



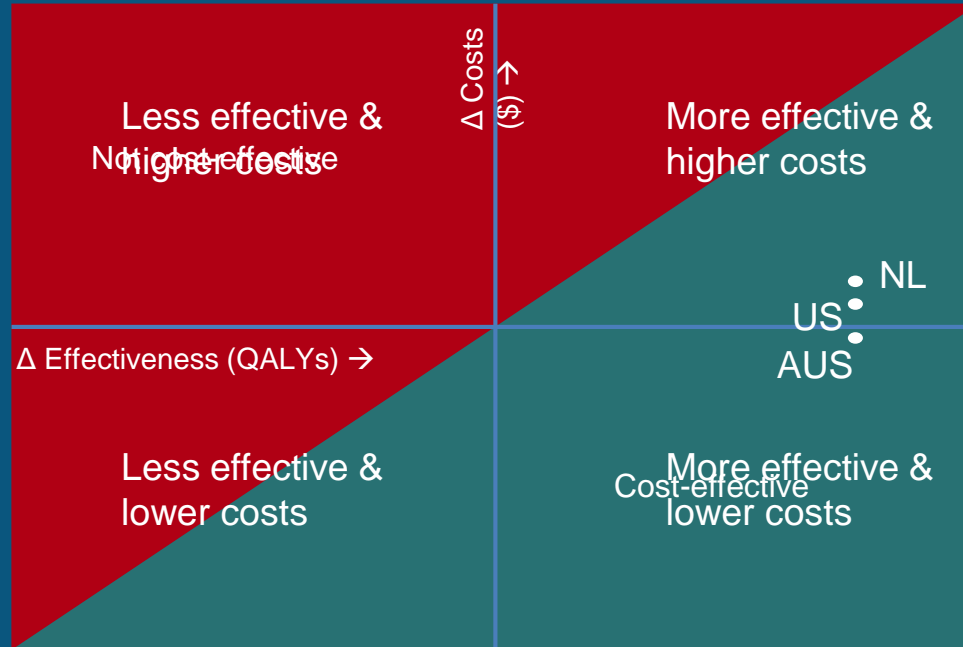
“The whole business Case from a patients view”

Prof. Jelle Barentsz

Prostate MR Reference/Expert Center Nijmegen

One of the Dancing Doctors

Cost-effectiveness



I have created followers



**ESUO 2017
Barcelona
Prof. Brausi
Chairman**

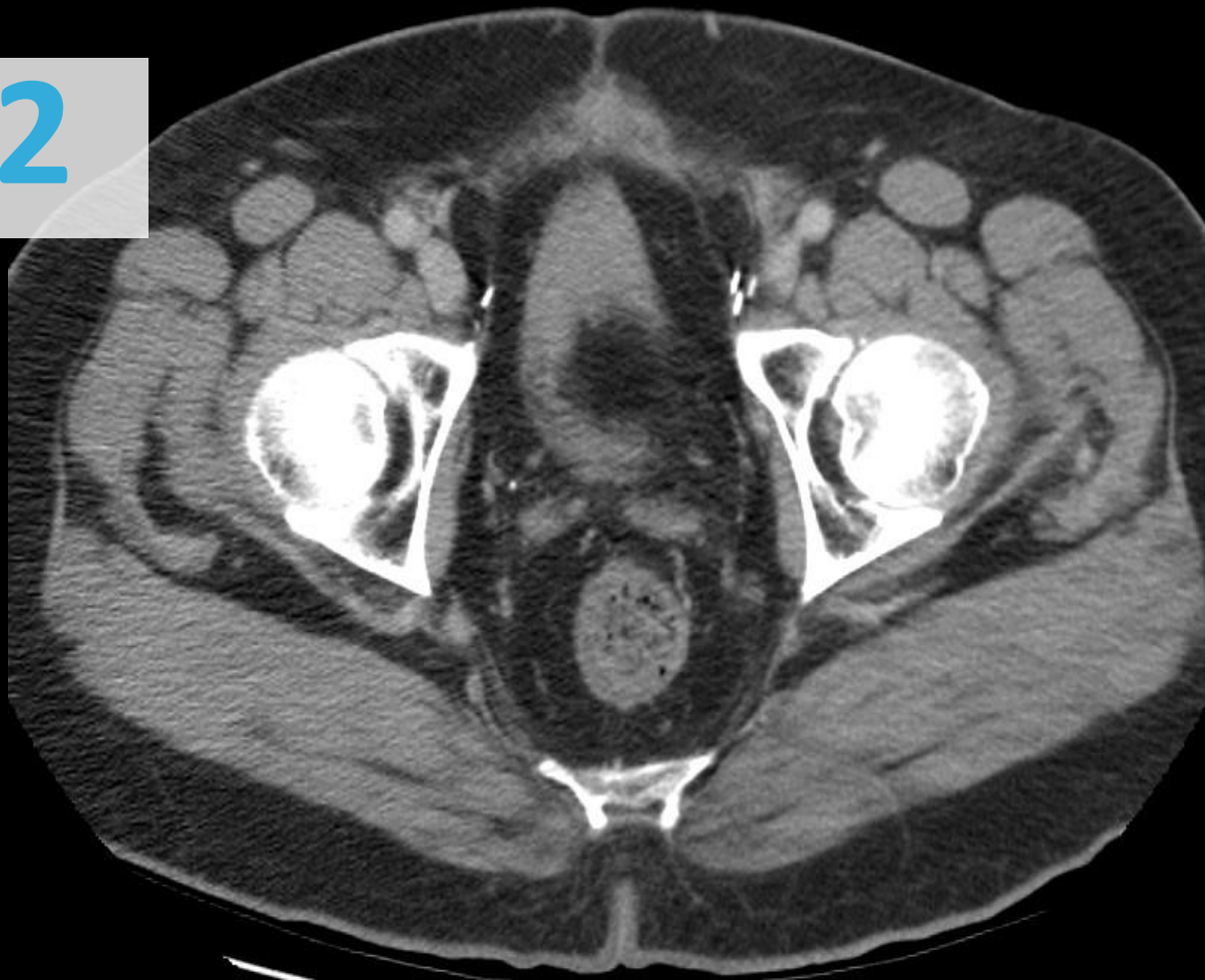
“MRI has improved in recent years, and urologists are learning to make better use of it. We are coming around to the idea that MRI is the best first step.”



EARLY DETECTION

Nodal Metastases

PSA 0.2

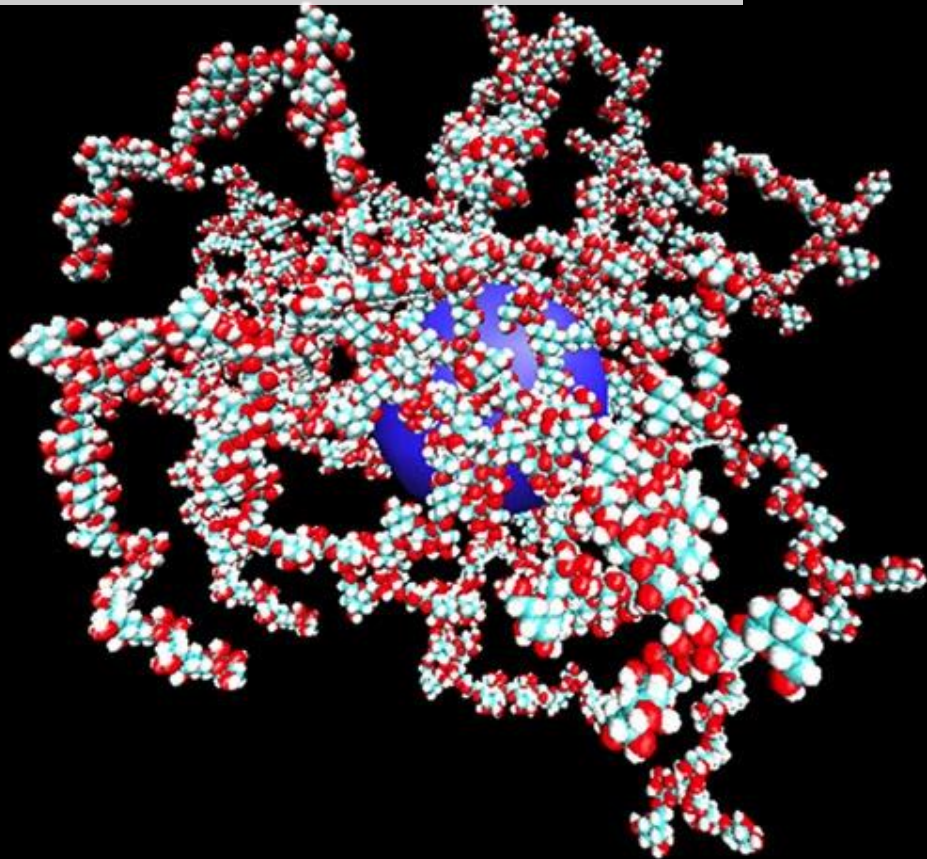


PSA 5

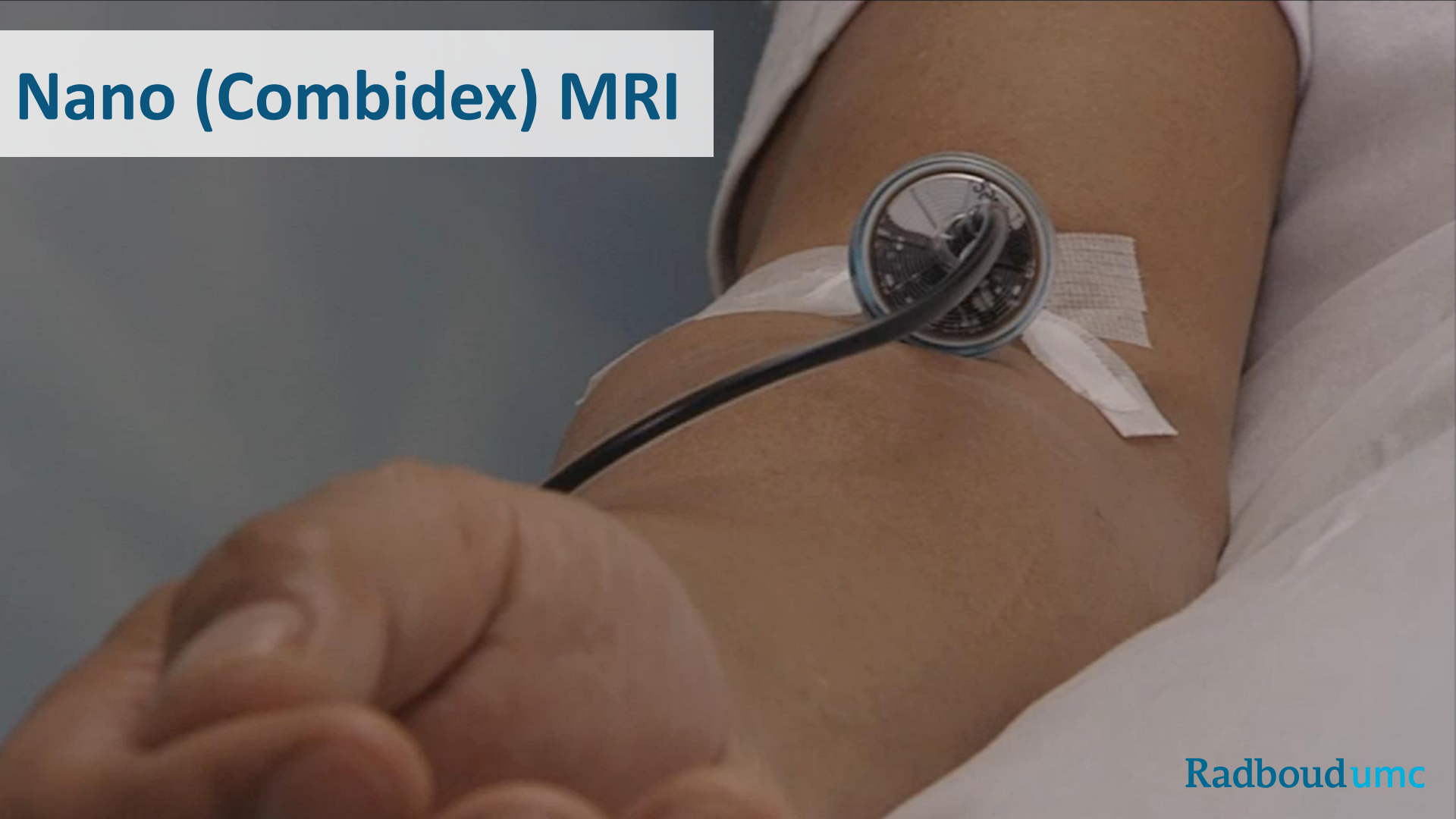




Nano (Combidex) MRI

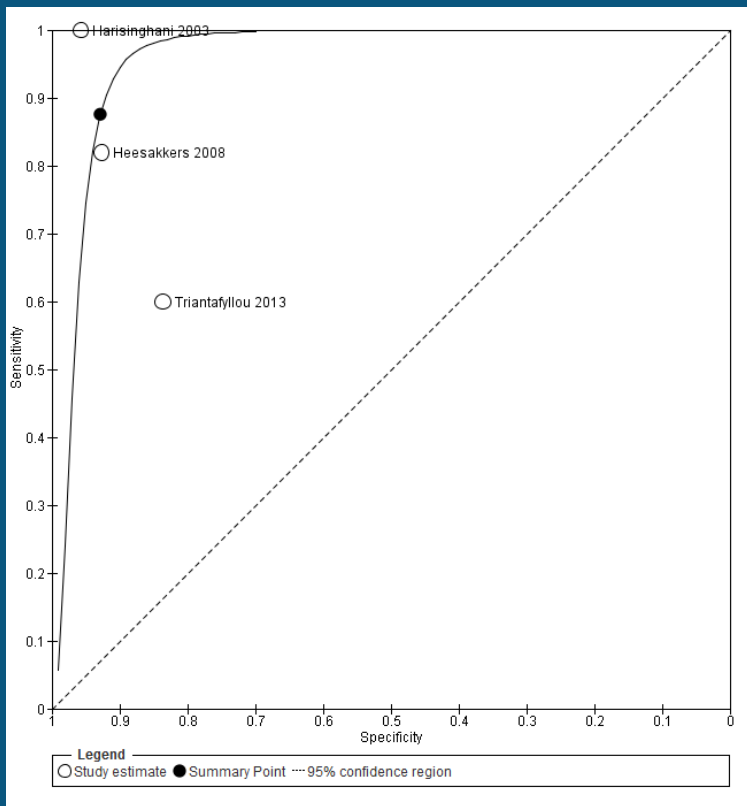


Nano (Combidex) MRI





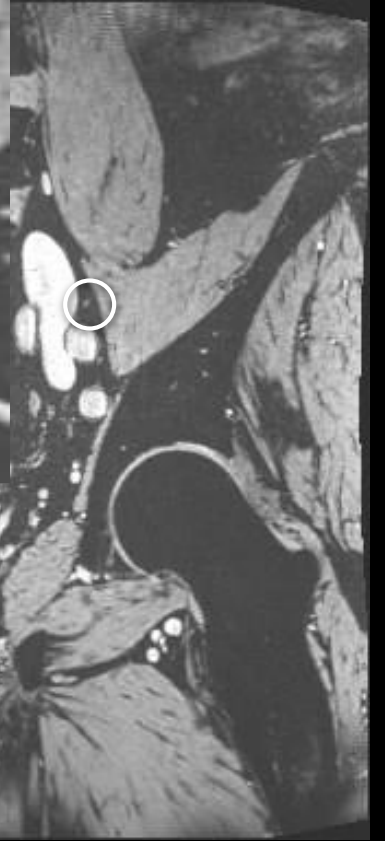
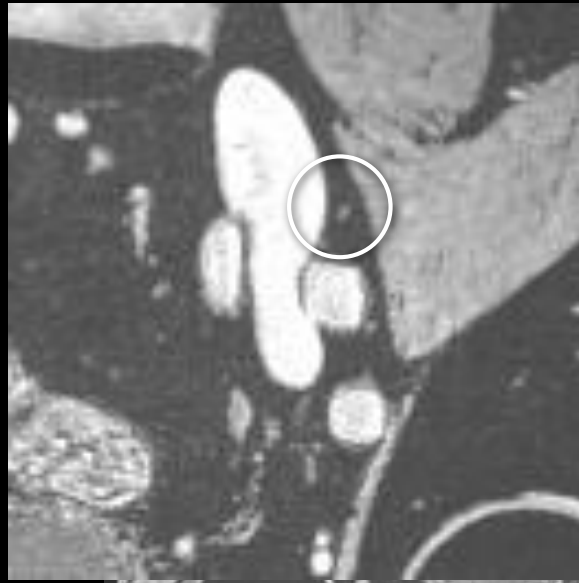
Nano-MRI is very accurate!



QUADAS-2 criteria

Specificity 93%

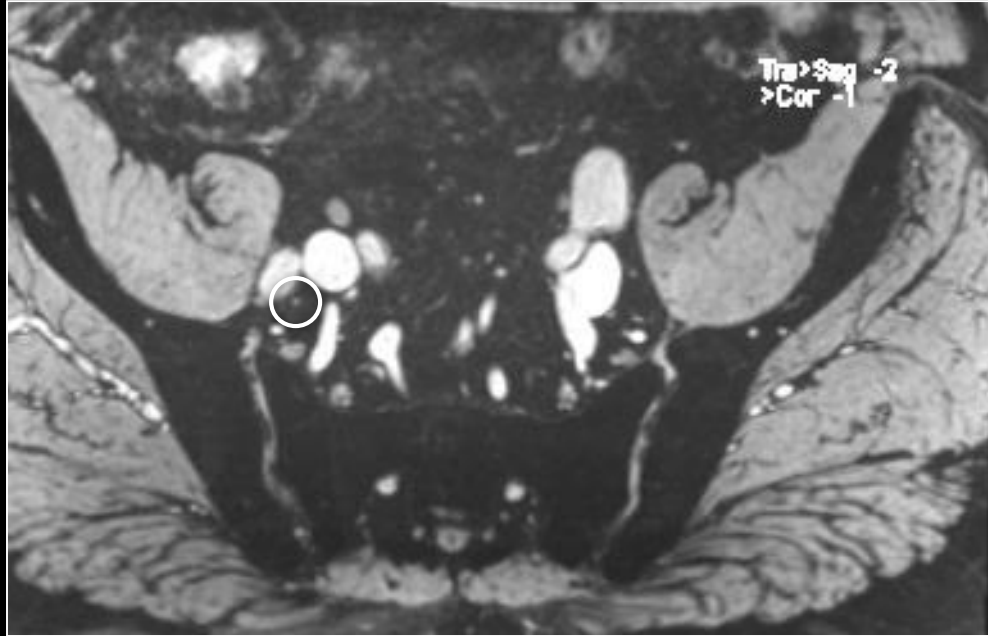
Sensitivity 88%



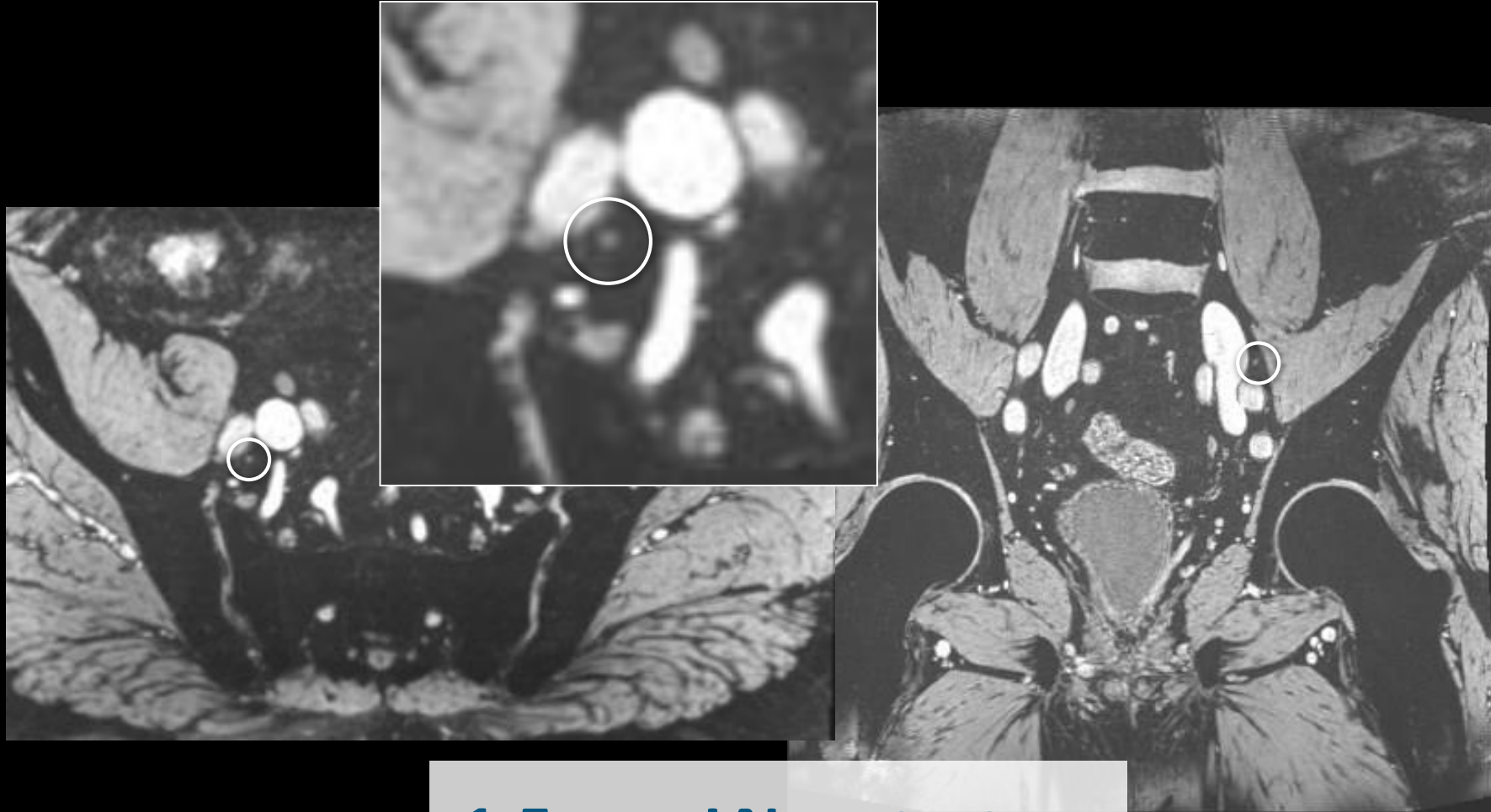
1.5 mm LN metastase



1.5 mm LN metastase



1.5 mm LN metastase



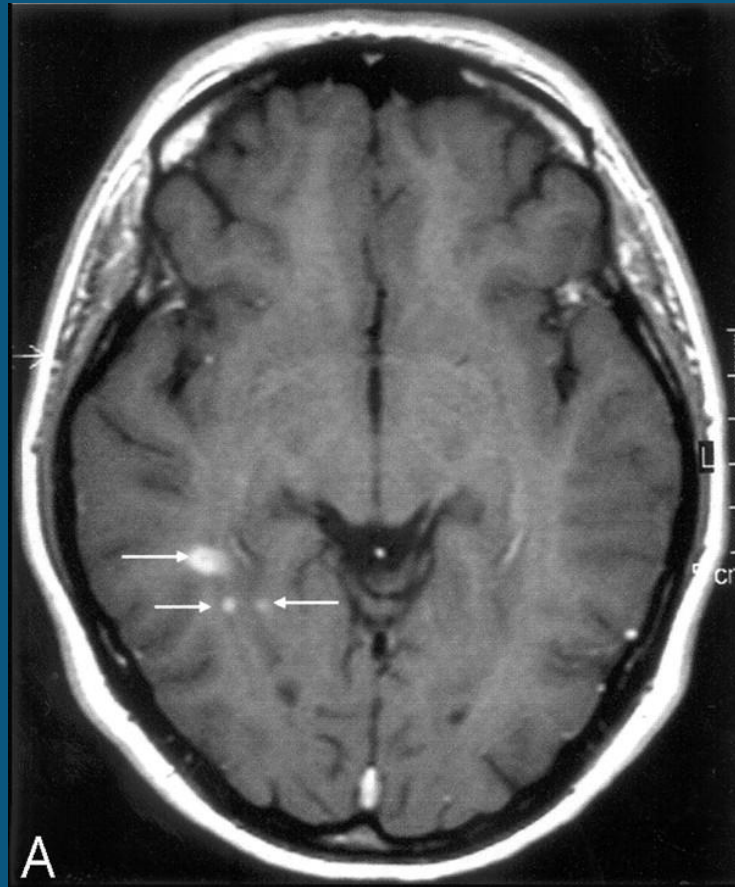
1.5 mm LN metastase

All Cancers



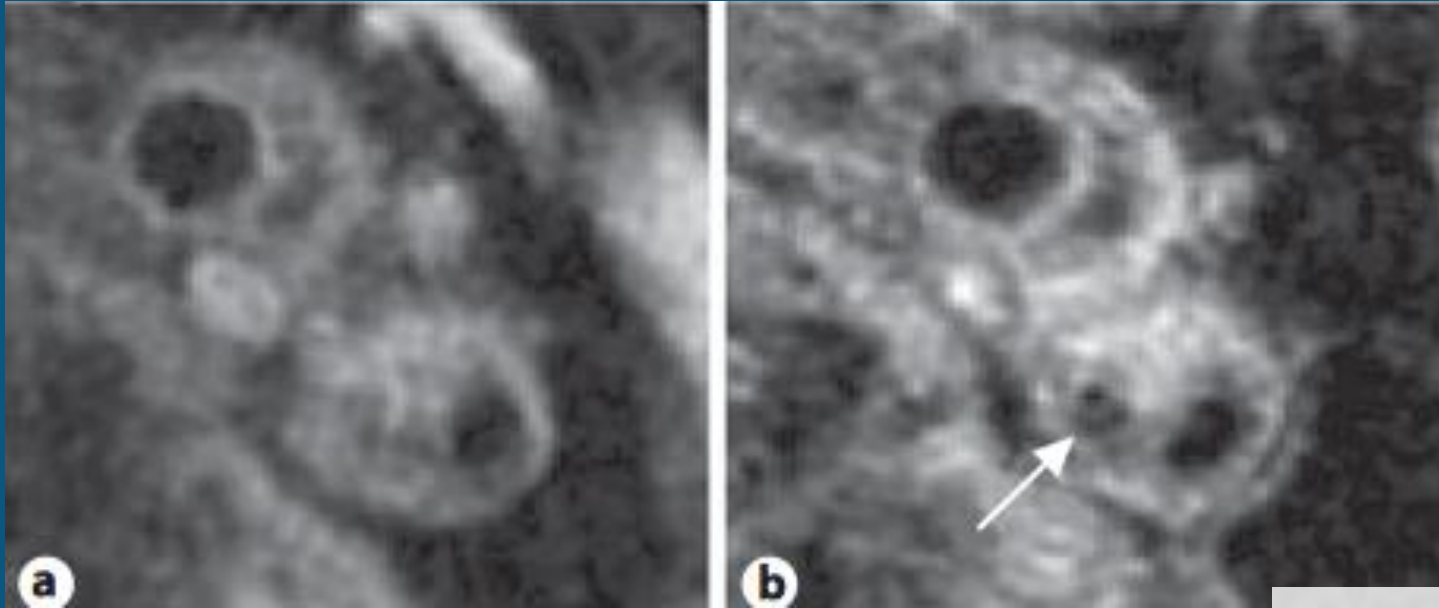
MS-activity beter detected with Combidex-MRI

V. Dousset, AJNR 2006



Gd-(normal)
MRI contrast

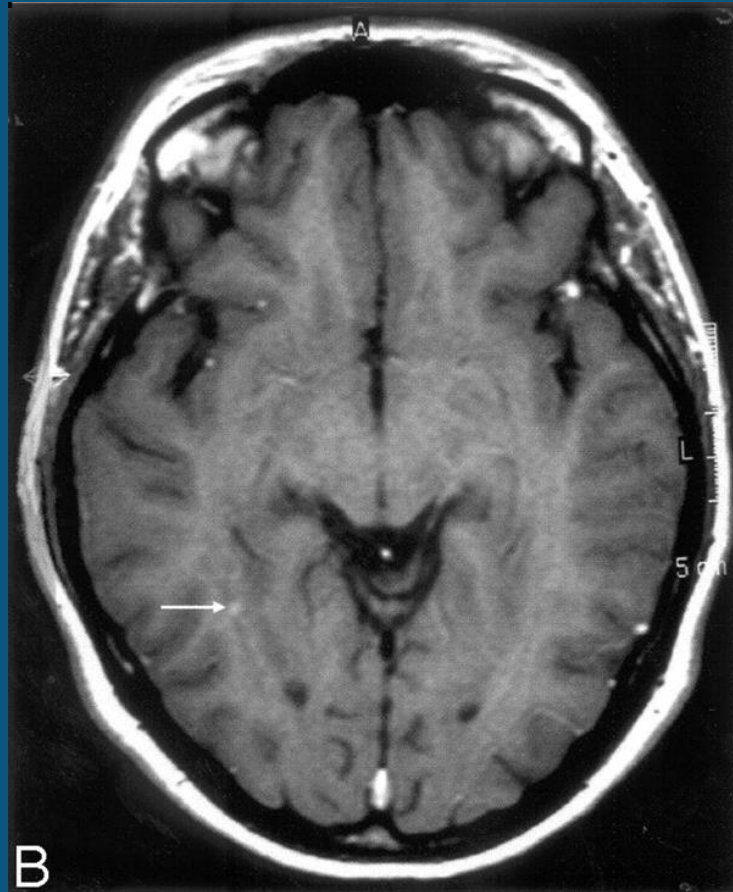
Vulnerable plaque can be identified with Nano (Combidx) MRI



Degnan, Cerebrovasc Dis. 2012
Ushman, Nanomedicine 2015

Nano-MRI

MS-activity beter detected with Combidex-MRI



V. Dousset, AJNR 2006

Combindex-MRI

**Best
Research
Evidence**



**Oncology Drugs Advisory Committee
(ODAC) March 3, 2005.**



BLOGGERS: MARK SCHOLZ, MD & RALPH H. BLUM

The co-authors of *Invasion of the Prostate Snatchers*, blog alternate posts weekly. We invite you to post your comments.

Tuesday, December 11, 2012

The FDA and Its Firing Squad (Combindex Part 3)

BY RALPH BLUM

After interviewing several staff members at Ad Mag, I became very aware of the financial reality. Contrast agents are not economically viable. Subjected to all the same requirements as a drug, a contrast agent like Combindex can cost over \$100 million to develop, and the likelihood of FDA approval is increased by having a narrow indication. But here's the irony: the narrower the indication, the less chance the company will ever recoup its money.

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PROSTATE SNATCHER VIDEOS



WHEN ARTIFICIAL INTELLIGENCE GOES WRONG.

PREY



MAY 2012

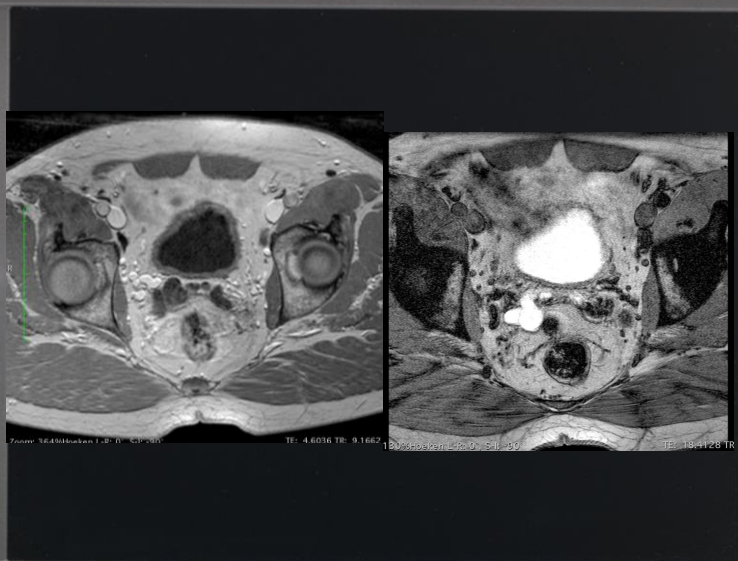
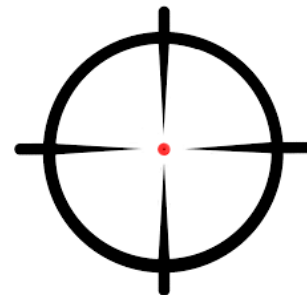
Guerbet



Contrast for Life

Best
Research
Evidence

Old laptops
No “cross-hairs”



Best
Research
Evidence

EMA 2009
Suboptimal
design off-center
centralised
reading

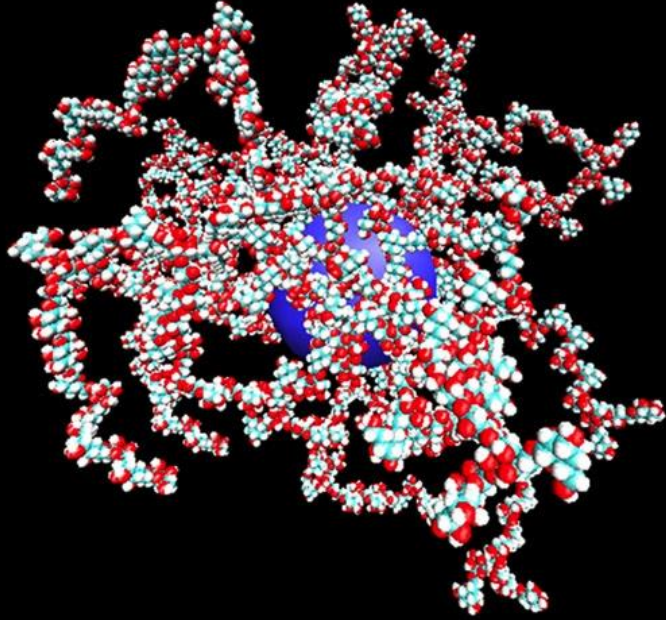
High inter-reader variability





130%Hoeken L-R: 0°, S-I: -90°

TE: 18,4128 TR



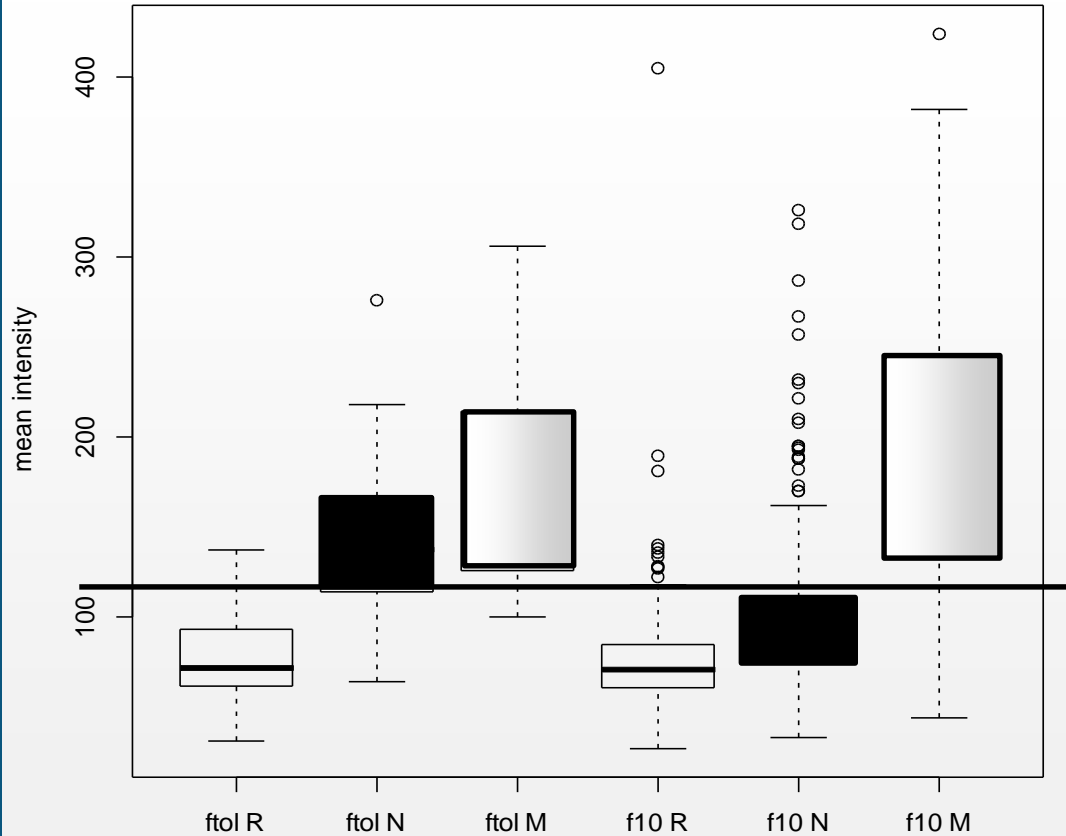
MISSION IMPOSSIBLE



New Patent Granted on
FERUMOXTOL



Combidex vs Feraheme



ftol=ferumoxytol; f10=ferumoxtran*10; R=reference region; M=metastasized; N=normal

Debats, Peer J 2016



CB 62977079F
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C3



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Mary Ellen Rothman
Director

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Monday, April 22, 2013

Combidx Technology Sale Opens Door to a Revolution in Diagnostic Cancer Imaging

Improved cancer diagnostic imaging is one step closer to reality with the sale of Combidx® by an American pharmaceutical company to a Dutch university that intends to launch global trials, reports the International Strategic Cancer Alliance. Combidx® is a nanoparticle fluid used with magnetic resonance imaging (MRI) that can visualize cancer metastases with pinpoint accuracy in lymph nodes as small as 2 - 3 millimeters, compared to conventional CT imaging, which can only visualize malignant nodes that are larger than 8 millimeters.

Kennett Sq., PA (PRWEB) April 08, 2013



The exclusive technology and development rights to Combidx® (ferumoxtran-10), a contrast agent showing great potential in the field of diagnostic imaging, have been sold by the U.S. pharmaceutical company AMAG Pharmaceuticals, Inc. to a Dutch University Medical center. The new owner of the technology package is Radboud University Nijmegen Medical Center (RUNMC), a part of Stichting Katholieke Universiteit, a non-profit foundation in The Netherlands. Under the direction of noted radiologist [Jelle Barentsz, M.D.](#), RUNMC will continue research and development of Combidx®, to include global clinical trials advancing towards regulatory application, a commercialized product and widespread patient access.

The sale agreement was negotiated with the assistance of Om Adalsteinsson, Ph.D., President and CEO of the International Strategic Cancer Alliance, a cancer research organization based in Kennett Square, PA.

Combidx® is an injectible nanoparticle fluid used in conjunction with magnetic resonance imaging (MRI). Clinical cancer studies have demonstrated Combidx's capability in visualizing malignant lesions in lymph nodes as small as 2-3 millimeters. By comparison, state-of-the-art CT imaging can only visualize malignant nodes that are larger than 8 millimeters. The potential of Combidx technology includes earlier, more specific lymph node cancer detection, resulting in more appropriate and effective therapy with reduced side effects and improved patient outcomes.

The details of upcoming clinical trials will be announced



Rebirth of Combidx 2014





EMA (CHMP) 2009

Acceptable safety profile (>2.000 p)

**Type of adverse event
all were Grade 1**

**Number of patients
(n= 7/310) 2%**

Minor back pain

2 (contrast related)

Minor nausea

1 (contrast related)

Flushing/feeling hot

1 (contrast related)

Dry mouth

3 (possibly contrast related)

Decision analytic model: Combidex-MRI vs PLND

Table 4

Comparison of MR Lymphography and PLND Strategies

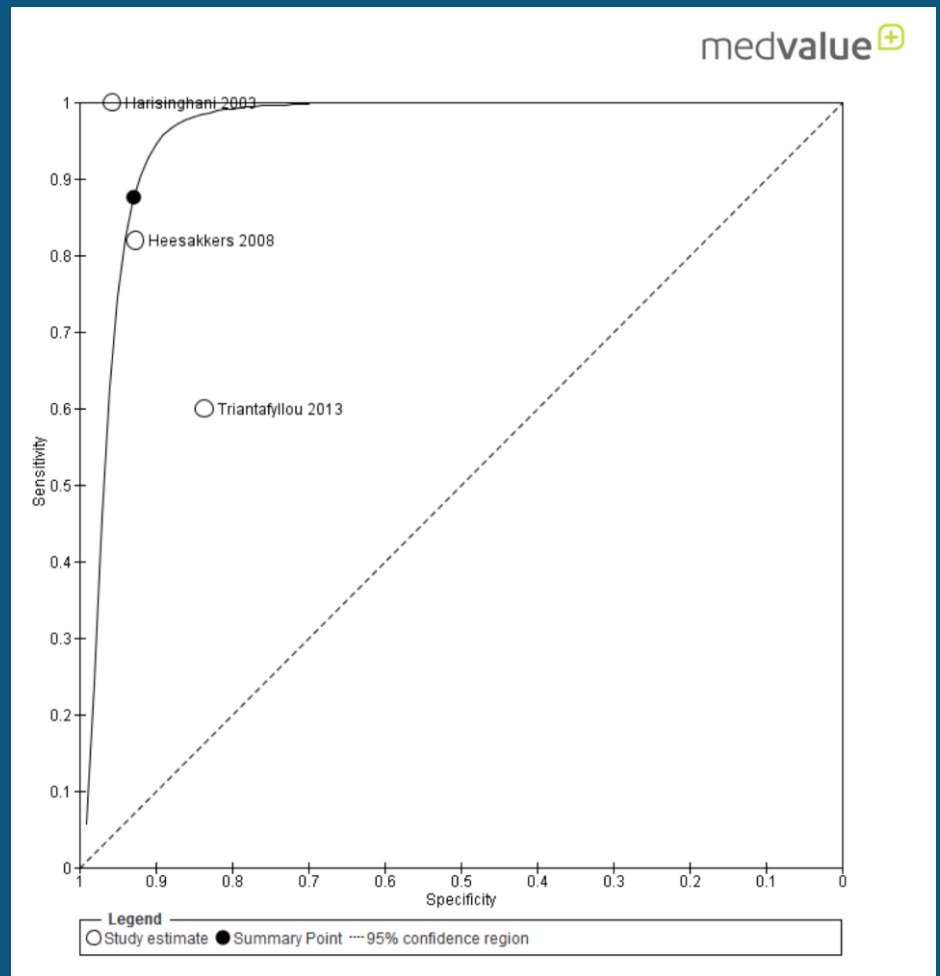
Category	MR Lymphography	PLND
Expected cost per patient, per strategy (\$)	8652	9789
Expected no. of life-years gained per strategy
Expected no. of QALYs per strategy	10	10
Health care costs per QALY (\$)	888	1014
Incremental costs per QALY	...	Dominated

Combindex

Sensitivity 88%

Specificity 93%

Saves \$2000 pp





Review – Prostate Cancer

The Benefits and Harms of Different Extents of Lymph Node Dissection During Radical Prostatectomy for Prostate Cancer: A Systematic Review

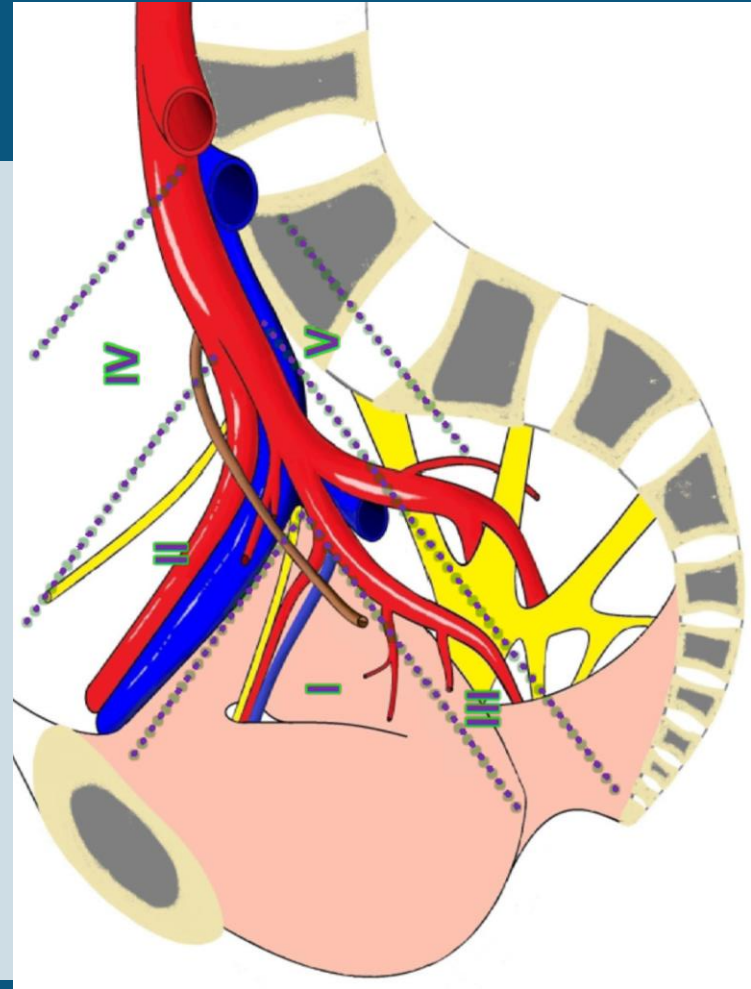
Nicola Fossati^{a,1}, Peter-Paul M. Willemse^{b,1}, Roderick C.N. van den Bergh^c, Thomas Van den Broeck^d, Cathy Yuhong Yuan^e, Erik Briers^f, Joaquim Bellmunt^{g,h}, Michel Bollaⁱ, Philip Cornford^j, Maria De Santis^k, Ekelechi MacPepple^l, Ann M. Henry^m, Malcolm D. Masonⁿ, Vsevolod B. Matveev^o, Henk G. van der Poel^p, Theo H. van der Kwast^q, Olivier Rouvière^r, Ivo G. Schoots^{s,t}, Thomas Wiegel^u, Thomas B. Lam^{v,w}, Nicolas Mottet^x, Steven Joniau^{d,}*

PLND and e-PLND

Worse intra- and
peri-operative outcome

Direct therapeutic
effect is still not evident

Has staging benefit



Combindex-MRI can solve this problem





SPLmedical

ACCURATE CANCER DIAGNOSTICS

MISSION  IMPOSSIBLE



**We need resources to help patients,
and do research within those 4 years**

