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Prophylactic cranial irradiation in extensive disease small cell lung cancer

(EORTC 08993-22993)

B. Slotman, C. Faivre-Finn, G. Kramer†, E. Rankin, M. Snee, M. Hatton, P. Postmus, L. Collette, M. Mauer, S. Senan, on behalf of the EORTC Radiation Oncology and Lung Cancer Groups

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Study Design
Chemotherapy
(4-6 cycles)
No response
Any response
Random
PCI
20-30 Gy in
5-12 fractions
No PCI
< 5 weeks
4-6 weeks
Stratification: - Institute
- Performance score

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Patient characteristics

	PCI (N=143)	Control (N=143)	Sign.
	N (%)	N (%)	
Median Age (years)	62.0	63.0	N.S.
Range	37.0 - 75.0	39.0 - 75.0	
Gender			N.S.
male	97 (67.8)	82 (57.3)	
female	46 (32.2)	61 (42.7)	
WHO performance status			N.S.
WHO 0	52 (36.4)	52 (36.4)	
WHO 1	80 (55.9)	76 (53.1)	
WHO 2	11 (7.7)	15 (10.5)	
Median time since diagnosis (months)	4.2	4.2	N.S.

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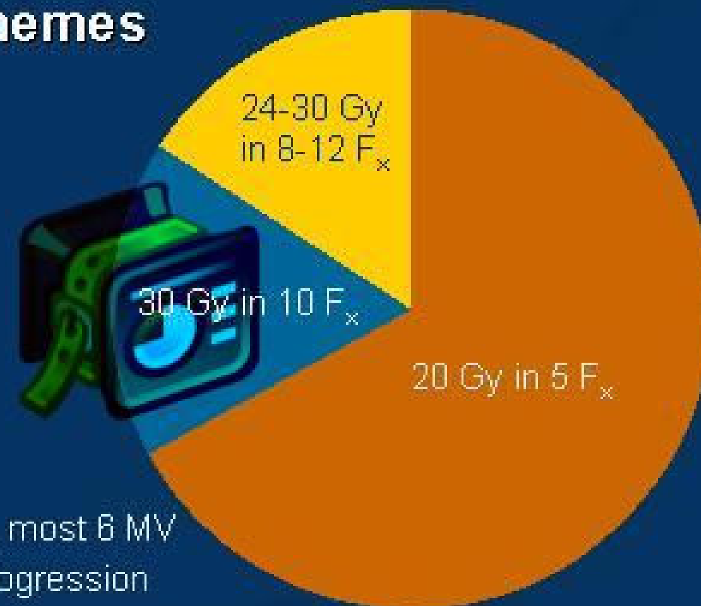
Radiotherapy schemes



- 2 parallel-opposed fields, most 6 MV
- 1 stopped due to early progression
- 4 treatment interruptions (3 logistical, 1 refusal)

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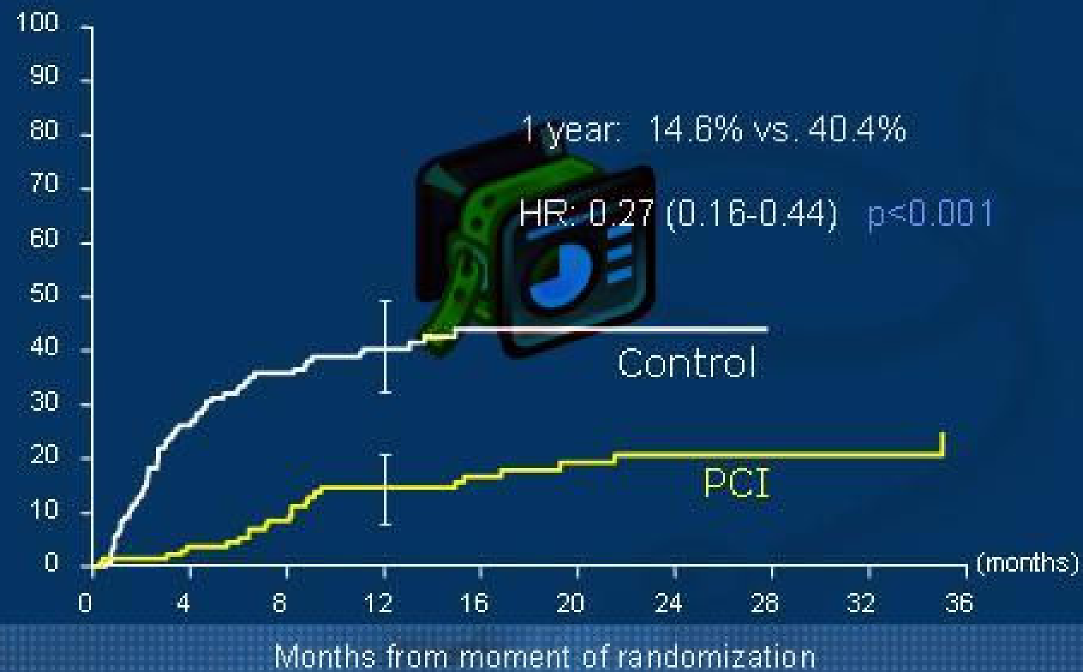
Type of first event

	PCI (N=143)	Control (N=143)
	N (%)	N (%)
No event	14 (9.8)	6 (4.2)
Symptomatic brain metastases	13 (9.1)	50 (35.0)
- followed by extracranial progression	13	48
Extracranial disease progression	109 (76.2)	85 (59.4)
- followed by brain metastases	11	9
Death due to other causes	7 (4.9)	2 (1.4)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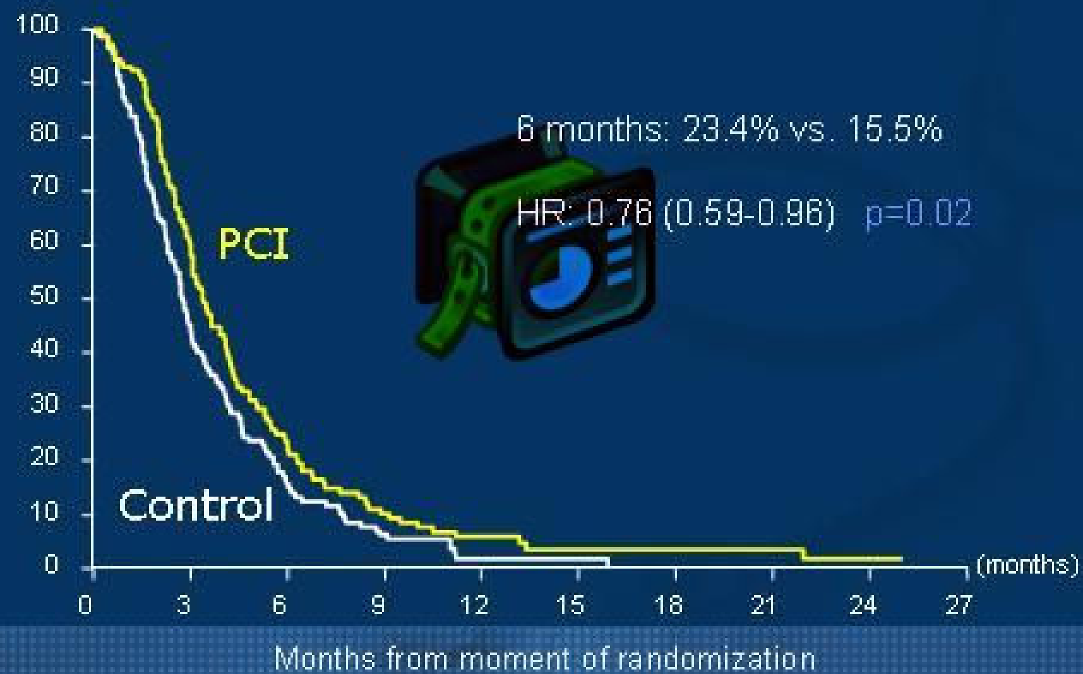
Symptomatic brain metastases
1 year: 14.6% vs. 40.4%
HR: 0.27 (0.16-0.44) p<0.001
Control
PCI
100
90
80
70
60
50
40
30
20
10
0
0
4
8
12
16
20
24
28
32
36
(months)
Months from moment of randomization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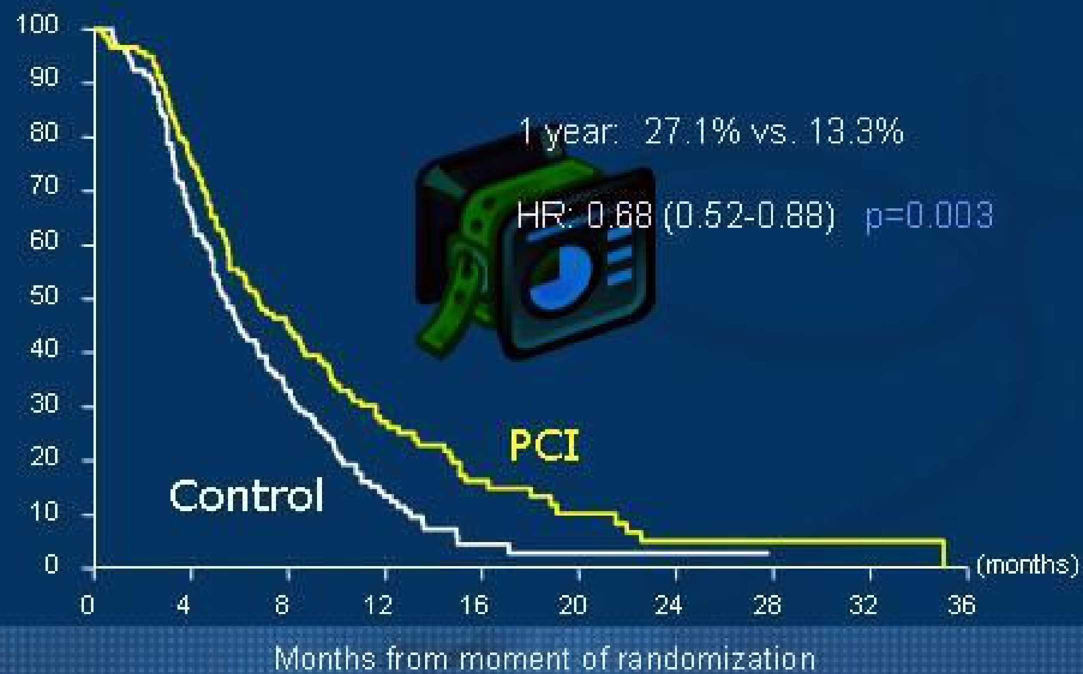
Failure-free survival
100
90
80
70
60
50
40
30
20
10
0
6 months: 23.4% vs. 15.5%
HR: 0.76 (0.59-0.96) p=0.02
PCI
Control
(months)
0 3 6 9 12 15 18 21 24 27
Months from moment of randomization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Overall survival
1 year: 27.1% vs. 13.3%
HR: 0.68 (0.52-0.88) p=0.003
PCI
Control
100
90
80
70
60
50
40
30
20
10
0
0
4
8
12
16
20
24
28
32
36
(months)
Months from moment of randomization

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Summary

- PCI significantly reduces the risk of symptomatic brain metastases ($p<0.001$; HR = 0.27; 14.6 vs. 40.4% at 1 yr)
- No difference for the time to extra-cranial progression
- PCI significantly prolongs failure-free survival and overall survival (Overall survival: $p=0.003$; HR = 0.68 ; 27.1 vs. 13.3% at 1 yr)
- PCI is well tolerated and does not adversely influence global QoL/health status

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Take home message

Patients with ED-SCLC

who respond to chemotherapy

should routinely

be offered PCI

Un tt local qui démontre un impact sur la survie globale dans une maladie disséminée

Intermittent versus continuous androgen suppression in advanced prostate cancer – a randomised prospective study (AUO AP 17/95)

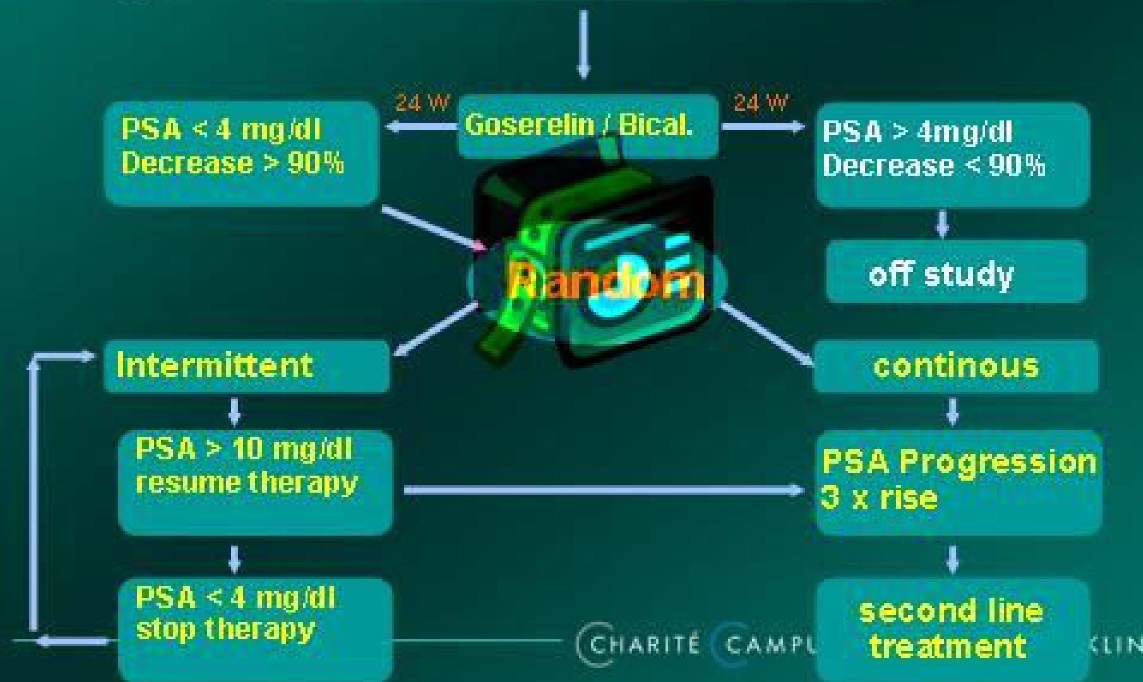
Kurt Miller,
Ursula Steiner, Anja Lingnau, Berlin;

Ulrich Witzch, Frankfurt,
Ahmad Haider, Bremerhaven,
Udo Wachter, Suhl,
Christoph Rüssel, Borcken,
Jens Altwein, Munic, Germany

Intermittent Androgen Blockade

PCA TxNxM1 / TxN1-3M0

AP 17/95



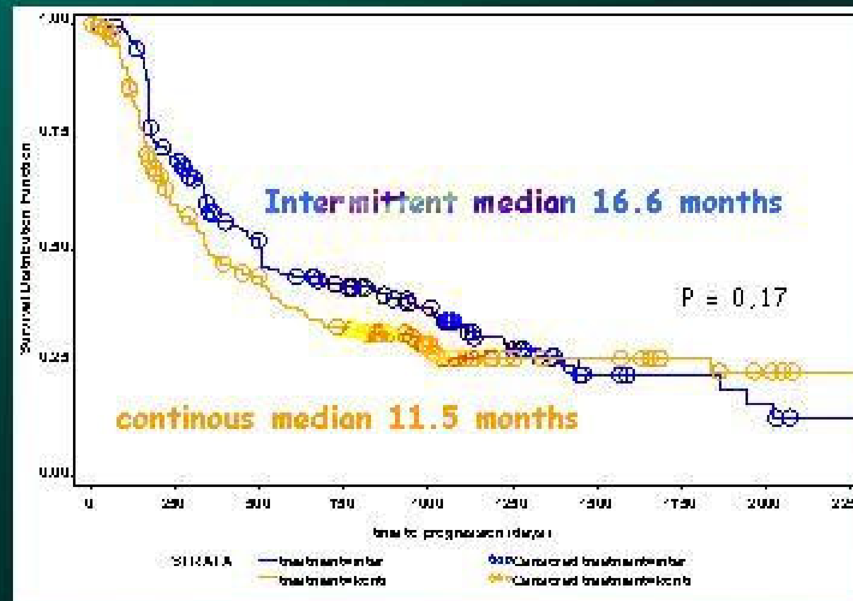
Patients

- 478 patients screened
- 335 patients randomised
- First patient in 10/97
- Last patient out 6/06

D2 patients	41% interm.	35 % contin.
Age:	70	68
PSA baseline	158	139 ng/ml

Median follow up 50,5 months

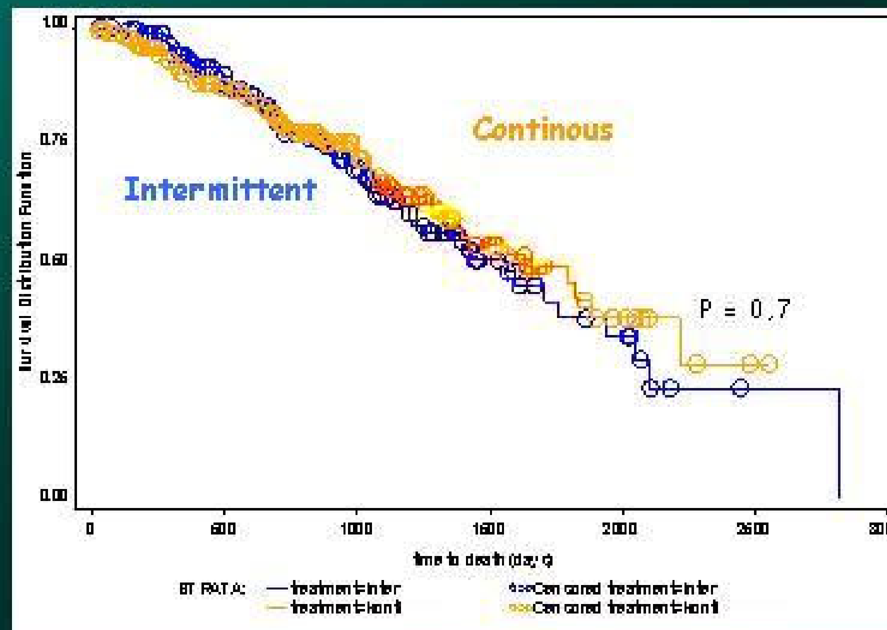
ITT Time to Progression



Progression free survival

	Treatment			
	Intermittent		Continuous	
	N	%	N	%
Total number of patients	165	100	170	100
Progression due to any reason	108	65.45	113	66.47

Overall survival



Reasons of patients´ death

	Intermittent		Continuous	
	N	%	N	%
Death by any reason	61	36.97	54	31.76
Death by progression of disease	39	23.64	30	17.65

Quality of life II

Items	QoL criteria	Results
Q18	Restriction of activity (number of days, last week)	no difference
Q19	Confinement to bed (number of days, last week)	
Q20	General well-being (last month)	Trend in favor of IAB
Q21–Q26	Physical capabilities (last month)	no difference
Q27–Q33	Sexual function (last month)	Trend in favor of IAB

Summary

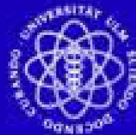
- No difference in progression free survival
- No difference in overall survival
- Small advantage in quality of life ?
- No difference in adverse events

Adjuvant RT versus „wait and see“ in patients with pT3 prostate cancer after radical prostatectomy -5 year results -

A study of the German Cancer Society
ARO 96-02 and AUO AP 09/95

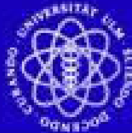
Thomas Wiegel, W. Hinkelbein, D. Bottke, N. Willich, P. Piechota, R. Souchon, M. Stöckle, C. Rübe, A. Hinke, and Kurt Miller

Supported by



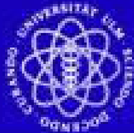
Material and Methods (I)
Study protocol

- Prostate cancer pT3 pN0
- PSA postoperative undetectable
  - No PSA reference kit (cut offs 0.03 - 0.1)
- Random: RT 60 Gy vs. „wait and see“
- Primary endpoint: 15% improvement of PSA bNED at 5 years
- Power: 80%



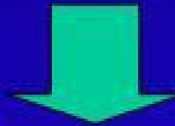
Material and Methods (II)
Stratification

- Gleason-score: <7 vs. ≥7
- Hormone treatment: Neoadjuvant vs. None
- Margins: R0 vs. R1
- Stage: pT3a vs. pT3b vs. pT3c

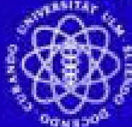


Material and Methods (IV)
Randomization

- Randomization 1 week after RP
  - **Practical reason (inpatient randomization)**
- Patients not reaching undetectable PSA
- planned exclusion out of study



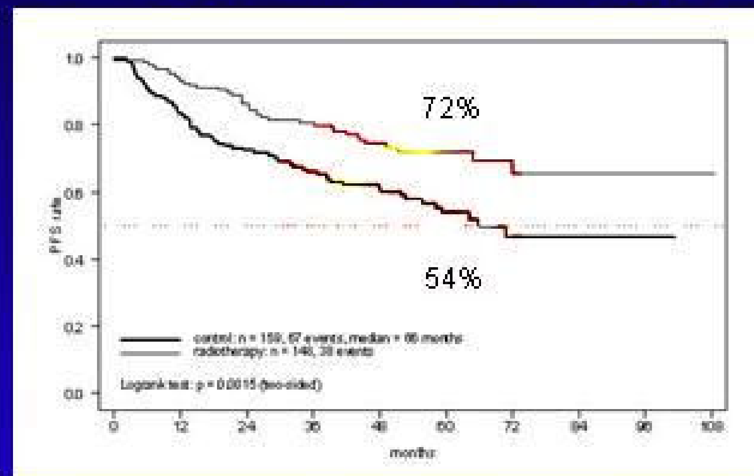
- Arm C - irradiation with 66,6 Gy



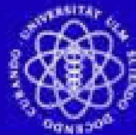
Patients – Follow up

- 4/1997 - 9/2004
- 385 patients randomised
- 86% reference pathology
- Adjuvant RT n=193
- Wait and see n=192
- Median Follow up: 55.4 months (range: 2 - 109)

Intend-to-treat analysis
Pts. with undetectable PSA only (307 pts.)



5-years: 18% advantage for bNED



Conclusions

- Adjuvant RT following RP significantly reduces the risk of biochemical progression in patients with pT3 tumors and postoperatively undetectable PSA levels

- Greatest benefit: R1, PSA>10, all Gleason, pT3a/b
- Low rate of side effects
- Comparable results with EORTC 22911

Adjuvant RT or RT for rising PSA after RP ???