

Β' Παθολογική -

Ογχολογική Κλινική,

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#### ριζική ακτινοθεραπεία στον καρκίνο του προστάτη αρχική θεραπεία και βιοχημική υποτροπή

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# ριζική ακτινοθεραπεία

#### The NEW ENGLAND JOURNAL C MEDICINE The NEW ENGLAND JOURNAL OF MEDICINE

ESTABLISHED IN 1812

ORIGINAL ARTICLE

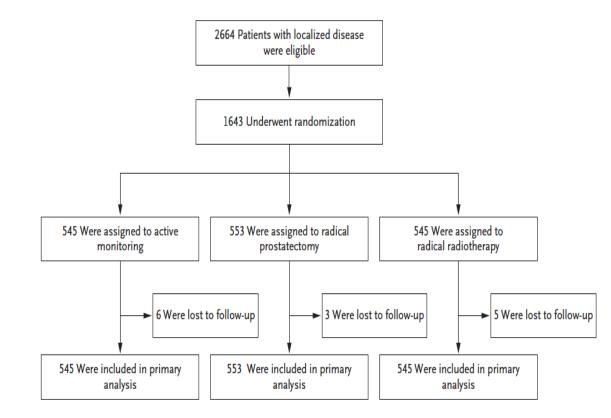
#### 10-Year Outcome

F.C. Hamdy, J.L. Donovan, J R.M. Martin, J. Oxley, M. Rot R. Kockelbergh, H. Kyn

#### Patient-Reported Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer

J.L. Donovan, F.C. Hamdy, J.A. Lane, M. Mason, C. Metcalfe, E. Walsh, J.M. Blazeby, T.J. Peters, P. Holding, S. Bonnington, T. Lennon, L. Bradshaw, D. Cooper, P. Herbert, J. Howson, A. Jones, N. Lyons, E. Salter, P. Thompson, S. Tidball, J. Blaikie, C. Gray, 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, M. Davis, E.L. Turner, R.M. Martin, and D.E. Neal, for the ProtecT Study Group\*

#### ProtecT



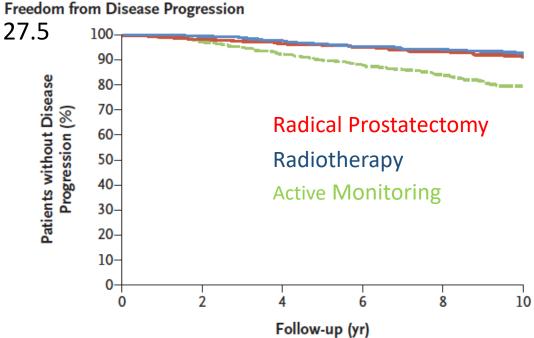
	Active monitoring (n=545)	Radiotherapy (n=545)	Radical prostatectomy (n=553)
Age at invitation (years)			
49-54	58 (11%)	62 (11%)	69 (12%)
55-59	140 (26%)	141 (26%)	137 (25%)
60–64	184 (34%)	176 (32%)	172 (31%)
65-69	163 (30%)	166 (30%)	175 (32%)
Median age (range)	62 (50-69)	62 (49–69)*	62 (50-69)
PSA (µg/L)			
3.0-5.9	373 (68%)	373 (68%)	371 (67%)
6.0-9.9	116 (21%)	121 (22%)	123 (22%)
≥10.0	56 (10%)	51 (9%)	59 (11%)
Median PSA (range; µg/L)	4.6 (3.0-20.9)†	4.6 (3.0-18.8)	4.7 (3.0-18.4)
Gleason score			
6	421 (77%)	423 (78%)	422 (76%)
7	111 (20%)	108 (20%)	120 (22%)
8-10	13 (2%)	14 (3%)	10 (2%)
Missing	0	0	1(<1%)
Clinical stage			
T1c	410 (75%)	429 (79%)	410 (74%)
T2	135 (25%)	116 (21%)	143 (26%)

### ProtecT

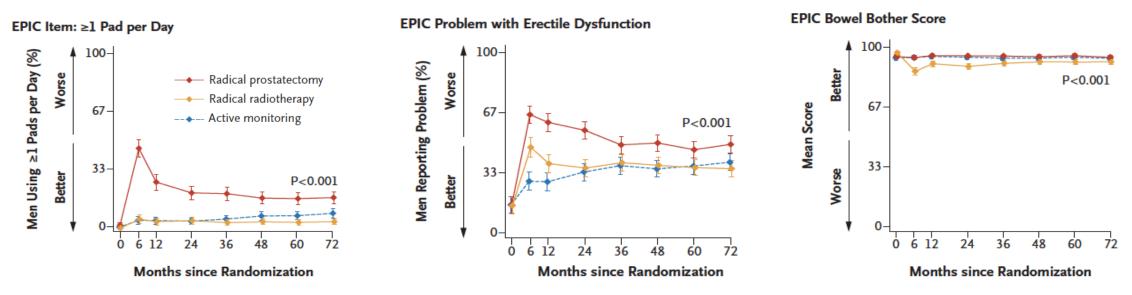
- 545 active monitoring
  - PSA q3 m x 1y, q6 m thereafter, rise of 50% in 12 m: consider biopsy
- 553 radical prostatectomy
- 545 radical radiotherapy
  - RT: 3DCRT 74 Gy (37 fr) + NAD (3-6 m)
- 10 y follow up
- Disease Progression, Cancer Specific Survival, Overall Survival, Metastasis
- Toxicity
- Quality of Life
  - baseline, 6 m, 12m and annually thereafter
    ICIQ: International Consultation of Incontinence Questionnaire
    EPIC: Expanded Prostate Cancer Index Composite
    ICSmaleSF: International Continence Society male Short Form
    SF12: Medical Outcomes Study 12
    HADS: Hospital Anxiety and Depression Scale
    EORTC- QLQ C30

# ProtecT αποτελέσματα θεραπείας

- Disease Progression
  - AM 112 men; 22.9 per 1000 person-years; 95% Cl, 19.0 to 27.5
  - RP 46 men; 8.9 per 1000 person-years; 95% CI, 6.7 to 11.9
  - RT 46 men; 9.0 per 1000 person-years; 95% Cl, 6.7 to 12.0 *p*<0.001
- Metastasis
  - AM 33 men; 6.3 per 1000 person-years; 95% CI, 4.5 to 8.8
  - RP 13 men; 2.4 per 1000 person-years; 95% Cl, 1.4 to 4.2
  - RT 16 men; 3.0 per 1000 person-years; 95% Cl, 1.9 to 4.9 *p*=0.004
- Prostate Cancer Specific Survival no significant difference

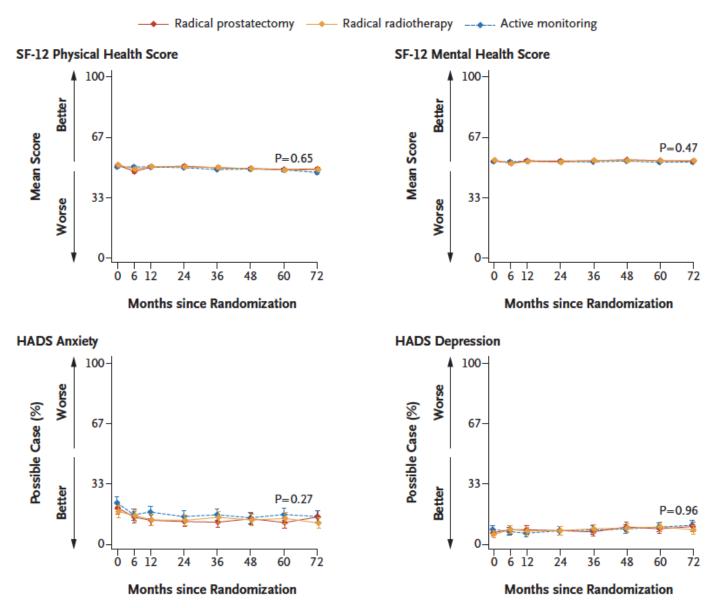


## ProtecT τοξικότητα θεραπείας



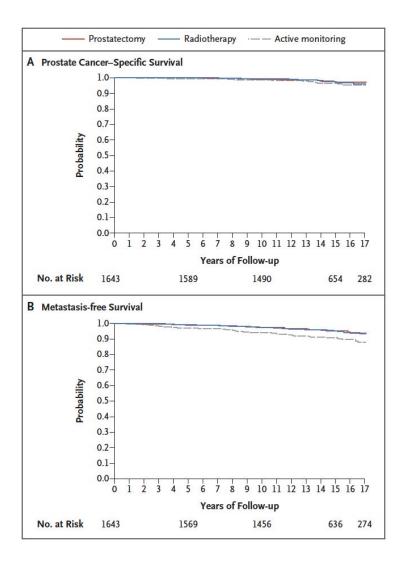
- prostatectomy greatest negative effect on urinary continence at 6 months; the effect of urinary incontinence on QoL worse in the prostatectomy group for 2 years, but then similar to that reported in the other groups
- nocturia increased in all groups; the increase particularly in the radiotherapy group at 6 months
- at baseline 67% of men reported erections firm enough for intercourse, but by 6 months this rate fell to 52% in the active-monitoring group, to 22% in the radiotherapy group, and to 12% in the prostatectomy group
- bowel function worse in the radiotherapy group than in other groups. However, there was then considerable recovery in the radiotherapy group for these measures, apart from more frequent bloody stools

### ProtecT σχετική με την υγεία ποιότητα ζωής



### ProtecT 15 year results

Outcome and Trial Group	No. of Events	No. of Person-Yr	Rate per 1000 Person-Yr (95% CI)	Hazard Ratio (95% CI)*
Primary outcome				
Death from prostate cancer†				
Active monitoring	17	7633	2.2 (1.4-3.6)	Reference
Prostatectomy	12	7766	1.5 (0.9-2.7)	0.66 (0.31-1.39)
Radiotherapy	16	7628	2.1 (1.3-3.4)	0.88 (0.44-1.74)
Secondary outcomes				
Death from any cause				
Active monitoring	124	7633	16.2 (13.6–19.3)	Reference
Prostatectomy	117	7766	15.0 (12.5–18.0)	0.89 (0.69–1.15)
Radiotherapy	115	7628	15.0 (12.5–18.0)	0.88 (0.68-1.13)
Metastatic disease				
Active monitoring	51	7324	7.1 (5.4–9.3)	Reference
Prostatectomy	26	7594	3.5 (2.4–5.1)	0.47 (0.29-0.76)
Radiotherapy	27	7467	3.7 (2.5-5.4)	0.48 (0.30-0.77)
Androgen-deprivation therapy				
Active monitoring	69	7197	9.4 (7.4–11.9)	Reference
Prostatectomy	40	7452	5.3 (3.9–7.2)	0.54 (0.37-0.80)
Radiotherapy	42	7328	5.6 (4.2–7.6)	0.54 (0.36–0.79)
Clinical progression‡				
Active monitoring	141	6596	21.4 (18.1–25.2)	Reference
Prostatectomy	58	7258	8.0 (6.2–10.3)	0.36 (0.27-0.49)
Radiotherapy	60	7173	8.4 (6.5-10.8)	0.35 (0.26-0.48)



#### ProtecT 15 year results

"after 15 years of follow-up, prostate cancer-specific mortality was low regardless of the treatment assigned. Thus, the choice of therapy involves weighing trade-offs between benefits and harms associated with treatments for localized prostate cancer"