Table 1: Rates of biopsy-detected PC by treatment and baseline characteristics

	Dutasteride	Placebo	Relative risk reduction, % (95% CI)
Subjects in efficacy population, n	3303	3423	
PCa, n (%)	659 (20.0)	857 (25.0)	22.8 (15.2, 29.7)
Age, years – n (%)			
<65	342 (17.5)	461 (22.5)	24.0 (13.4, 33.4)
⩾65	317(23.5)	396 (28.9)	22.1 (10.8, 31.9)
Family history of PCa, n (%)			
Yes	105 (23.4)	141 (32.3)	31.9 (13.0, 46.7)
No	554 (19.4)	716 (24.0)	21.6 (13.1, 29.3)
Baseline prostate volume tertile, cc, n (%)			
<36.6	268 (25.2)	349 (31.1)	20.3 (7.8, 31.1)
36.6–<51.8	214 (19.6)	250 (22.1)	16.0 (0.3, 29.3)
⩾51.8	169 (15.4)	244 (22.0)	32.1 (18.4, 43.6)
Baseline % free PSA tertile, n (%)			
<13.7	261 (24.0)	346 (29.8)	22.5 (10.4, 33.0)
13.7–<18.6	213 (19.0)	266 (23.4)	20.1 (5.5, 32.4)
⩾18.6	184 (16.8)	244 (21.8)	25.4 (10.8, 37.7)
Number of cores at entry biopsy			
⩽9	377 (22.3)	480 (27.4)	21.6 (11.3, 30.8)
⩾10	282 (17.5)	375 (22.5)	24.3 (12.5, 34.5)

7007 ORAL

Three years of adjuvant androgen deprivation with goserelin in patients with locally advanced prostate cancer treated with radiotherapy: Results at 10 years of EORTC trial 22863

M. Bolla[1], L. Collette[2], G. Van Tienhoven[3], P. Warde[4], J.B. Dubois[5], R.O. Mirimanoff[6], G.A. Storme[7], J. Bernier[8], A. Kuten[9], M. Piérart[10]. *[1]Centre Hospitalier de Grenoble, Radiation Oncology Department, Grenoble, France; [2]EORTC Headquarters, Statistics Department, Brussels, Belgium; [3]Academisch Medisch Centrum, Radiotherapy Department, Amsterdam, The Netherlands; [4]Princess Margaret Hospital, Radiation Oncology Department, Toronto, Canada; [5]CRLC Val d'Aurelle, Radiotherapy Department, Montpellier, France; [6]Centre Hospitalier Universitaire Vaudois, Radiation Oncology Department, Lausanne, Switzerland; [7]Universitair Ziekenhuis Brussel, Oncology Department, Brussels, Belgium; [8]Clinique de Genolier, Radiotherapy Department, Genolier, Switzerland; [9]Rambam Medical Center, Oncology Department, Haïfa, Israel; [10]EORTC Headquarters, Operations Department, Brussels, Belgium*

Background: To confirm if the significant increase in overall and progression-free survival of patients with locally advanced prostate cancer reported at 5 years follow-up with the addition of long term androgen deprivation (LTAD) to external irradiation (RT) (Bolla M et al. N Engl J Med 1997; Lancet 2001) is maintained at 10 years and to assess the impact on cardiovascular and bone toxicity.
Materials and Methods: From 1987 to 1995, 415 patients with locally advanced (T1–2 WHO grade 3 M0 or T3–4 N0–1 M0) prostate cancer aged = 80 years were randomly allocated to combined RT plus LTAD or RT alone, followed by the same hormonotherapy in case of relapse. The whole pelvis was irradiated with photons ⩾10 MV up to 50 Gy (25 fr/5 wks), followed by a boost of 20 Gy (10 fr) to the prostate and seminal vesicles. LTAD consisted in monthly injections of goserilin (Zoladex®) 3.6 mg started on d1 of irradiation continued until progression or maximum 3 years. Comparisons are by intention-to-treat, with Logrank test (2-sided a = 5%). Heterogeneity of results by tumor stage and grade are investigated using a meta-analysis methodology.
Results: Disease and patient characteristics were well balanced in the two groups with median age 71 years. The median follow-up is 9.1 years. 192 of 415 patients have died (112 on RT alone and 80 on RT plus LTAD). LTAD added to RT increased the 10-year overall survival from 39.8% with RT alone to 58.1% (HR = 0.60, CI: 0.45–0.80, P = 0.0004), clinical progression-free survival (PFS) from 22.7% to 47.7% (HR = 0.42, CI: 0.33–0.55, P < 0.0001), distant metastases-free survival from 30.2% to 51.0 % (HR = 0.50, CI: 0.38–0.65, P < 0.0001) and biochemical PFS from 17.6% to 37.9% (HR = 0.43, CI: 0.30–0.60, P < 0.0001). Cumulative prostate cancer mortality at 10 years was 31.0% on RT and 11.1% on RT plus LTAD (HR = 0.38, CI: 0.24–0.60; P < 0.001). The cumulative cardiovascular mortality at 10 years was 11.1% and 8.2% (HR = 1.11, CI: 0.59–2.09, P = 0.75), with and without LTAD, respectively. Two pathological fractures were reported with RT plus LTAD (respectively at 7.2 and 9.9 years after treatment start). In patients with N0-x disease, the survival treatment effect was greater for T3–4 disease, but was independent of differentiation grade.
Conclusion: For patients with locally advanced prostate cancer, three years of LTAD with external irradiation improves overall survival without apparently increasing late cardiovascular toxicity.

Poster presentations (Tue, 22 Sep, 09:00–12:00)
Genitourinary malignancies – Prostate cancer

7008 POSTER

Prospective study evaluating salvage radiotherapy plus 2-year androgen suppression for post-radical prostatectomy patients with PSA relapse

R. Choo[1], C. Danjoux[2], S. Gardner[2], G. Morton[2], E. Szumacher[2], A. Loblaw[2], P. Cheung[2]. *[1]Mayo Clinic Cancer Center, Radiation Oncology, Rochester Minnesota, USA; [2]Odette Cancer Center, Radiation Oncology, Toronto Ontario, Canada*

Background: To determine the efficacy of a combined approach of salvage radiotherapy (RT) plus 2-year androgen suppression (AS) for patients with PSA relapse after radical prostatectomy (RP).
Materials and Methods: A total of 104 patients with PSA relapse after RP were treated with RT plus 2-year AS, as per a phase I/II study. Patients were assigned into three groups: Group1: persistently detectable post-operative PSA (i.e. PSA never declined below 0.2 ng/ml after RP), Group 2: PSA relapse alone after initially undetectable post-operative PSA, and Group 3: PSA relapse with clinically palpable or biopsy proven local recurrence. AS started within 1 month after RT, and consisted of nilutamide for 4 weeks and buserelin acetate depot every 2 months for 2 years. Relapse-free rate including freedom from PSA relapse was estimated using the Kaplan-Meier method. PSA relapse was defined as a rise above 0.2 ng/ml with two consecutive increases over a minimum of 3 months.
Results: See table. All achieved undetectable PSA with the protocol treatment. Relapse-free rate including freedom from PSA relapse for the entire cohort was 90% at 5 years and 75% at 7 years (range: 68–81.1%).

Patient Characteristics and Outcomes

	Group 1	Group 2	Group 3
No. of patients	29	49	26
Median age (years)	60	63	63.5
Pre-operative PSA (ng/ml)			
Median	12	9	9.1
Gleason score (%)			
5	0	4	0
6	10	18	12
7	52	65	69
8–10	38	12	19
Pathological stage (1997 TNM) (%)			
PT2N0	45	61	58
PT3aN0	14	22	23
PT3bN0	41	16	19
PT4N0	4	0	0
Margin status (%)			
Positive	88	45	81
Interval from RP to PSA relapse			
<2 vs. ⩾ 2years (%)	100 vs. 0	59 vs. 41	56 vs. 44
PSA prior to salvage RT (ng/ml)			
Median (mean)	1.2 (2.2)	0.7 (1.4)	1.7 (2.0)
Range (%): 0.06- 0.19	0	6	8
0.2–0.99	41	61	23
1–1.99	28	18	23
2–4.99	24	8	42
> 5	7	6	4
PSA doubling time (months)			
Median (mean)	N/A	7.7 (10.0)	6.2 (12.4)
%: <3 months		5	13
3–<6		29	35
6–<12		38	22
12–<24		24	22
⩾ 24		5	9
Time from RP to RT (months)			
Median	6	34.8	41.6
Total RT Dose (Gy)			
Median (range)	66 (60–70)	66 (60–66)	66 (66)
AS after RT			
% completing 2-year AS	79	88	85
% not completing (median AS duration, months)	21 (17)	12 (21)	15(11)
Follow-up from RT (years)			
Median (range)	6.2 (0.6–8.4)	6.3 (3.7–9.8)	6.7 (2.0–9.3)
Relapse-free and Survival Rates (%)			
5-year relapse free rate	84.7	91.5	91.6
7-year relapse free rate (95% CI)	68.0 (41.6–84.4)	81.1 (62.5–91.1)	75.6 (44.3–90.9)
7-year survival (95% CI)	93.1 (75.1–98.2)	95.9 (84.4–99.0)	88.3 (67.9–96.1)

Conclusion: The combined treatment of salvage RT plus 2-year AS yielded an encouraging result for patients with PSA relapse after RP. A confirmatory study is needed.