of 14 months, Breslow $p < 0.04$; progression free survival: median of 13 months vs median of 4 months, Breslow $p < 0.01$).

Conclusion: In patients with progressive metastatic renal cell carcinoma, outpatient chemo immunotherapy with SC Interleukin-2, SC Alpha-2a-interferon, and IV 5-FU is more effective (objective response rate, progression free survival, and overall survival) than single agent tamoxifen

152 ORAL

Survival in renal cell carcinoma (RCC) – A randomised evaluation of tamoxifen versus interleukin-2, α-interferon (leukocyte) and tamoxifen

R. Henriksson[1], S. Nilsson[2], S. Colleen[3], P. Wersäll[4], M. Helsing[5], R. Zimmerman[6], K. Engman. *[1]Dept of Oncology, University of Umeå; [2]Dept of Oncology, University of Uppsala; [4]Dept of Oncology, Karolinska Institute; [5]Dept of Oncology, University of Örebro; [6]Dept of Oncology, University of Södersjukhuset, Stockholm; Dept of Urology; [3]Lund University, Sweden*

Purpose: Biotherapy causes encouraging results in terms of objective responses. No conclusive studies exist with a controlled evaluation of survival in advanced RCC. The aim was to compare IL-2/IFN-α with relatively atoxic tamoxifen (T).

Methods: Randomized multicentre study (life expectancy >3 months, PS WHO 0–2). Interim analysis when 100 patients evaluable. The control patients (n = 63) received only tamoxifen 40 mg p.o. daily. The other patients (n = 65) subcutaneous IL-2/IFN-α in two treatment cycles of 42 days (see Atzpodien) and maintenance treatment (5 days, every 4 weeks) 1 year or until progression. Two patients in the T only group received biotherapy when the disease progressed without any effect. The patients received appropriate local treatment.

Results: The interim analysis showed no advantage for either group. Inclusion of patients was stopped. Mean follow-up: 11 months (range 0.4–48). The final survival analysis displayed no differences from the day of primary diagnosis, first evidence of metastasis, or from the onset of treatment. This was valid with regard to intention to treat or when directed *only* to patients that managed at least one treatment cycle of IL-2/IFN-α. CR was seen in both groups. Adverse effects were pronounced in the IL-2/IFN-α group.

Conclusions: The results raise doubt about IL-2/IFN-α as a routine treatment in advanced RCC. Difference in expenses of drugs and health care (drug costs/patient: IL-2/IFN- α 27,000$ vs Tamoxifen 360$) and quality of life are also of importance. The study emphasizes the need of further controlled studies.

153 ORAL

Testis cancer: Carcinoma-in-situ in testes with germ cell tumour

T.S. Pottek[1], H. Lauke[2], M. Hartmann[1]. *Dept. of Urology Armed Forces Hospital Hamburg; [2]Institute of Anatomy, Department of Microscopic Anatomy, Hamburg University Hospital, Germany*

Testicular tissue of 380 consecutive patients (169 Seminoma and 211 NSGCT) from 1990 to 1995 has been examined in semithin sectioning technique adjacent and distant to solid germ cell tumours. The samples were fixed in glutaraldehyde and osmium tetroxide then embedded in Epon. Semithin sections (1 μm) were stained with toluidine blue-pyronine. 303 (80%) patients showed CIS in biopsies near or distant of the tumour. Of 327 testes either tumour-near as -distant biopsies were examined. CIS was found in 262 testes tumour-near (80%), in 206 tumour-distant (63%) and both in 196 (60%). CIS only tumour-near showed 65 (20%), only tumour-distant 10 testes (3%).

In 78% of seminomas CIS was found tumour-near and in 54% tumour-distant, of non-seminomas in 86% -near and 67% -distant.

A weak statistically significant relationship between tumour size and occurrence of CIS in the biopsies is demonstrated.

As long as no prospective parameters of high probability are established, every testicle with a germ cell tumour should be respected as CIS-contaminated. The individual decision for radiation or surveillance after organ-preserving surgery depends on the patients intention regarding the fertility. Not to develop a solid tumour in future, testes which have CIS should be irradiated.

154 ORAL

Early stage testicular seminoma – A prospective multicenter trial

J. Classen, H. Schmidberger, R. Souchon, M. Bamberg. *University Tübingen, Department Radiotherapy, Tübingen, Germany*

Purpose: Adjuvant radiotherapy in stage I, IIA/B testicular seminoma (Royal Marsden Classification) offers cure rates of 95% and 80–90%, respectively. However, treatment volume and total dose are still object of discussion. Thus, we conducted a multicenter prospective clinical trial for radiotherapy of early stage testicular seminoma with reduced total treatment doses and portals.

Method: Patients with stage I (CSI) seminoma received radiotherapy to the paraaortic lymph nodes only. Treatment portals reached from the upper border of thoracic vertebra 11 (T11) to the lower border of lumbar vertebra 4. Stage IIA/B (CSIIA/B) patients were treated to the paraaortic and ipsilateral iliac lymph nodes. A hockey stick field stretched from the upper border of T11 to the upper border of the ipsilateral acetabulum. Total dose in 2 Gy daily fractions was 26 Gy for CSI, 30 Gy and 36 Gy for CSIIA/B, respectively.

Results: Between 4/91 and 3/94 827 patients were entered into the trial. 492 patients with CSI disease and 59 patients with CSIIA/B disease were eligible for an interim analysis in 12/96. Mean follow up was 28 months. In CSI and CSIIA/B there were 18 (3.7%) and 2 (3.4%) relapses, respectively. No in-field recurrence was observed. 18/20 patients were salvaged. One patient died of embolism after surgery for relapse, a second patient was lost to follow up after diagnosis of recurrent disease. Overall survival (28 months follow up) accounts to 99.6% in CSI and 100% in CSII. Acute side effects of adjuvant treatment were moderate. 59% of all patients suffered from nausea, 14.9% experienced diarrhea during treatment.

Conclusions: Low dose radiotherapy with reduced portals in early stage testicular seminoma yields high cure rates with only moderate acute side effects.

155 ORAL

Lessons from prospective multicenter study on seminomas

L. Weißbach[1], R. Bussar-Maatz[1], U. Löhrs[2], K. Mann[3], G. Schubert[4]. *Seminoma study group; [1]Department of Urology, Krankenhaus Am Urban Berlin; [2]Institute of Pathology, University Hospital of Munich; [3]Department of Endocrinology, University Hospital Essen; [4]Institute of Pathology Klinikum Barmen, Wuppertal, Germany*

Purpose: We conducted a prospective multicenter study to assess the prognostic value of HCG in seminomas.

Methods: From 1986–1991 we recruited 806 seminomas from 96 urological departments in FRG. Austria, Switzerland, 726 were evaluable. 288 of these cases were retrospectively reviewed from 14 of the participating hospitals (all seminomas of the same time period) because the original idea to compare the results with historical series, proved to be insufficient. The outcome after standard therapy (radiotherapy in stages IIB and chemotherapy in more advanced stages) was established. Univariate and multivariate analyses were performed in order to assess adverse prognostic factors.

Results: In the cubital vein, the incidence of HCG is 35%, of LDH and PLAP 34% and 56% resp. 84% of all seminomas are marker positive. Nearly all seminomas produce HCG, in most cases it is measurable only in the testicular vein. HCG is associated with tumor mass but it has no prognostic relevance. Multivariate analysis revealed metastatic disease, pT > T, LDH and its prolonged marker decay as prognostic factors, multivariate analysis pT > T and metastatic disease. Stage II B disease showed a poorer outcome after radiotherapy than more advanced stages after chemotherapy.

Conclusion: Elevated HCG has no influence on the prognosis of seminomas. This fact results in a stage related uniform therapy for HCG positive and negative seminomas. Stage II B disease should probably be better managed by chemotherapy.

156 ORAL

Long-term survival and late toxicities after high-dose chemotherapy in patients suffering from germ cell cancer

O. Rick, J. Beyer, N. Schwella, D. Kingreen, A. Krusch, D. Huhn, W. Siegert. *Department of Internal Medicine, Division of Hematology/Oncology, Virchow Clinic, Humboldt University Berlin, Germany*

Purpose: High-dose chemotherapy (HDCT) followed by autologous stem cell rescue can cure patients suffering from refractory or relapsed germ-cell