months; % S = 44). Total: 2 CR, 8 PR, 11 SD, 21 PD, 6 NE (MOS = 17 months; % S = 38). 21 patients died; 21 are still alive.

Conclusions: (1) we observed 43% of responses (CR + PR + SD) in all patients; (2) a higher (but not significant) rate of CR + PR was observed in the groups treated with IL-2 including regimens (27 and 26% vs 11%) (3) survival was in accordance with these observations.

469 POSTER

SERUM PSA 1-10 YEARS BEFORE THE DIAGNOSIS OF PROSTATE CANCER—COMPARISON WITH BPH AND HEALTHY CONTROLS

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Background: Serum prostate specific antigen (PSA) is widely used for screening of prostate cancer, but little is known about its kinetics during development of the disease.

Patients: Twenty-five prostate cancers were detected among 5908 middle aged men participating in a primary prevention trial for coronary heart disease. Two age matched control groups were chosen: 50 subjects each with BPH and without urologic symptoms, resp. During 1980–1986 blood samples were drawn at 3 mo intervals and 1986–1990 at 6–12 mo intervals.

Results: Serum PSA was $\geqslant 4$ μg/l in 54% of samples drawn $\geqslant$ 4–<5 years before prostate cancer diagnosis. In samples from the same period the proportion was 28% among BPH patients and 3% among healthy controls. The respective proportions were 60%, 22% and 5% $\geqslant$2–<3 years before the diagnosis. In cancer patients the pattern of PSA kinetics was highly variable.

Conclusions: PSA is a valuable tool for prostate cancer screening, but overlapping with other clinical conditions is considerable. Prostate cancer is a heterogenous malignancy, and this is reflected on variable PSA kinetics.

470 POSTER

ORIGINAL REGIMEN OF SUBCUTANEOUS INTERLEUKIN 2 (IL2) AND INTERFERON ALPHA (IFN) IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA (MRCC) INELIGIBLE TO RECEIVE INTRAVENOUS (I.V.) IL2

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We are conducting a multicentric randomized study (IFN vs IL2 vs IL2 + IFN) called Crecy requiring an important selection of the patients. Indeed, only 40% referred patients (pts) are found eligible. For this reason, we set up a study using a more adopted regimen of immunotherapy: subcutaneous IL2 at 9×10^6 UI/day for 6 days associated with IFN 6×10^6 U/day 3 days a week; this cycle is repeated for 5 weeks with one week rest between each treatment cycle. All patients with measurable disease but ineligible for the Crecy study could be proposed to join this trial. 50 patients were treated on an out-patient basis in 18 centers in a period of 7 months. Toxicity was of concern with 2 grade IV (OMS) toxic events including massive pulmonary embolism and sudden death. Most toxic signs were fever, fatigue, anorexia, cutaneous rash, nausea and vomiting. All patients developed various degrees of inflammatory reaction at IL2 injection sites. In terms of tumor response, 2 partial and 1 complete tumor regression were observed among the initial 20 patients. This regimen appeared feasible in most patients ineligible for i.v. IL2 but toxicity is not negligeable and requires careful management. This study confirms that subcutaneous IL2 + IFN regimen can induce tumor responses despite a defavorable selection of the patients.

471 POSTER

THE MANAGEMENT OF PAIN IN ADVANCED PROSTATIC CANCER

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Pain in advanced prostate cancer is mainly caused by boney metastases. Other causes, such as lower or upper urinary tract obstruction, infection and local spread of the tumor must always be considered. The most satisfactory treatment of pain is to stop the growth of the tumor by hormonal radiotherapeutic or chemotherapeutic measures. When these fail, there is a need for a structured program of analgetic therapy, to maximize its effect. In the early stages, the mainstay of therapy, is the prostaglandin synthetase inhibitors (P.S.I.). Possible side effects of this therapy must be considered in this elderly population. Later combination therapy with opiates with P.S.I. for breakthrough pain will be necessary. The treating physician must familiarize himself with the pain pathways involved, the various receptor proclivities of different opiate preparations and the possible side effects of combination therapy. A structured program for the management of these different patients used in the Free University in Amsterdam, will be presented.

472 POSTER

ADJUVANT AND NEOADJUVANT CHEMOTHERAPY FOR NODAL METASTASES FROM SQUAMOUS CELL CARCINOMA (SCC) OF THE PENIS

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The 5-year survival of patients with radically resected nodal metastases from SCC of the penis is approximately 40%, and the outcome of patients with fixed inguinal nodes is usually poor. Between 1979 and 1990, we submitted to 12 weekly courses of home administered adjuvant VBM (vincristine 1 mg. i.v. day 1, bleomycin 15 mg. i.m. 6 and 24 h. after vincristine, and methotrexate 30 mg. p.os day 3) 25 consecutive patients with radically resected nodal metastases from SCC of the penis. Other 13 patients received the same chemotherapy as primary treatment for fixed inguinal nodes, and 3 patients poorly responsive to neoadjuvant VBM plus other 3 fresh cases with fixed inguinal nodes were treated with 4 courses of PF combination chemotherapy (cisplatin 100 mg/m^2 day 1 followed by fluorouracil 1 g/m^2/day for a 96 h. i.v. infusion).

After a minimum follow-up of 4 years, only 4 patients (16%) relapsed in the adjuvant group, and the only poor prognostic indicator was bilateral nodal metastases (4 of 8 relapsed). As far as fixed nodes are concerned, 5 of the 7 partial responders (54%) to VBM primary chemotherapy could undergo radical surgery: 3 relapsed 15, 27 and 32 months after surgery, and 2 (15%) are alive disease free since 5 and 13 years, respectively, while 5 of the 6 treated with PF achieved a partial remission and 4 could undergo radical surgery with 3 patients (50%) being alive disease free from 3 to 10 years. Toxicity of both regimens was tolerable.

473 POSTER

INTERLEUKIN 2 (RIL2) IN THE TREATMENT OF METASTATIC RENAL CELL CARCINOMA-DURABLE COMPLETE RESPONSE WITH LONG TERM FOLLOW-UP

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Metastatic renal cell carcinoma has a poor prognosis with a 5 y survival < 10%. Results of treatment with conventional chemotherapy have been disappointing warranting the use of novel treatment regimens including rIL2 either alone or in combination with conventional chemotherapy. We report the Cardiff experience. 25 patients with metastatic renal cell carcinoma at various sites received rIL2 in the period 1989–1994. 18 patients received rIL2 by continuous intravenous infusion (3 MU/m^2/day for 5 days repeated after a 2-day break); 2 patients received subcutaneous rIL2 (9–18 MU daily, 5 days/week for up to 6 weeks initially) and 5 patients received rIL2 in combination with recombinant human interferon-alpha and 5-fluorouracil as described by Atzpodien (*Eur J Cancer* **29A Suppl.**5:56–58; 1993). Three patients (12%) achieved a complete response—2 after iv rIL2 and 1 after sc, 4 patients (16%) achieved a partial response and 5 patients (20%) had stable disease. The duration of response ranged from 3–64 months (median 8.5 months). The 3 patients achieving a complete response are alive and disease-free at 27, 59 and 64 months respectively. Overall 24% (95% CI 7.3%–40.7%) of patients in this series achieved an objective response which is consistent with results from other centres. Complete responses may be durable in some patients after rIL2 therapy.

474 POSTER

THE ROLE OF TRANSRECTAL ULTRASOUND (TRUS) AND SERUM PSA FOR CLINICAL EVALUATION OF RADICAL RADIOTHERAPY (RT) IN LOCALIZED PROSTATIC CANCER

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Between 1/'93 and 12/'94, 50 patients with clinically localized (11-3,Nx,M0) prostatic adenocarcinoma histologically confirmed, were submitted to RT at our Department. Gleason Pattern Score averaged 5