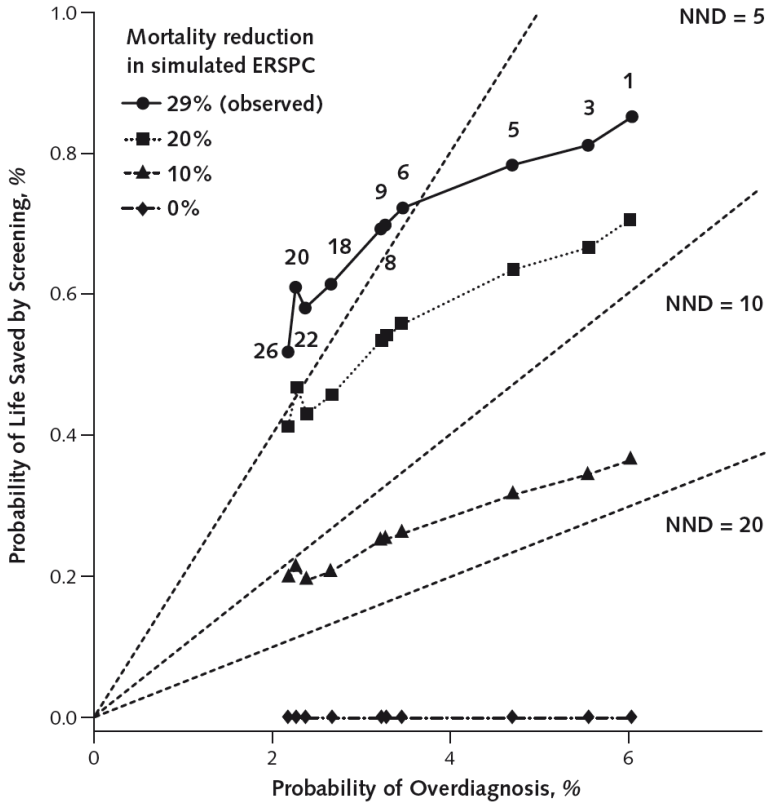
Comparative Effectiveness of Alternative Prostate-Specific Antigen–Based Prostate Cancer Screening Strategies

Model Estimates of Potential Benefits and Harms

Roman Gulati, MS; John L. Gore, MD; and Ruth Etzioni, PhD

Ann Intern Med. 2013;158:145-153.

Compared with standard screening, PSA screening strategies that use higher thresholds for biopsy referral for older men and that screen men with low PSA levels less frequently can reduce harms while preserving lives.



Prostate Cancer Screening: A Brief Tool to Incorporate Patient Preferences in a Clinical Encounter

Anita D. Misra-Hebert[1,2] and Michael W. Kattan[2]*

Frontiers in Oncology | November 2016 | Volume 6 | Article 235

Yes, you may benefit from being screened with the PSA if higher scores:

Younger age, treating prostate cancer may have more benefits than risks
Extensive family history of prostate cancer
Higher risk racial group
Abnormal digital rectal exam or no previous digital rectal exam
Previous PSA in higher risk range or no Previous PSA
Excellent health status, life expectancy not reduced related to comorbid conditions
Urinary incontinence would not be bothersome
Sex life is not important
Extremely concerned about having or developing prostate cancer

No, you may not benefit from being screened with the PSA if lower scores:

Older age, treating prostate cancer may have more risks than benefits
No family history of prostate cancer
Lower risk racial group
Normal previous digital rectal exam
Previous PSA in lower risk range
Poor health status, life expectancy reduced related to comorbid conditions
Urinary incontinence would be extremely bothersome
Sex life is extremely important
Not concerned about having or developing prostate cancer

Ruolo del PSA nello screening

Giovanni L. PAPPAGALLO