anorexia and elevation of AST and ALT levels. Some AEs, including hand-foot skin reaction, hypertension, and elevation of lipase or amylase levels, emerged specifically in the early stage of treatment, while others, such as flu-like syndrome and elevation of AST and ALT arose throughout the treatment period. Eleven pts died within 30 days of receiving sorafenib, but no deaths were considered drug-related. Ten pts were on treatment at the end of the extension study; these pts were transferred to treatment with commercially available sorafenib.
Conclusions: In this study of Japanese pts, sorafenib 400 mg BID was found to be a safe and effective long-term treatment in pts with unresectable/metastatic RCC.

Median treatment duration, wk (range)	33.6 (0.6−168)
PFS, wk (95% CI)	34.4 (27.9, 47.1)
OS, wk (95% CI)	110.1 (82.6, 139.3)
Tumor response, no. (%)	
Partial response	25 (19.4)
Stable disease	87 (67.4)
Progressive disease	13 (10.1)
Disease control rate, % (95% CI)	73.6 (65.2, 81.0)

7148 POSTER

Prognostic value of tumor cell proliferative activity in disseminated kidney cancer

D. Nizamov[1], M. Gafur-Akhunov[1], M. Tillyashaikhov[1], D. Nishanov[1], N. Rahimov[1]. [1]*National Research Center of Oncology, Urology, Tashkent, Uzbekistan*

Background: To study prognostic value of the nuclear antigen Ki-67 expression in disseminated kidney cancer.
Material and Methods: There were studied 34 patients with primary generalizes kidney cancer. Of 34 patients there were males 22 and females 12. The age of patients fluctuated from 35 to 73 years. The mean age was 55.4 years. The primary tumor was localized in the right kidney in 17 patients, and in the left kidney in 17 patients. All patients had primary-generalized form of kidney cancer. The symptoms of disease depended on localization of metastases except primary tumor. The degree of tumor process dissemination was evaluated as T2−4Nl-2Ml. Of 34 patients 15 (44%) had metastases in the lungs, 1(3%) patient has them in the liver, 2(6%) in the bones of the skeleton, one (3%) in the pleura, 1(3%) in the adrenal gland, one (3%) in the brain and one (3%) in the bed of kidney removed. In 12 (35%) patients there was noted lesion in two and more organs (lungs, liver, bones of skeleton, juxtaregional lymph nodes, soft tissues). The involvement of retroperitoneal lymph nodes was noted in 11 cases (32%). Of 34 patients 30 (88%) underwent palliative nephrectomy, 3 (9%) expanded nephrectomy and one (3%) nephrureterectomy. The operative samples were studied with use of immunohistochemical method (by technique of firm “DAKO”) with measurement of proliferative activity marker, that is nuclear antigen Ki-67. On the basis of Ki-67 indices of 34 patients 13 (38%) had negative results and 9 (26%) had weak-positive results and 12 (36%) had moderate-positive findings.
Results: The patients underwent long-term observation during the period from 2 months to 8 years. Of 34 patients 26 (76%) dead and 8 (24%) are under control. We studied effect of Ki-67 parameters on life durability. In cases of negative indices of Ki-67 the life durability was 27 months, in weak positive and moderate positive results – 20 and 8 months respectively.
Conclusion: The high level of expression of the nuclear antigen Ki-67, marker of proliferative activity, is an unfavorable factor for prognosis of patient survival and it may be used as molecular biological factor for prognosis of kidney cancer.

7149 POSTER

Prognostic significance of gene-suppressor p53 and Bcl-2 in disseminated kidney cancer

D. Nizamov[1], M. Gafur-Akhunov[1], M. Tillyashaikhov[1], D. Nishanov[1], O. Kutliev[1]. [1]*National Research Center of Oncology, Urology, Tashkent, Uzbekistan*

Background: To study prognostic value of gene-suppressor p53 and Bcl-2 in disseminated kidney cancer.
Material and Methods: We have study 34 patients with primary generalized kidney cancer. Of 34 patients males were 22, and females 12. The age of patients was from 35 to 73 years, mean age was 55.4 years. In 17 patients the primary tumor was located in the right kidney and in 17 patients in the left one. All patients had primary generalized form of the kidney cancer. The symptoms of disease except primary tumor depended on localization of distance metastases too. The degree of tumor process extension was evaluated as T2−4N1−2M1. Of 34 patients 15 (44%) had metastases located in the lungs, and one (3%) patients had in the liver, and in 2 (6%) in the skeleton bones, and in 1 (3%) in the pleura, 1 (3%) in the adrenal gland, in 1 (3%) in the brain and in 1 (3%) in the bed of kidney removed. In 12 (35%) cases there were noted lesions in the two and more organs. Of 34 patients, 30 (88%) underwent palliative nephrectomy, 3 (9%) enlarged nephrectomy and 1 (3%) nephruterectomy. The intraoperative samples were investigated with use of immunehistochemical method with measurement of gene-suppressor p53 and bcl-2. In this case by parameters of p53 of 34 patients 15 (44%) had negative, 6 (18%) had mild, 6(18%) had moderately positive and 7(20%) had marked positive values. According to bcl-2 of 34 patients 15 (44%) had negative, 11 (32%) gas weak positive and 8(23%) had moderately positive results.
Results: The patients were observed during follow up period from 2 months to 8 years. Of 34 patients 26 (76%) died and 8 (24%) are under regularly control. We studied effect of the parameters p53 and bcl-2 on the life duration. In cases with negative parameters p53 the life durability was 27 months, in moderate and weak positive parameters 12 and 19 months, respectively and in marked positive results 5 months. In negative parameters bcl-2 the average life durability was 14 months and weak and moderate positive results life durability was 24 and 20 months, respectively.
Conclusion: The measurement of parameters p53 and bcl-2 has prognostic value and they should be used as molecular-biological prognostic factors in kidney cancer.

7150 POSTER

Response of renal lesions in patients with metastatic renal cell carcinoma (mRCC) treated with sunitinib − a single center retrospective analysis

C. Seidel[1], M. Fenner[1], C. Reuter[1], P. Ivanyi[1], A. Ganser[1], V. Grünwald[1]. [1]*Hannover Medical School, Klinik für Hämatologie Hämostaseologie Onkologie und Stammzelltransplantation, Hannover, Germany*

Backround: Multi-target tyrosin kinase inhibitors (MTKI), such as sunitinib has to be considered as standard treatment of patients with mRCC. Treatment with sunitinib may achieve partial remissions (PR) in 39% of patients with metastatic disease. During the era of immunotherapy objective responses remain scarce and renal lesions have not been reported to respond to such therapies after all. Palliative nephrectomy prior to immunotherapy improves overall survival and is considered a prerequisite for such therapies. Response of the primary renal lesion has been reported with sunitinib and fostered the debate whether or not palliative nephrectomy is necessary in these patients. We report on nine patients with mRCC and renal lesions who received sunitinib.
Materials and Methods: Nine patients with stage IV clear cell RCC with renal lesions treated with sunitinib 50 mg (4/2 scheme) were evaluated. The average age at the beginning of treatment was 58 years (range 49−72), the MSKCC-Score was 0 (n = 1), 1 (n = 5) and 2 (n = 3), while the ECOG performance status was predominantly 0 (n = 8) with the exception of one patient with ECOG performance status 1. The tumour grading on histopathology was G2 (n = 6) and G3 (n = 3). Tumour assessment was according to local practice, which included CT scans every 2 cycles. Early assessment was additionally performed in 4 patients after cycle 1.
Results: Altogether 50 target lesions were analysed for RECIST. During treatment in two cases dose reduction from 50 mg to 37.5 mg was necessary to reduce side effects, while in one case dose reduction to 25 mg was essential. The median progression free survival (PFS) was 347 days after a median number of 6 applied cycles. Tumour response of target lesions according to RECIST consisted of 44% (n = 4) PR, 44% SD (n = 4) and 11% (n = 1) PD. Response of renal lesions was similar and achieved a $\geqslant$30% reduction of tumour size in 44% (n = 4), 20−30% reduction of tumour size in 33% (n = 3) and lack of response in 22% (n = 2). 2 of 9 patients are still ongoing and receive sunitinib. One patient received nephrectomy after 2 courses of treatment.
Conclusion: Sunitinib is effective in patients with renal lesions with mRCC. Our data support the use of sunitinib in these patients.