Management of Men with PSA Recurrence or Persistence after Prostatectomy

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Speakers Bureau	**Astellas/Pfizer, Janssen**
Honoraria	**Astellas/Pfizer, Janssen, MDxHealth**
Scientific Advisory Board	**Astellas, Janssen, MDxHealth**

Special Thanks to:
Derya Tilki, Martini Klinik, Hamburg
Declan Murphy, Sir Peter MacCallum Cancer Centre, Melbourne

Topics to cover

- PSA persistence/recurrence
  - Definitions and clinical implications
- Imaging
- Management
  - Salvage radiotherapy
  - Salvage lymphadenectomy

AUA and NCCNs Definition of BCR

- **AUA: Remission after prostatectomy is defined as nadir PSA < 0.2 ng/ml**

- **NCCN: PSA persistence/recurrence after RP is defined as failure of PSA to fall to undetectable levels (PSA persistence) or undetectable PSA after RP with a subsequent detectable PSA that increases on 2 or more determinations (PSA recurrence).**

PSA Persistence after RP

- **Between 5 and 20% of men continue to have persistent PSA after RP (defined in the majority of studies as detectable post-RP PSA of > 0.1 ng/mL within four to eight weeks of surgery).**

- **It may result from persistent local disease, pre-existing metastases or residual benign prostate tissue.**
  - **In my experience > 0.1 ng/mL is not residual benign disease**

- **First steps are to repeat it for validation and follow at (2-3 month intervals) to get an initial read on the etiology.**

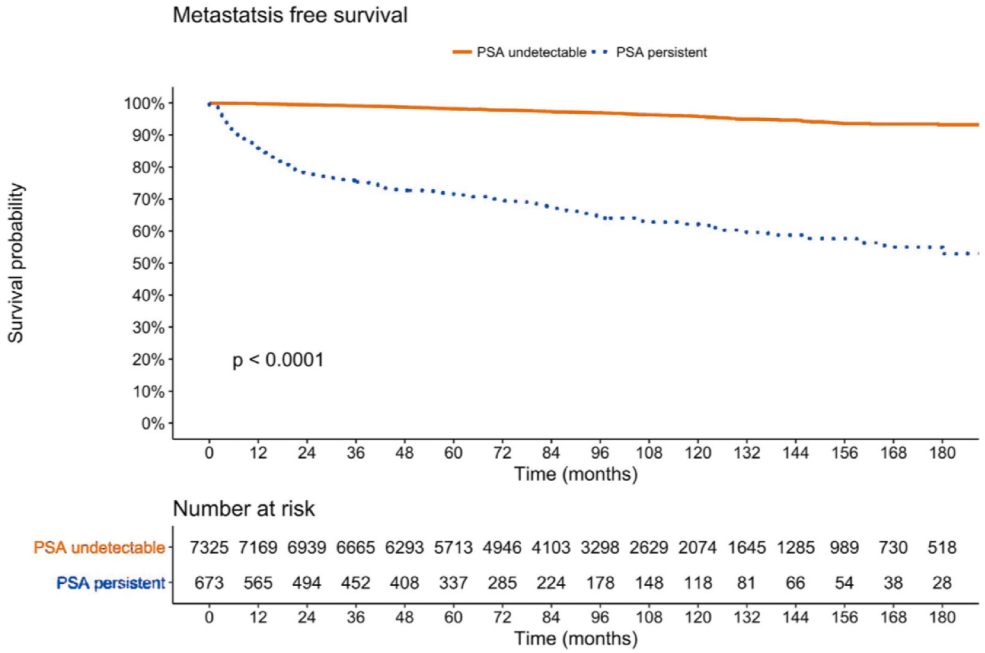
Prostate Cancer

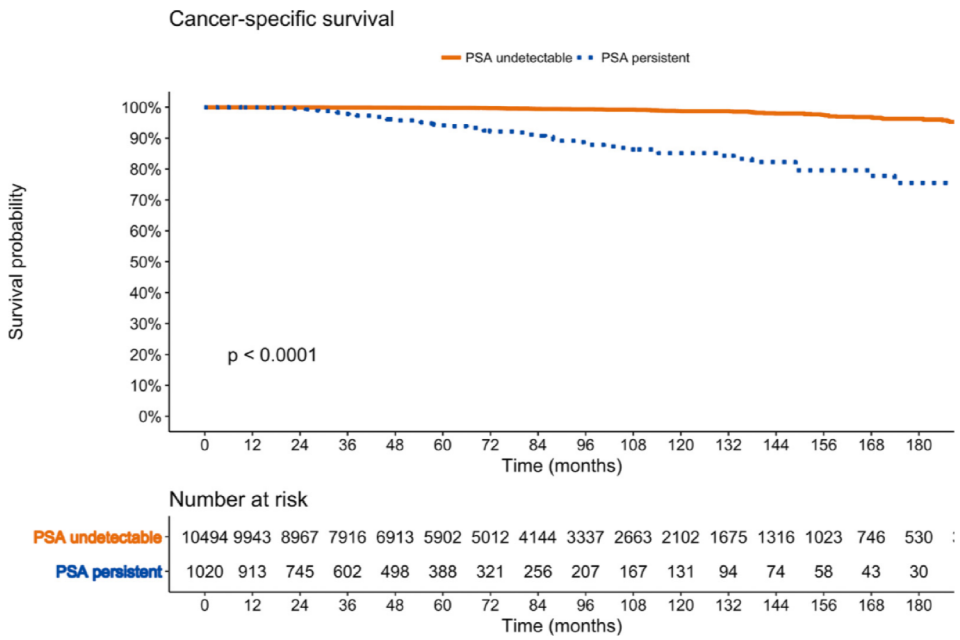
Persistent Prostate-Specific Antigen After Radical Prostatectomy and Its Impact on Oncologic Outcomes

Felix Preisser[a,b], *Felix K.H. Chun*[b], *Raisa S. Pompe*[c], *Alexander Heinze*[a], *Georg Salomon*[a], *Markus Graefen*[a], *Hartwig Huland*[a], *Derya Tilki*[a,c,*]

- **Of 11,604 patients (RP 1992-2016), 8.8% (n=1,025) harbored persistent PSA (≥0.1ng/ml)**

Eur Urol. 2019 Jul;76(1):106-114.





- **At 15-years after RP, MFS and CSS was 53.0 vs. 93.2% (p<0.001) and 75.5 vs. 96.2% (p<0.001) for persistent vs. undetectable PSA**

Eur Urol. 2019 Jul;76(1):106-114.

Prostate Cancer

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Felix Preisser[a,b], *Felix K.H. Chun*[b], *Raisa S. Pompe*[c], *Alexander Heinze*[a], *Georg Salomon*[a], *Markus Graefen*[a], *Hartwig Huland*[a], *Derya Tilki*[a,c,*]

[a] *Martini-Klinik Prostate Cancer Center, University Hospital Hamburg-Eppendorf, Hamburg, Germany;* [b] *Department of Urology, University Hospital Frankfurt, Frankfurt am Main, Germany;* [c] *Department of Urology, University Hospital Hamburg-Eppendorf, Hamburg, Germany*

In multivariable analyses, higher preoperative PSA, more advanced pathologic tumor stage, pathologic GG3–5, positive surgical margins,and pN1 were associated with an increased risk for persistent PSA (all p<0.01).

Eur Urol. 2019 Jul;76(1):106-114.

Table 2 – Multivariable logistic regression models predicting persistent PSA (≥0.1 ng/ml) at 6 wk after radical prostatectomy

	OR	95% CI	*p* value
Clinical model			
Year of surgery	1.04	1.02–1.05	<0.001
Age	0.99	0.99–1.01	0.8
Preoperative PSA	1.05	1.04–1.05	<0.001
Clinical tumor stage T1c (referent)	1.00	–	–
Clinical tumor stage T2a	1.50	1.24–1.8	<0.001
Clinical tumor stage T2b	2.43	1.93–3.03	<0.001
Clinical tumor stage ≥T2c	3.50	2.50–4.88	<0.001
Biopsy GG1 (referent)	1.00	–	–
Biopsy GG2	1.52	1.25–1.85	<0.001
Biopsy GG3	2.73	2.19–3.39	<0.001
Biopsy GG4	3.96	3.12–5.03	<0.001
Biopsy GG5	5.06	3.85–6.64	<0.001
Pathological model			
Year of surgery	1.01	0.99–1.03	0.1
Age	0.99	0.98–0.99	0.04
Preoperative PSA	1.02	1.02–1.03	<0.001
Pathologic stage ≤T2c (referent)	1.00	–	–
Pathologic stage T3a	1.96	1.61–2.38	<0.001
Pathologic stage T3b	3.76	3.02–4.7	<0.001
Pathologic GG1 (referent)	1.00	–	–
Pathologic GG2	1.25	0.95–1.66	0.1
Pathologic GG3	3.51	2.58–4.82	<0.001
Pathologic GG4	3.96	2.16–7.0	<0.01
Pathologic GG5	4.95	3.41–7.24	<0.001
Negative surgical margin (referent)	1.00	–	–
Positive surgical margin	1.66	1.40–1.95	<0.001
Pathologic lymph node status N0 (referent)	1.00	–	–
Pathologic lymph node status N1	2.32	1.88–2.85	<0.001
Pathologic lymph node status Nx	1.04	0.84–1.28	0.7

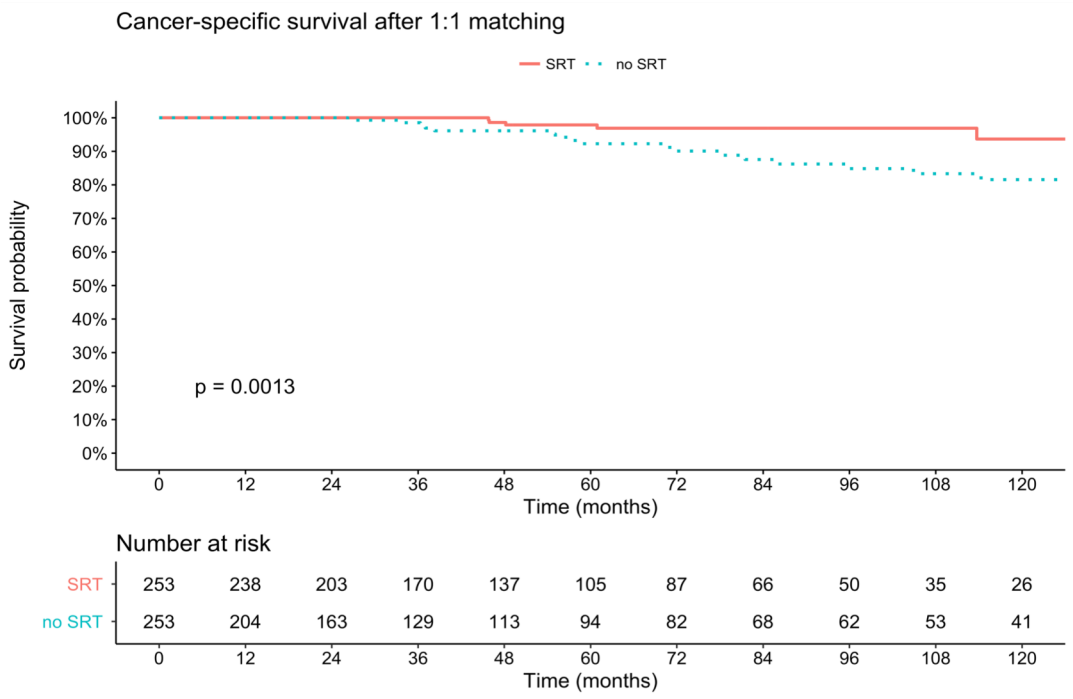
CI = confidence interval; GG = Gleason grade group; OR = odds ratio; PSA = prostate-specific antigen.

Prostate Cancer

Persistent Prostate-Specific Antigen After Radical Prostatectomy and Its Impact on Oncologic Outcomes

Effect of Salvage Radiation on Cancer-specific survival

- **after Propensity Score Matching between patients with Salvage RT vs. no RT CSS at 10 years after RP was 93.7 vs. 81.6% in the entire cohort (p<0.01)**



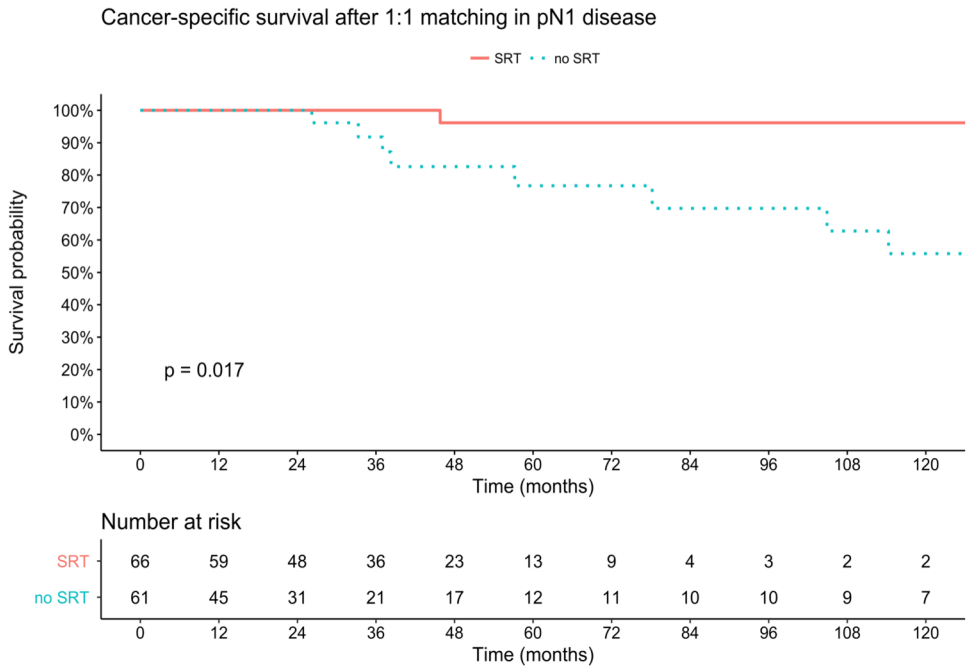
Eur Urol. 2019 Jul;76(1):106-114.

Prostate Cancer

Persistent Prostate-Specific Antigen After Radical Prostatectomy and Its Impact on Oncologic Outcomes

Effect of Salvage Radiation on Cancer-specific survival

- **after Propensity Score Matching between patients with Salvage RT vs. no RT CSS at 10 years after RP was 96.2 vs. 55.8% in pN1 disease (p<0.01)**



Eur Urol. 2019 Jul;76(1):106-114.

Prostate Cancer

Impact of Early Salvage Radiation Therapy in Patients with Persistently Elevated or Rising Prostate-specific Antigen After Radical Prostatectomy

Nicola Fossati [a,], R. Jeffrey Karnes [b], Michele Colicchia [b], Stephen A. Boorjian [b], Alberto Bossi [c], Thomas Seisen [c], Nadia Di Muzio [d], Cesare Cozzarini [d], Barbara Noris Chiorda [d], Claudio Fiorino [e], Giorgio Gandaglia [a], Paolo Dell'Oglio [a], Shahrokh F. Shariat [f], Gregor Goldner [g], Steven Joniau [h], Antonino Battaglia [h], Karin Haustermans [i], Gert De Meerleer [i], Valérie Fonteyne [j], Piet Ost [j], Hendrik Van Poppel [h], Thomas Wiegel [k], Francesco Montorsi [a], Alberto Briganti [a]*

When patients were stratified into five risk groups using regression tree analysis (area under the curve: 85%), early SRT administration provided better metastasis-free survival in three groups only:

(1) low risk: undetectable PSA after RP, Gleason score ≤ 7, and tumour stage ≥ pT3b,
(2) intermediate risk: undetectable PSA after RP with Gleason score ≥ 8,
(3) high risk: PSA persistence after RP with Gleason score ≤ 7.

Conversely, very low-risk (undetectable PSA after RP, Gleason score ≤ 7, and tumour stage ≤ pT3a and very high-risk patients (PSA persistence after RP, and Gleason score ≥ 8) did not benefit from early salvage treatment

Eur Urol. 2018;73(3):436–444

Biochemical recurrence

- **Biochemical recurrence (BCR) continues to be reported in up to 35% of men undergoing RP**
- **The natural history of BCR after RP is variable and does not always translate into systemic progression or prostate cancer death**

DEFINING PROSTATE SPECIFIC ANTIGEN PROGRESSION AFTER RADICAL PROSTATECTOMY: WHAT IS THE MOST APPROPRIATE CUT POINT?

CHRISTOPHER L. AMLING, ERIK J. BERGSTRALH, MICHAEL L. BLUTE, JEFFREY M. SLEZAK AND HORST ZINCKE

From the Department of Urology, Naval Medical Center, San Diego, California, and Department of Urology and Section of Biostatistics, Mayo Clinic, Rochester, Minnesota

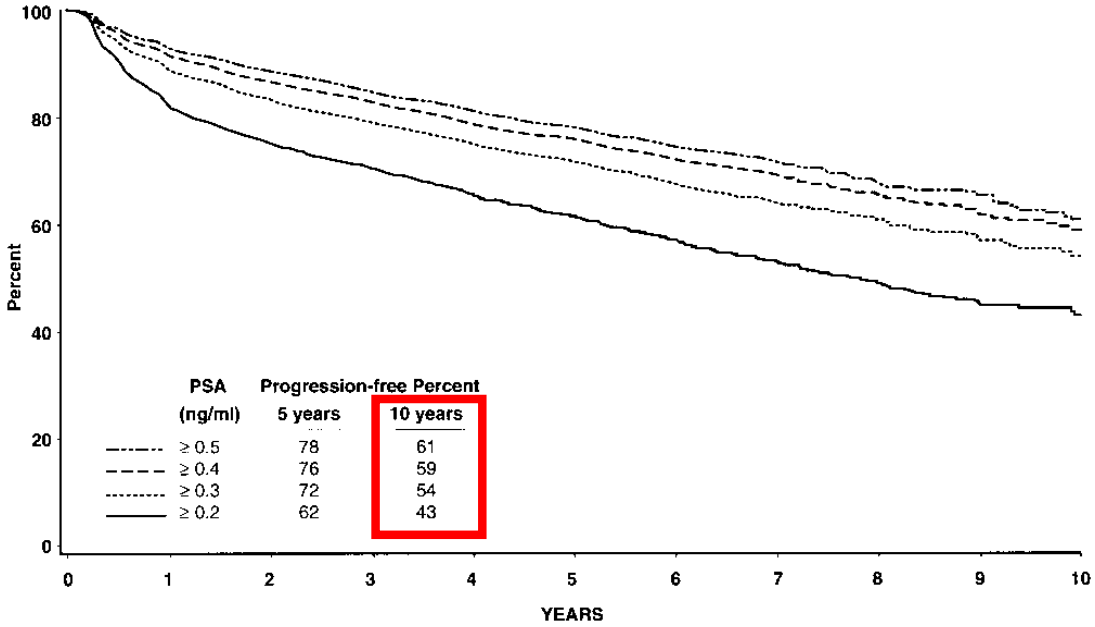


FIG. 1. Biochemical progression-free percent using different PSA cut points to define progression after radical prostatectomy. Number of patients at risk for progression at 5, 7 and 10 years ranged 1,354 to 1,728, 497 to 703 and 53 to 83, respectively.

Natural History of Progression After PSA Elevation Following Radical Prostatectomy

- **Retrospective review of 1997 men who underwent RP between 1982 and 1997**
- **Of the 1997 men, 315 (15%) developed biochemical PSA level elevation**
- **Eleven of these underwent early hormone therapy after the recurrence and are not included in the study**

Pound et al., JAMA, 1999

Natural History of Progression After PSA Elevation Following Radical Prostatectomy

Figure 1. Actuarial Likelihood of Metastasis-Free Survival in 1997 Men Treated With Radical Prostatectomy

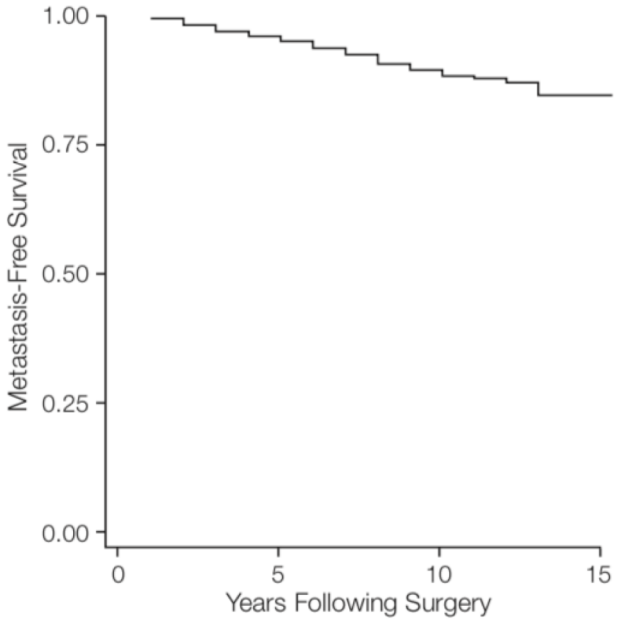
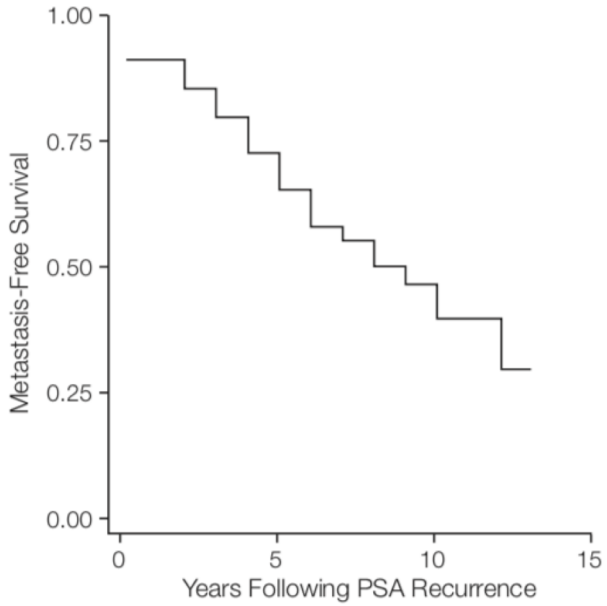


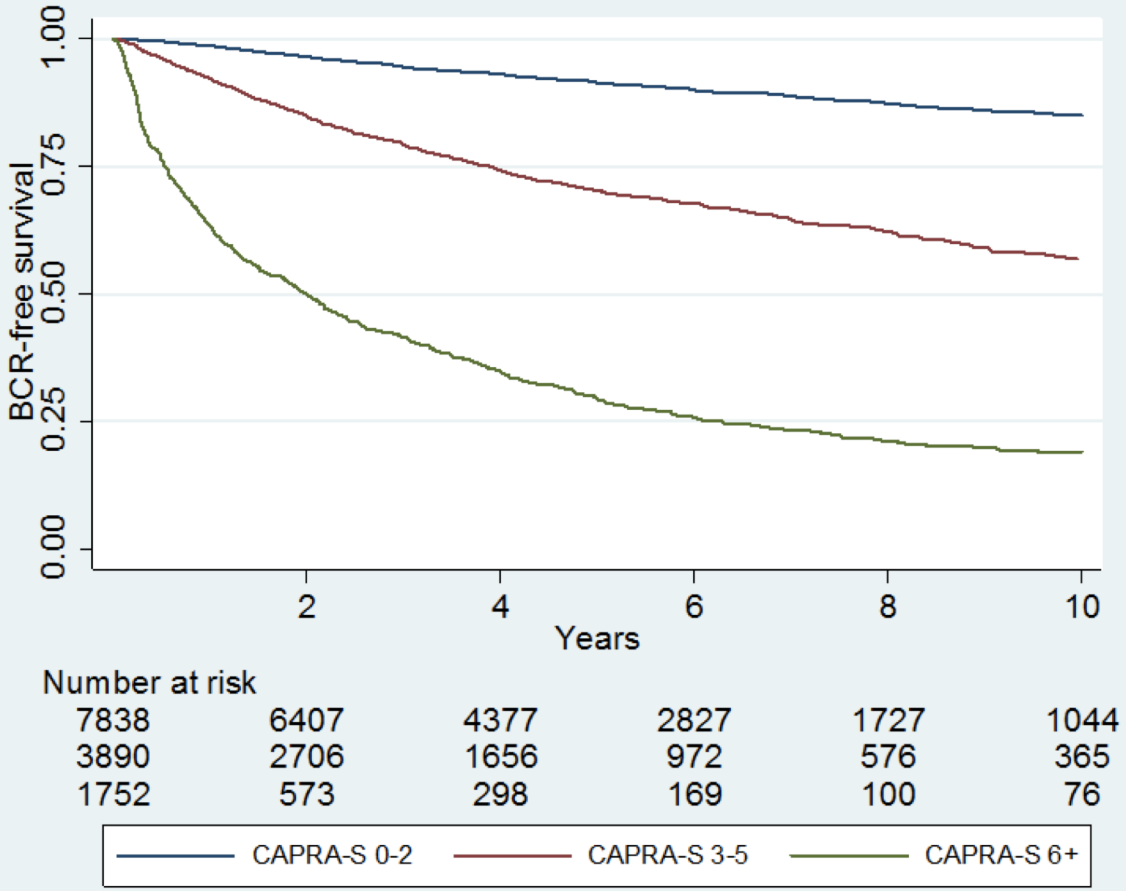
Figure 2. Actuarial Likelihood of Metastasis-Free Survival in 304 Men With Prostate-Specific Antigen (PSA) Elevation After Radical Prostectomy



- **5-yr MP-free survival rate of 64% among 304 RP BCR patients who were observed until MP.**

Pound et al., JAMA, 1999

Biochemical recurrence after Radical Prostatectomy



- **14,532 patients after RP (1992-2012)**
- **No neoadjuvant or adjuvant therapy**
- **Median follow-up: 50.8 months**
- **Biochemical recurrence occurred in 2950 (20.3%) men**

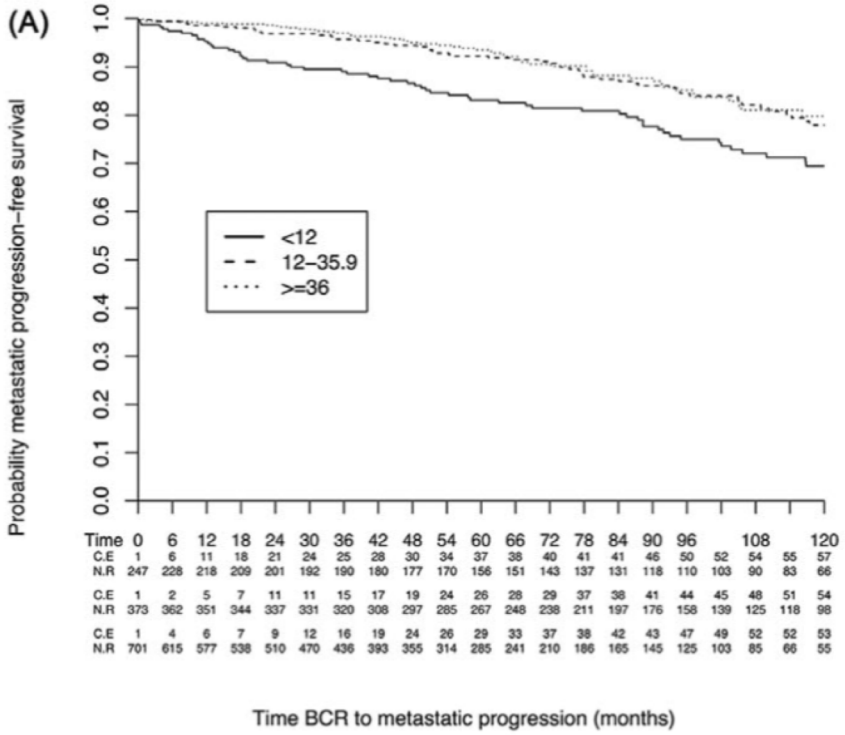
Tilki et al., J Urol, 2016

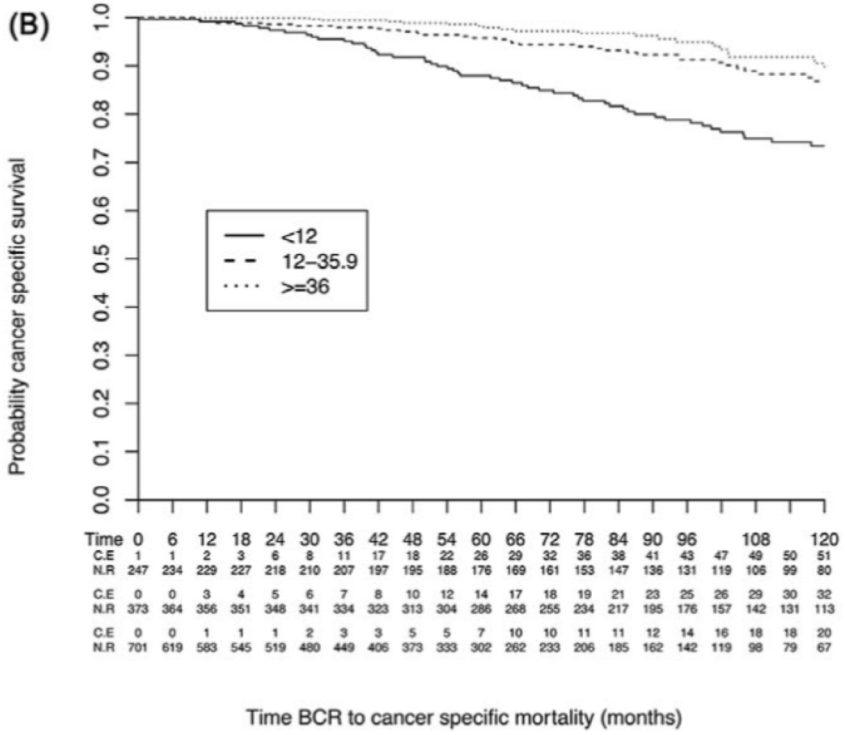
Long-term cancer control outcomes in patients with biochemical recurrence and the impact of time from radical prostatectomy to biochemical recurrence

Raisa S. Pompe[1,2,3] | Philipp Gild[2] | Pierre I. Karakiewicz[3] | Lea-Philine Bock[1] | Thorsten Schlomm[1,2] | Thomas Steuber[1] | Markus Graefen[1] | Hartwig Huland[1] | Zhe Tian[3] | Derya Tilki[1,2]

The Prostate

2018





Review – Prostate Cancer

Prognostic Value of Biochemical Recurrence Following Treatment with Curative Intent for Prostate Cancer: A Systematic Review

Thomas Van den Broeck [a,b,1,], Roderick C.N. van den Bergh [c,1], Nicolas Arfi [d,1], Tobias Gross [e], Lisa Moris [a,b], Erik Briers [f], Marcus Cumberbatch [g], Maria De Santis [h,i], Derya Tilki [j,k], Stefano Fanti [l], Nicola Fossati [m,n], Silke Gillessen [o,p,q], Jeremy P. Grummet [r], Ann M. Henry [s], Michael Lardas [t], Matthew Liew [u], Olivier Rouvière [v], Jakub Pecanka [w,x], Malcolm D. Mason [y], Ivo G. Schoots [z], Theo H. van Der Kwast [aa], Henk G. van Der Poel [c], Thomas Wiegel [bb], Peter-Paul M. Willemse [cc], Yuhong Yuan [dd], Thomas B. Lam [ee,ff], Philip Cornford [gg], Nicolas Mottet [hh]*

EAU – EANM – ESTRO – ESUR – SIOG Guidelines on

Prostate Cancer

N. Mottet (Chair), R.C.N. van den Bergh, E. Briers (Patient Representative), P. Cornford (Vice-chair), M. De Santis, S. Fanti, S. Gillessen, J. Grummet, A.M. Henry, T.B. Lam, M.D. Mason, T.H. van der Kwast, H.G. van der Poel, O. Rouvière, D. Tilki, T. Wiegel

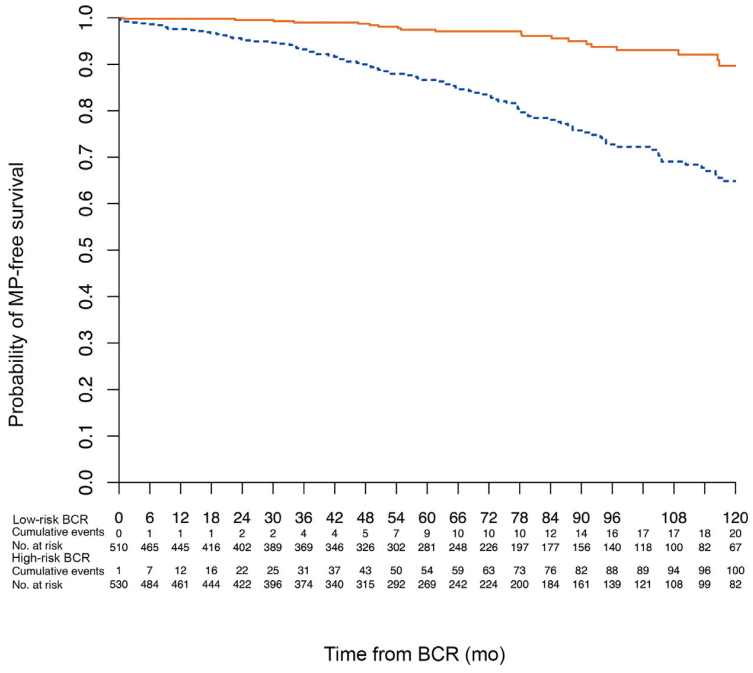
- **Only approximately 30% of patients with BCR after primary surgery develop clinical recurrence, with only 16.4% dying from their disease**
- **Based on the review, proposal was to stratify patients into:**
  - **EAU Low-Risk BCR: PSA-DT > 1 year AND pGS<8 for RP**
  - **EAU High-Risk BCR: PSA-DT ≤ 1 year OR pGS8-10 for RP**

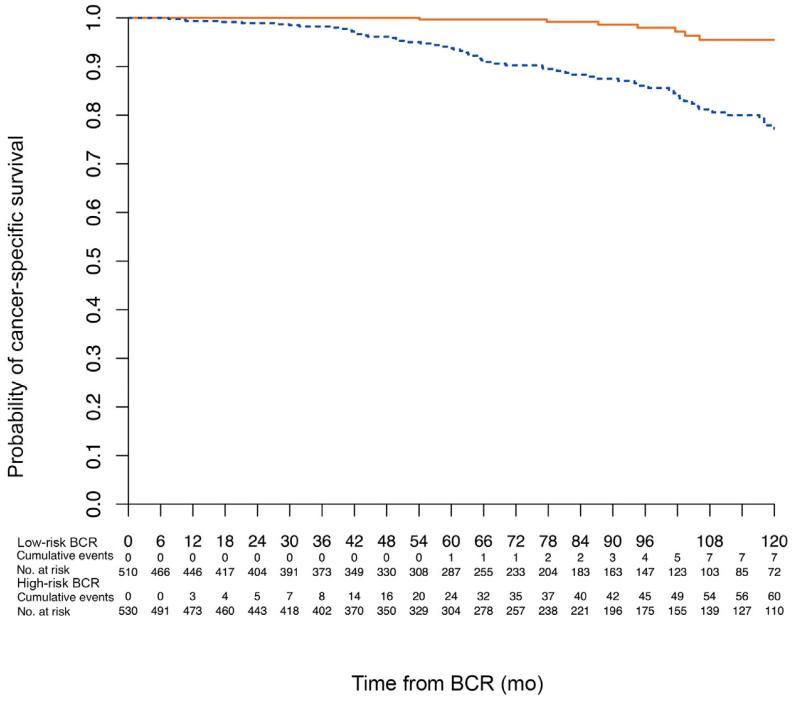
Eur Urol. 2019 Jun;75(6):967-987

External Validation of the European Association of Urology Biochemical Recurrence Risk Groups to Predict Metastasis and Mortality After Radical Prostatectomy in a European Cohort

Derya Tilki [a,b,*], *Felix Preisser* [a], *Markus Graefen* [a], *Hartwig Huland* [a], *Raisa S. Pompe* [a,b]

510 patients were considered EAU low-risk BCR; 530 patients met the EAU high-risk BCR criteria (RP between 1992 and 2006).

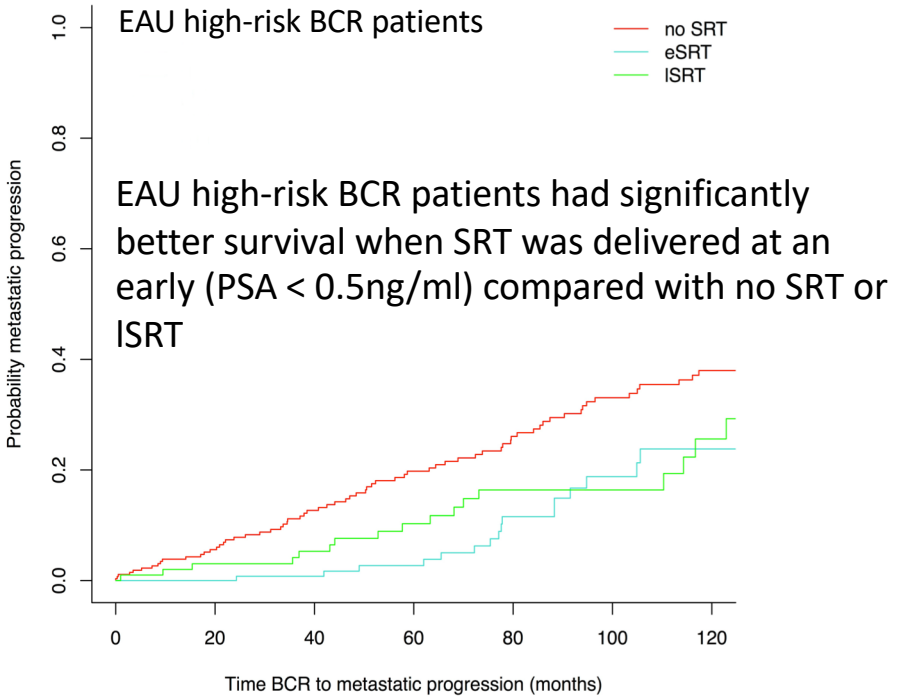




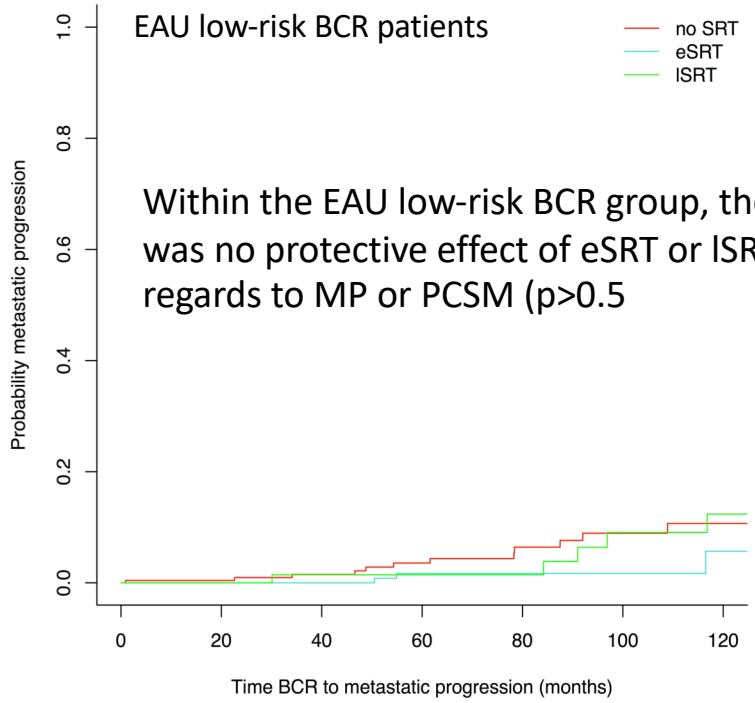
Eur Urol. 2019 Jun;75(6):896-900

External Validation of the European Association of Urology Biochemical Recurrence Risk Groups to Predict Metastasis and Mortality After Radical Prostatectomy in a European Cohort

Derya Tilki [a,b,*], *Felix Preisser* [a], *Markus Graefen* [a], *Hartwig Huland* [a], *Raisa S. Pompe* [a,b]



EAU high-risk BCR patients had significantly better survival when SRT was delivered at an early (PSA < 0.5ng/ml) compared with no SRT or lSRT

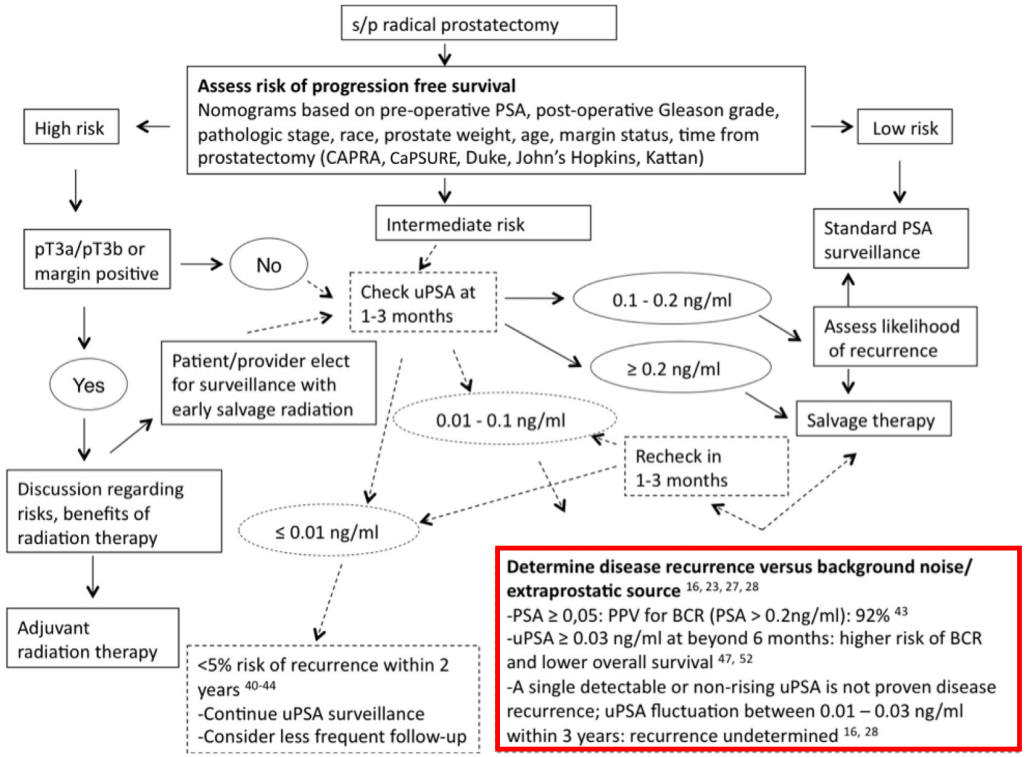


Within the EAU low-risk BCR group, there was no protective effect of eSRT or lSRT with regards to MP or PCSM (p>0.5

Eur Urol. 2019 Jun;75(6):896-900

Ultrasensitive Prostate Specific Antigen and Its Role after Radical Prostatectomy: A Systematic Review

Derya Tilki,*,† Sun Il Kim,† Brian Hu, Marc A. Dall'Era and Christopher P. Evans



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Imaging

National Comprehensive Cancer Network®

NCCN Guidelines Version 4.2019
Prostate Cancer

NCCN Guideli
Table o
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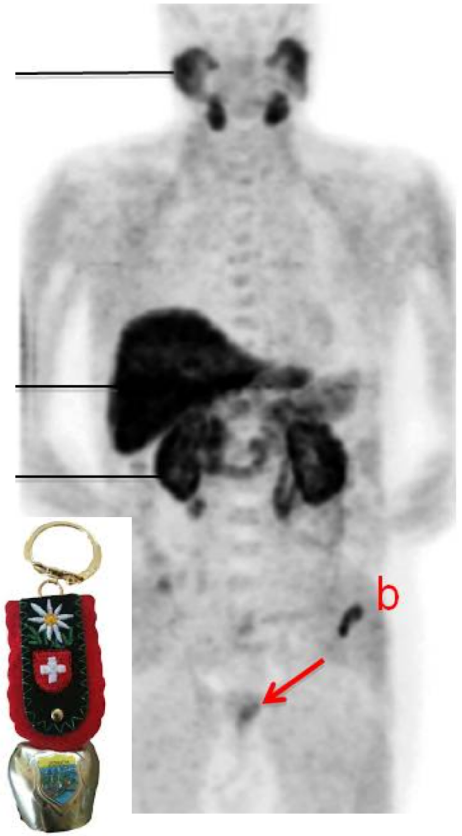
Table 2. Summary of Main PET Imaging Tracers Studied in Prostate Cancer*

Tracer	Half-life (min)	Cyclotron	Mechanism of Action	Excretion	Sensitivity (%)*	Specificity (%)*	FDA Status	Panel Recommendation
C-11 choline	20	Onsite	Cell membrane synthesis	Hepatic	32–93	40–93	• Cleared	• May be used for detection of biochemically recurrent small-volume disease in soft tissues • May be used after bone scan for further evaluation of equivocal findings
F-18 fluciclovine	110	Regional	Amino acid transport	Renal	37–90	40–100	• Cleared	• May be used for detection of biochemically recurrent small-volume disease in soft tissues • May be used after bone scan for further evaluation of equivocal findings
F-18 NaF	110	Regional	Adsorption within bone matrix	Hepatic	87–100	62–89	• Cleared	• May be used after bone scan for further evaluation of equivocal findings
C-11 acetate	20	Onsite	Lipid synthesis	Lung	59–69	83–98	• Not cleared	• May be used in clinical trial or registry
Ga-68 PSMA	68	Generator (no cyclotron)	PSMA analog	Renal	76–86	86–100	• Not cleared	• May be used in clinical trial or registry

* Interpret with caution; few studies used biopsy/surgery as gold standard; see *Nuclear Imaging*, above, for references.



Imaging

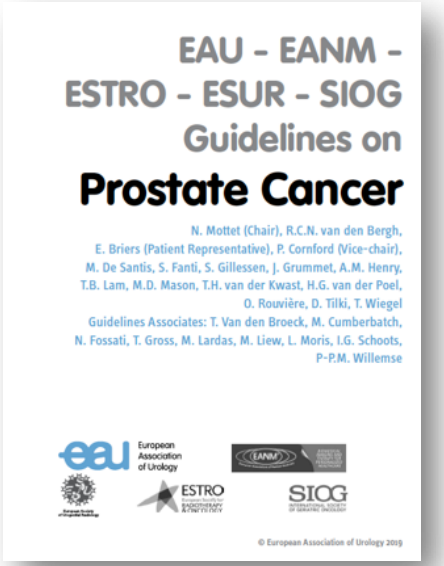
Gallium-68 Prostate-specific Membrane Antigen Positron Emission Tomography in Advanced Prostate Cancer—Updated Diagnostic Utility, Sensitivity, Specificity, and Distribution of Prostate-specific Membrane Antigen-avid Lesions: A Systematic Review and Meta-analysis

Marlon Perera [a,b,c,], Nathan Papa [a], Matthew Roberts [b,c], Michael Williams [b], Cristian Udovicich [d], Ian Vela [b,e], Daniel Christidis [a], Damien Bolton [a,f], Michael S. Hofman [g], Nathan Lawrentschuk [a,f,h,i], Declan G. Murphy [h,i]*

- **Systematic review of PSMA PET**
- **36 articles**
- **N=4467 patients**
- **Per lesion:**
  - **Sensitivity: 75%**
  - **Specificity: 95%**
- **Gleason score not predictive**
  - **Gleason 7: 75%**
  - **Gleason 8-10: 79%**

PSA level	Positive scan rate
0-0.19ng/ml	33%
0.2-0.49ng/ml	42%
0.5-0.99ng/ml	59%
1-1.99ng/ml	75%
>2ng/ml	95%

Perera et al Eur Urol 2019 **Courtesy of Declan Murphy**

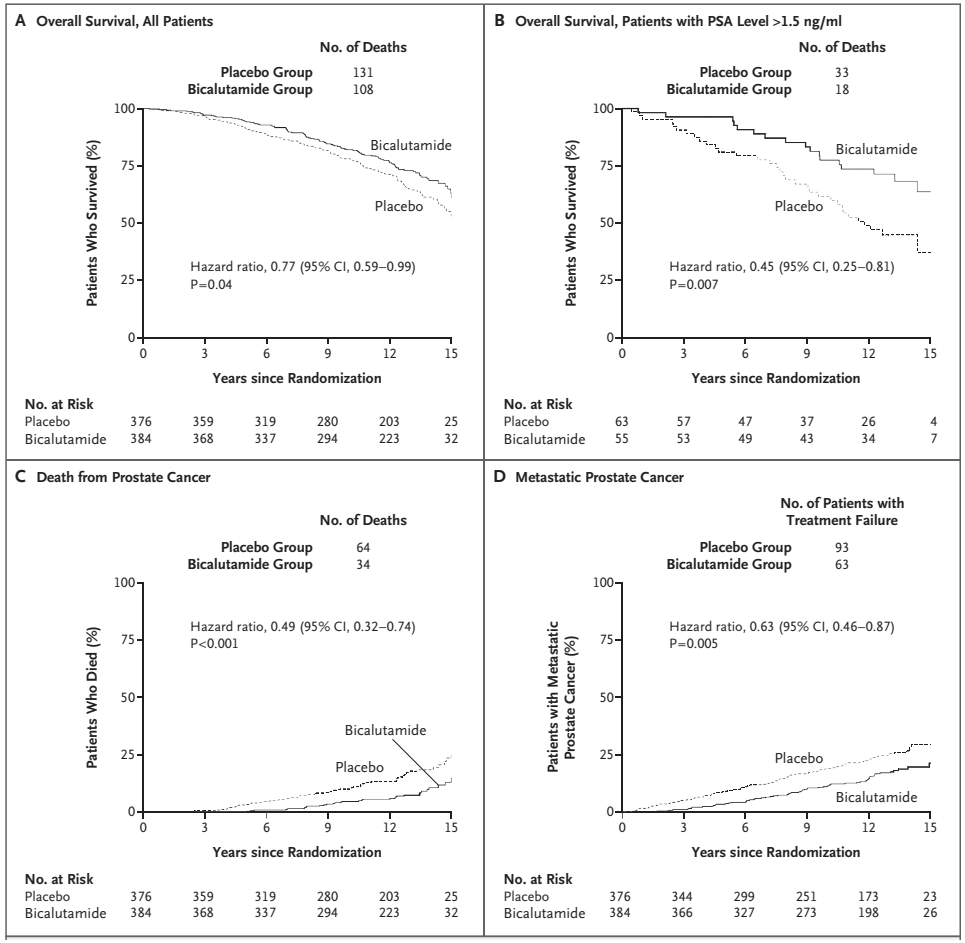


Prostate-specific antigen (PSA) recurrence after radical prostatectomy	LE	Strength rating
Perform prostate-specific membrane antigen (PSMA) positron emission tomography (PET) computed tomography (CT) if the PSA level is > 0.2 ng/mL and if the results will influence subsequent treatment decisions.	2b	Weak
In case PSMA PET/CT is not available, and the PSA level is ≥ 1 ng/mL, perform fluciclovine PET/CT or choline PET/CT imaging if the results will influence subsequent treatment decisions.		Weak
PSA recurrence after radiotherapy		
Perform prostate multiparametric magnetic resonance imaging to localise abnormal areas and guide biopsies in patients fit for local salvage therapy.	3	Strong
Perform PSMA PET/CT (if available) or fluciclovine PET/CT or choline PET/CT in patients fit for curative salvage treatment.	2b	Strong

EAU Guidelines 2019

Courtesy of Declan Murphy

Prostate Cancer: Radiotherapy



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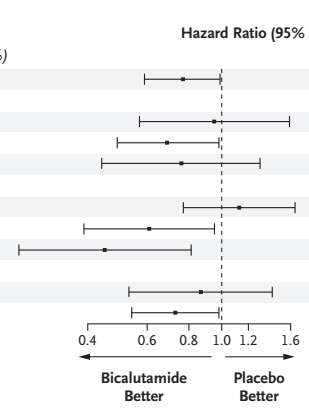
Radiation with or without Antiandrogen Therapy in Recurrent Prostate Cancer

W.U. Shipley, W. Seiferheld, H.R. Lukka, P.P. Major, N.M. Heney, D.J. Grignon, O. Sartor, M.P. Patel, J.-P. Bahary, A.L. Zietman, T.M. Pisansky, K.L. Zeitzer, C.A.F. Lawton, F.Y. Feng, R.D. Lovett, A.G. Balogh, L. Souhami, S.A. Rosenthal, K.J. Kerlin, J.J. Dignam, S.L. Pugh, and H.M. Sandler, for the NRG Oncology RTOG*

Subgroup	No. of Patients (%)	Bicalutamide Group	Placebo Group	Hazard Ratio (95% CI)	P Value
		12-yr overall survival rate (%)			
Overall	760 (100.0)	76.3	71.3	0.77 (0.59–0.99)	0.04
Gleason score					
2–6	214 (28.2)	79.5	79.2	0.95 (0.57–1.59)	0.84
7	413 (54.5)	78.5	70.9	0.69 (0.49–0.98)	0.04
8–10	131 (17.3)	63.9	58.4	0.76 (0.44–1.30)	0.32
PSA level at trial entry					
<0.7 ng/ml	405 (53.3)	76.8	80.7	1.13 (0.77–1.65)	0.53
0.7–1.5 ng/ml	237 (31.2)	77.0	67.5	0.61 (0.39–0.95)	0.03
>1.5 ngl/ml	118 (15.5)	73.5	48.9	0.45 (0.25–0.81)	0.007
Positive surgical margin					
No	191 (25.1)	73.5	72.9	0.87 (0.53–1.41)	0.56
Yes	569 (74.9)	77.3	70.7	0.73 (0.54–0.98)	0.04



Prostate Cancer: Radiotherapy

	Radiotherapy alone (n=373)	Radiotherapy and goserelin (n=369)
Age (years)	67 (52–85)	67 (49–80)
Gleason score		
<8	332 (89%)	329 (89%)
≥8	41 (11%)	40 (11%)
Pathological tumour stage (TNM 2005)		
pT2a	37 (10%)	29 (8%)
pT2b	76 (20%)	75 (20%)
pT2c	88 (24%)	92 (25%)
pT3a	121 (32%)	127 (34%)
pT3b	50 (13%)	44 (12%)
pT4 bladder neck involvement	0	1 (<1%)
Missing	1 (<1%)	1 (<1%)
Pathological node involvement (TNM 2005)		
pN0	274 (74%)	273 (74%)
pNX	99 (27%)	96 (26%)
Positive surgical margins	196 (53%)	175 (47%)
No seminal vesicle involvement	318 (85%)	312 (85%)
PSA doubling time >6 months	276 (74%)	270 (73%)
ECOG performance status		
0	345 (92%)	329 (89%)
1	13 (4%)	22 (6%)
Missing	15 (4%)	18 (5%)
PSA at baseline randomisation (µg/L), median (IQR)*	0·30 (0·20–0·50)	0·30 (0·20–0·50)
Time between surgery and relapse (months), median (IQR)*	29·99 (19–52)	33·98 (21–53)
Presurgery PSA (µg/L), median (IQR)†	8·10 (6–12)	8·35 (6–12)

Date are n (%) or median (range) unless otherwise noted. PSA=prostate-specific antigen. ECOG=Eastern Cooperative Oncology Group. TNM=TNM Classification of Malignant Tumours. Percentages might not sum to 100 because of rounding. *Four missing values. †169 missing values.

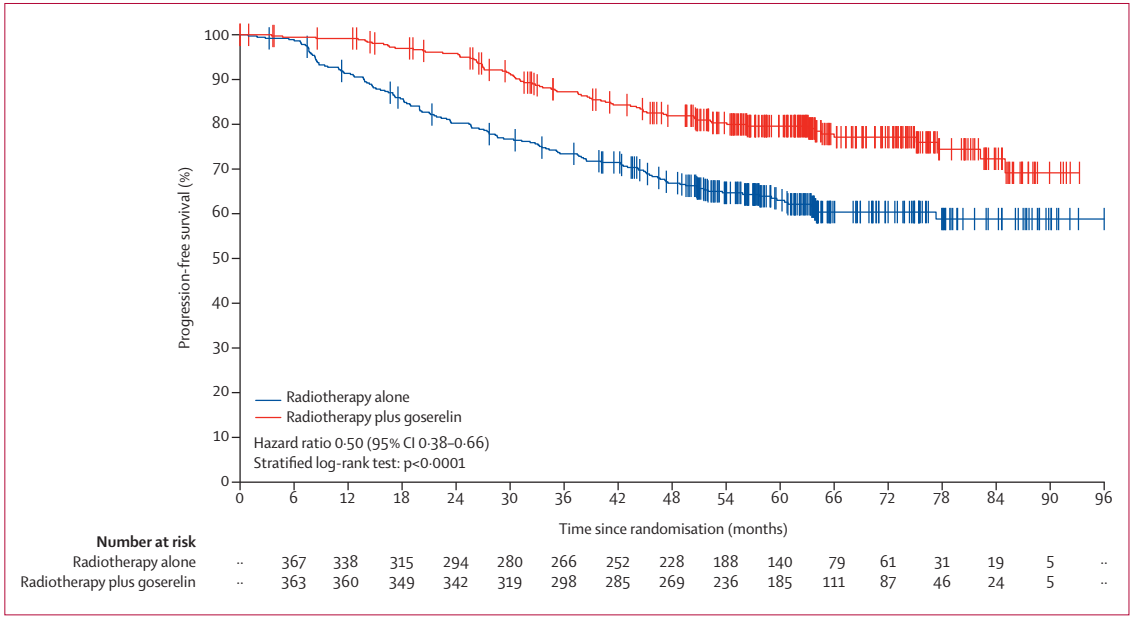
Table 1: **Baseline characteristics in the intention-to-treat population**

Carrie, C. et al. Lancet;2016:747-56.

Salvage radiotherapy with or without short-term hormone therapy for rising prostate-specific antigen concentration after radical prostatectomy (GETUG-AFU 16): a randomised, multicentre, open-label phase 3 trial

Christian Carrie, Ali Hasbini, Guy de Laroche, Pierre Richaud, Stéphane Guerif, Igor Latorzeff, Stéphane Supiot, Mathieu Bosset, Jean-Léon Lagrange, Véronique Beckendorf, François Lesaunier, Bernard Dubray, Jean-Philippe Wagner, Tan Dat N'Guyen, Jean-Philippe Suchaud, Gilles Créhange, Nicolas Barbier, Muriel Habibian, Céline Ferlay, Philippe Fourneret, Alain Ruffion, Sophie Dussart

- **PSA 0.2-2.0ug/L after RP**
- **No apparent clinical disease**
- **66Gy XRT ± 6 months ADT**



Review – Prostate Cancer

Salvage Lymph Node Dissection for Nodal Recurrent Prostate Cancer: A Systematic Review

Guillaume Ploussard[a,], Giorgio Gandaglia[b], Hendrik Borgmann[c], Pieter de Visschere[d], Isabel Heidegger[e], Alexander Kretschmer[f], Romain Mathieu[g], Cristian Surcel[h], Derya Tilki[i,j], Igor Tsaur[c], Massimo Valerio[k], Roderick van den Bergh[l], Piet Ost[m], Alberto Briganti[b], on behalf of the EAU-YAU Prostate Cancer Working Group*

- **Overall, 27 SLND series have been selected for synthesis.**
- **The 2- and 5-yr biochemical progression-free survival rates ranged from 23% to 64% and from 6% to 31%, respectively.**
- **Main drawbacks limiting the interpretation of the effectiveness of SLND were the retrospective design of single-center series, heterogeneity between series in terms of adjuvant treatment, endpoints, definitions of progression and study population, as well as the absence of long-term follow-up.**

Eur Urol. 2018, 73;3:436–444

Salvage Lymphadenectomy (sLND) series – PSMA-guided

Original Article	No. of patients	PSA	Imaging method	Mean No. removed LNs	Median follow-up (months)	Complete PSA response	PFS	CSS (%)
Linxweiler et al. Surg Oncol 2018	36	1.98	Choline(n = 11) PSMA (n = 25) PET/CT	6.5	14 (PSMA) 48 (choline)	36% (44% if PSMA, 18% if choline)	Median 12 mo if PSMA, 4.7 mo if choline	NR
Maurer et al. Eur Urol 2018	31	1.13	99Tc-PSMA PET/ CT	4.3	12.2	64.5	1 yr: 43%	NR
Siriwardana et al. BJUI 2017	35	2.2	PSMA PET/CT	9	12.0	43.0	1 yr: 23%	NR
Rauscher et al. BJUI 2017	31	1.3	PSMA PET/CT	12	11.2	60.0	1 yr: 64% (treatment-free survival)	NR
Fossati et al. Eur Urol 2018 (9 centers)	654	2.1	Choline(n = 460) PSMA (n = 194) PET/CT	26	30	44	Optimal candidates: <Gleason grade group 5 Longer time RP to BCR No retroperitoneal uptake at PET/CT <3 positive spots at PET/CT Lower PSA at PET/CT	

adapted from Ploussard et al., Eur Urol, 2018

Conclusions

- PSA persistence >0.1 has poorer prognosis but SRT beneficial
- PSA recurrence has several definitions
  - New EAU guidelines move from absolute value to risk groups
- Ultrasensitive PSA not specifically recommended in guidelines
  - >0.03 and rising correlates with BCR >0.2
- New imaging has a relevant and evolving role
- EAU low risk is at small risk of metastatic progression or cancer specific mortality
- SRT earlier and with ADT should be given in EAU high-risk
- Salvage surgical approaches are immature and should be considered cautiously

Thank You