times 9 Gy each (until 10/93: 10 Gy) ^{192}Iridium brachytherapy was given, followed by 40 Gy percutaneous RT (grom 10/95: 45 Gy).

Results: The median follow up is 27 months. The median PSA before start of treatment was 11.4 ng/ml and 0.72 ng/ml 12 months and 0.4 ng/ml 24 months after RT. 17/26 pts. (60%) had negative biopsies 12 months after RT, 4 were positive and 5 showed regression grade II/III. 24 months after RT 10/17 biopsies were negative and only 3 were positive. 5 pts. showed a PSA > 3 ng/ml. Severe side effects occurred in 2 pts., both had additional biopsies from the rectal wall.

Conclusions: The early results are encouraging. The rate of severe side effects (4%) is tolerable and seems to be lower with 9 Gy HDR-brachytherapy. The dose to the ant rectal wall is now limited to 6 Gy.

133 POSTER

Potential doubling time (T_{POT}) in adenocarcinoma of the prostate

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Purpose: To relate the T_{POT} with grade of differentiation and clinical stage in prostate cancer.

Methods: A hybrid T_{POT} was determined as a combination of the S-phase time (by FCM) and LI (by histology) after *in vivo* labelling with iododeoxyuridine in 45 patients with adenocarcinoma of the prostate. The histological LI was determined in hot-spots. Tumours were classified according to the UICC 1992 classification and graded according to the WHO grading system.

Results: The median histological LI was 7.5% (0.7;31.9) and the median hybrid T_{POT} 2.1 days (0.5;27.0). They were significant different from the FCM LI of 2% (0.0;10.0) and the FCM T_{POT} of 27.8 days (5.8;304.4). There was a statistical significant relation between grade of differentiation and the histological LI ($p = 0.02$) and hybrid T_{POT} ($p = 0.002$). Tumour stage >T2 and/or M1 were related with a significantly higher histological LI ($p = 0.02$) and lower hybrid T_{POT} ($p = 0.005$). FCM LI and T_{POT} correlated with differentiation, but not clinical stage.

Conclusions: Results of the study indicate that hot-spot LI and hybrid T_{POT} are related with the aggressiveness in prostatic cancer.

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134 POSTER

Local intratumoral immunotherapy of prostate cancer with interleukin-2 reduces tumor growth significantly

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Purpose: This study was designed to determine effectiveness and toxicity of local continuous immunotherapy of prostatic cancer.

Methods: 60 juvenile male Kopenhagen rats with Dunning adenocarcinoma of the prostate, implanted subcutaneously into both flanks after proven tumor growth, were treated with either human interleukin-2 (IL-2) depot preparations (n = 30) or albumin (placebo) depot preparations (n = 30) implanted directly in one tumor site. IL-2 depots released IL-2 reliably for more than 24 days. Rat serum was tested during treatment for human IL-2, possibly absorbed from depots, and for rat interferon gamma.

Results: IL-2 treatment reduced tumor growth significantly ($p < 0.001$) compared with albumin treated sites or untreated contralateral sites. No toxicity was observed during treatment. That neither human IL-2 nor rat interferon gamma was detected in serum indicates an exclusively local IL-2 effect.

Conclusion: IL-2 depot preparations reduce tumor growth in Dunning adenocarcinoma of the prostate significantly without toxicity.

135 POSTER

Phase II study of vinorelbine in patients with hormone refractory prostate cancer

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Forty seven patients with hormone refractory prostatic cancer (HRPC) were treated with vinorelbine, a hemisynthetic vincaalkaloid. The objectives were to determine time to progression, specific survival, PSA response and toxicities. **Entry Criteria:** Patients with proven adenocarcinoma of the prostate with metastatic disease clinically progressing after endocrine deprivation based on parameters derived from NPCP criteria. **Treatment:** Vinorelbine was given at 25 mg/m^2 weekly for at least 8 weeks or until progression or toxicity.

Patient Characteristics: Median age 69 yrs (50–81), modal PS = 1, prior surgery 35, prior radiotherapy 29, hormonotherapy 43 pts. 37/43 had bone metastases, 22 local prostate tumors, 13 lymph nodes, 4 lung metastases and 6 liver metastases. Median PSA at inclusion was 82.5 (10–3790). It appear that 21 patients/43 had more than one line of classical hormonal deprivation. At entry duration of hormonal treatment were 20 months for LH-RH, 16 months for antiandrogens.

Results: Median number of cycle administered per patients: 7 (1–21) with a dose intensity of 17.8 mg/m2/w. Median time to progression was 11.7 weeks (5–55) and median overall survival was 32 weeks (6–59+). PSA decrease was observed in 19/43 patients, 3 partial response of measurable lesions were observed. There was no treatment related death. The main event was neutropenia CALGB grade III–IV (48.8%) without severe infection and rapid recovery (one week). Non hematological toxicity was mild.

Conclusion: This study suggest activity of vinorelbine in HRPC and provide data for future selection of patients and optimization of treatment schedule.

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Morbidity of external beam irradiation in patients with locally advanced prostate cancer: Analysis of our experience

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Objectives: To study the risk of developing bladder and bowel complications after radiotherapy (RT) in patients (pts) with prostate cancer T1-T4NxM0.

Material and Methods: In the period 1984 to 1991 125 pts received RT. Mean follow-up was 41.5 months (10–99 m.) The mean total was 63.6 Gy (55–71 Gy) ICRU to the prostate and 47 Gy (26.6–55.2 Gy) ICRU to the pelvis. Acute as well as late complications were evaluated according to EORTC grade.

Results: Mild and moderate cystitis (1–2 grade) were observed in 105 (84%). 7 pts had severe cystitis (grade 3). Grade 1–2 late bladder morbidity was presented in 31 (25%) pts. Only 1 patient (0.8%) developed severe cystitis (grade 3). The actuarial (5 year) bladder complication rate for all grades was 40%. Acute mild and moderate (grade 1–2) bowel complications were observed in 99 (74%) pts. There was no incidence of severe acute bowel complications (grade 3). Grade 1–2 late bowel complications were found in 26 (20.8%) pts. One patient (0.8%) required colostomy because of rectal bleeding (grade 3). The actuarial (5 year) incidence of total bowel complications was 30%. We observed that irradiation of larger pelvic volumes is associated with significantly increased only acute bowel complications.

Conclusion: Our experience shows that the external beam irradiation is the safe method of treatment in patients with locally advanced prostate cancer. In our series the incidence of severe (grade 3) late urinary and intestinal complications was very low.

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Health-related quality of life and sequelae in patients treated with external beam irradiation (EBI) and brachytherapy for localized prostate cancer (LPC)

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Purpose: To evaluate late physical and psychosocial sequelae in patients treated with an association of EBI and brachytherapy for LPC.

Methods: 71 patients free of disease, treated from 1988 to 1992, were matched on age and residency with 71 healthy controls. The French translation of the Nottingham Health Profile questionnaire and that of the EORTC QLQ-C30 core questionnaire were used to evaluate physical-, role-, emotional-, cognitive- and social functioning, global health status as well as tonus and sleep disturbance. Specific problems related to prostate cancer were explored using the prostate specific module developed by the EORTC Genito-Urinary Tract Cancer Cooperative Group. Concordance between clinical complications reported by patients and those reported by physicians was also analyzed.

Results: General health quality of life scale and general symptom scale scores did not significantly differ between patients and controls, However,