(range 2–9). Digital rectal examination, TRUS, TC or MR of the pelvis, radioisotope bone scan and measurement of serum PSA were performed for clinical staging, RT was delivered to the prostatic grand only, using 18 MV linear accelerator and a rotational technique. Total dose was 68–70 Gy (200 cGy/day 5 days/week) in continuous course. TRUS and PSA were repeated at 6 months after the end of the irradiation for clinical evaluation of RT effectiveness. At the present, 21 patients have a follow-up longer than six months. In 8/21 cases RT followed an hormonal therapy (OT) whereas 3/8 patients prolonged OT during RT. 11/21 patients had a lesion confirmed by TRUS before RT start and 10/11 showed no dimensional modification at the follow-up. 8/21 showed a reduction of the prostatic volume > 10%.

Pre-RT mean PSA was 6.4 ng/ml (range 0.1–19.4 ng/ml) versus 1.6 ng/ml (0.1–5.4 ng/ml) at the follow-up, six months after the end of RT.

The role of TRUS for the detection of local relapses is undisputed. On the other hand, PSA is a good index to evaluate clinical response to treatment.

75 POSTER

## CONFORMAL RADIOTHERAPY OF LOCALIZED PROSTATIC CARCINOMA: ACUTE TOLERANCE AND EARLY EVALUATION OF EFFECTIVENESS

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Acute tolerance and early effectiveness of conformal 3D-planned radiotherapy of prostate cancer was investigated in a prospective trial.

32 men (44–80 years old) with locally advanced carcinoma of the prostate (stage B2 or C) have been treated by 3D-planned conformal radiotherapy using high energy photons. Total doses from 50 to 70 Gy (mean:  $63.9 \pm 4.9$  Gy) were applied with single doses of 2.0 Gy in 46  $\pm$  4 days. 3D treatment volume was 274.1  $\pm$  113.4 cm<sup>3</sup>. Median follow-up is 1.5 years (11–30 months).

11 patients had none, 15 mild (WHO Grade 1) and 6 moderate symptoms (WHO Grade 2, mainly diarrhea, dysuria and polyuria). Acute complications leading to treatment interruption did not occur. In 19 patients symptoms disappeared within 6 weeks after radiotherapy. Only 2 men had symptoms which lasted longer than 3 months. Up to now no relapses and no late complications were detected. Incidence and severety of toxicity was significantly related to the size of treatment volume and to the irradiated volume of bladder and rectum quantified by dose-volume-histograms.

We conclude that 3D-planned conformal radiotherapy allows an effective and well tolerated therapy of localized prostatic carcinoma.

476 PUBLICATION

## COMBINED MODALITY TREATMENT OF RENAL CANCER PATIENTS WITH TUMOR THROMBUS INVADING VENA CAVA INFERIOR

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To estimate the efficacy of various regimens of radiotherapy, the results of the treatment of 39 renal cancer patients with tumor thrombus in vena cava inferior, without distant and regional metastases and without tumor invasion of adjacent organs were studied. All the patients were administered radical surgery. The 5-year survival rate in 14 patients who received only surgical treatment (control arm) amounted to 26.92 ± 12.0%. In 14 patients administered preoperative large fraction radiotherapy (single dose 7 Gy to total target dose of 14 Gy), the five-year survival was 63.46 + 13.5% (P < 0.05). In 11 patients who received additional postoperative radiotherapy (single dose 2 Gy to total target dose of 40 Gy), the 5 year survival did not significantly differ from that in the 1st study arm and made up 52.94 + 15.37%. The data obtained indicate that combined modality treatment using preoperative large fraction radiotherapy of renal cancer patients with tumor thrombus in vena cava inferior significantly (more than two-fold) increases the 5-year survival rate compared with surgical treatment.

77 PUBLICATION

# CHEMO-IMMUNOTHERAPY OF METASTATIC RENAL CELL CANCER (MRCC) WITH SUBCUTANEOUS LOW DOSES OF RE-COMBINANT INTERLEUKIN 2 (IL2) AND 4-EPIRUBICIN (EPI)

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The clinical use of IL 2 and anthracycline in MRCC is based on preclinical studies that have shown a synergistic antitumor activity, due to an increased specific antitumor immunity (Gautam, Cancer Res. 1991; 51:6133-7). Seventeen pts (6 females and 11 males) with MRCC have been treated in a multicenter phase II study to test the safety and efficacy of low dose subcutaneous IL 2 in combination with EPI. The cycle consisted of IL 2 at 9 million I.U. for the first two days of the first week followed by 4.5 million I. U. for the remaining three days of the first week and for five days/week for five weeks, plus EPI at 25 mg/mq the first day of each week. Median age was 56 years (46-71); median Karnofsky index was 90. Thirteen pts had prior nephrectomy. Three of these had syncronous metastases and were subjected to debulking surgery. Only two pts received prior chemotherapy or immunotherapy. The disease sites were: lung in 9 pts, lymph nodes in 7, kidney in 2, adrenal glands in 2, bone in 3 and renal bed in 2 pts. Fourteen pts are evaluable for response and toxicity, 3 are early to evaluate. We observed one CR and one PR lasting 14+ and 6 months, respectively. In the 8 pts with SD (57%) the median time to progression was 9 months (range 4+ to 12+). CR was obtained after two cycles in superficial lymph nodes and bone lesions while PR was noted in the lung. The toxicity was mild: only one pt had grade 3 hypotension; the most frequent toxicities (grade 1-2) were fever (9 pts) and malaise (5 pts). No pts required a decrease in IL 2 or EPI dosage. This study is ongoing and a larger number of patients are necessary to draw definitive conclusions concerning the efficacy of this chemo-immunotherapy combination in MRCC.

#### 478 PUBLICATION

**BRAIN METASTASES FROM HYPERNEPHROMA** 

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A retrospective analysis of 22 cases treated between Oct 83 and Dec 94 was performed. 13 patients had solitary, 9 multiple brain metastases (b.m.). 19 suffered from extracranial metastases too. In 7 cases (6/7 with solitary b.m.) surgery plus whole-brain irradiation was performed (OP + RT). 15 patients received RT alone. The median total dose was 30 Gy. Median survival was 311 days (OP + RT), 116 days (RT, P = 0.006), and 132 days (all). After OP + RT improvement of performance status was more frequent. Only 4 patients achieved partial remission of their b.m. after RT alone. Extracerebral metastases and number of b.m. were prognostic factors. Conclusion: OP + RT was sign. better than RT alone. A standard palliative schedule of 30 Gy failed to achieve local remission of b.m. and clinical improvement in most of the cases. For hypernephroma metastases a higher total dose might be useful if RT alone is applied.

479 PUBLICATION

### RADICAL IRRADIATION TREATMENT IN PATIENTS WITH PROSTATE CANCER: RESULTS AND PROGNOSTIC FACTORS

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Urology-Oncology Dept, Cancer Center & Institute, Warsaw, Poland From October 1984 to June 1991, 261 patients with prostate cancer registered in Cancer Center, Warsaw. A group of 133 pts were selected for radical irradiation. The material was divided into two groups: an "early"-stage T1 (9 pts) and T2 (36 pts) and an "advanced"-stage T3 (73 pts) and T4 (7 pts).

8 pts with Tx were eliminated from the analysis. Overall actuarial 5-years survival, 5-years local control and 5-years disease-free survival were analyzed. Actuarial 5-years survival rate was 98% in the "early" group and 44% in the advanced group (P < 0.00001). The actuarial 5-years local control was 93% and 60% respectively (P = 0.004). The actuarial 5-years disease-free survival was 85% in the "early" group and 20% in the "advanced" group (P < 0.00001). Multivariate analysis demonstrate that T stage, age, elongation time of treatment were independent covariates for overall survival. A log-rank test and Cox regression model were performed for statistic. The late radiation related morbidity was acceptable. The results of radiotherapy of intracapsular disease were very good, but they were not satisfactory in patients with direct extracapsular extension.