extent of stained cells and intensity of corresponding immunostained cells; 0+ to 3+.
Results: Expression of FGFR1 was observed in 98% (98/100) of primary renal tumors and in 82.5% (33/40) of lymph node metastases. Intensity was 3+ in all cases. Nuclear expression of FGFR1 was found in 68% (95/140). FGFR2 staining was seen in 4% (4/100) of primary tumors and in 5% (2/40) of lymph node metastases. FGFR2 was expressed in RCC of non-clear cell histology. Expression of FGFR1 was significant lower in the normal tissue of kidney ($P < 0.01$) and was detected in 2.5% of cases (1/40); no FGFR2 expression was found.
Conclusions: In this study we have shown for the first time that FGFR1 is highly expressed in RCC patients. FGFR1 is an interesting alternative target as it can be targeted relatively easy. Human monoclonal antibodies IO-1/IO-2 for therapy and imaging in RCC patients were developed.

7117 POSTER DISCUSSION

Do circulating tumor cells (CTCs) correlate with response to first-line sunitinib in metastatic renal carcinoma?

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Background: Circulating tumor cells (CTCs) are frequently present in pts with different types of epithelial cancer, and low values before and during cytotoxic chemotherapy are an independent predictor of longer progression-free and overall survival in pts with metastatic breast and colorectal carcinoma. First-line Sunitinib obtains radiological responses and improves survival in pts with metastatic renal cancer, but no predictive markers of activity are currently available. Recent data have provocatively shown that sunitinib may increase systemic diffusion of tumor cells in pre-clinical models [Paez-Ribes M. et al. Cancer Cell 2009].
Materials and Methods: Since the antiangiogenic properties of sunitinib would suggest interference with extravasation and circulation of tumor cells, we designed a pilot study to measure CTCs prospectively during treatment with sunitinib and to assess their correlation with tumor response in previously untreated pts with metastatic renal cell carcinoma. The automated analysis of CTCs was conducted by means of Cellsearch platform (Veridex). Peripheral blood samples were drawn on day 1 and 28 of cycles 1 and 2, on day 1 of cycles 3, 5 and 7, then at radiological progression. Sunitinib was administered by the 4 weeks on-2 weeks off regimen, at daily dosages ranging from 50 to 25 mg according to age and toxicity. Reduction of either tumor diameter or tumor density at CT scan was considered response.
Results: 20 pts have been accrued so far, median age 68 years (range, 34 to 87). Clear cell histology was predominant (85%), then papillary or rarer histologies (15%). Sixty percent of patients had 2 or more sites of disease. Most frequently involved organs were lungs (65% of total patients), lymph-nodes (35%), liver (20%), bone (30%). After a mean of 2.2 cycles (range, 1 to 8), there were 42.8% of responses in 14 evaluable pts. At baseline, 80% of pts had 1 or more CTCs/7.5 mL, while 50% had at least 2 CTCs (range, 0−10). Using an arbitrary cut-off of 4 CTCs, no correlation was found between baseline CTC count and age, number of metastatic sites, and response to sunitinib. Indeed, CTC count fluctuated in most pts during treatment, mean change was $\pm$6.8 cells (0−12). CTCs either disappeared in one responsive pt (3 CTCs found at baseline, then 0 after 2 cycles of sunitinib) or increased in three responsive pts (from 5 CTCs at baseline to 16 after sunitinib, from 0 to 3, from 1 to 8, respectively).
Conclusions: CTCs are often present in pts with metastatic renal cancer but baseline count does not appear to correlate with extension of disease and subsequent response to sunitinib. Moreover, radiological response of metastatic disease may be accompanied by either reduced or increased levels of CTCs.

Poster presentations (Mon, 21 Sep, 14:00−17:00)
Genitourinary malignancies − Renal cancer

7118 POSTER

An Asian subpopulation analysis of the safety and efficacy of sunitinib in metastatic renal cell carcinoma

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Background: Sunitinib (SU) is an oral, multitargeted receptor tyrosine kinase (RTK) inhibitor of VEGFRs, PDGFRs, and other RTKs. It is approved multinationally for the treatment of metastatic renal cell carcinoma (mRCC). In order to evaluate SU among ethnic populations, safety and efficacy of SU treatment was assessed in Asian and non-Asian patients (pts).
Materials and Methods: This ongoing, expanded-access, phase 3B prospective open-label clinical trial (A6181037; ClinicalTrials.gov number NCT00531544) was performed at 246 sites in 52 countries. Pts: had histologically confirmed mRCC; were both previously-treated and treatment-naïve; had not received prior SU; an ECOG performance status ranging from 0−2. SU was self-administered at a starting dose of 50 mg/day orally in 6-wk cycles (4 wks of SU followed by 2 wks off). Dose interruptions or reductions to 37.5 mg or 25 mg were allowed to manage AEs. AEs and hematology parameters were assessed on days 1, 14, and 28 of cycle 1, days 1 and 28 of cycle 2, and day 1 on cycles $\geqslant$3. Efficacy (ORR, PFS and OS) was evaluated according to schedules determined by local institutional standards of care.
Results: Data from 325 Asians pts (7%) and 4046 non-Asian pts (93%) was available at the time of analysis. Baseline characteristics were similar for both groups. Among Asian pts, 35% were treated at non-Asian sites. Common non-hematologic AEs in Asians and non-Asians, respectively, were diarrhea (42% and 45%), fatigue (40% and 37%), stomatitis (39% and 26%), and hand-foot syndrome (39% and 23%); the frequency of diarrhea was lower in Asians at non-Asian sites (29%) compared to Asian sites (49%). Grade 3−4 non-hematologic AEs in Asians and non-Asians, respectively, included hand-foot syndrome (13% and 6%), fatigue (8% for both), and diarrhea (7% and 5%). Grade 3−4 hematologic AE's in Asians at Asian sites, Asians at non-Asian sites, and non-Asians, respectively, included leukopenia (29%, 9%, and 12%) and thrombocytopenia (30%, 17%, and 13%). ORR was 18% (95% CI: 13.8−22.5) for Asian and 14% (95% CI: 12.5−14.6) for non-Asians. Median PFS was 8.7 months (95% CI: 8.1−11.1) for Asians and 10.9 months (95% CI: 10.5−11.3) for non-Asians. OS was 18.9 months (95% CI: 15.5−23.5) for Asians and 18.4 (95% CI: 17.4−19.2) months for non-Asians.
Conclusions: The results of this study demonstrate that the safety profile of SU treatment is similar for Asian and non-Asian pts for most AEs. SU is similarly effective and well-tolerated in Asian and non-Asian pts.

7119 POSTER

Genitourinary malignancies - Renal cancer Quality of life (QOL) in treatment-naïve and cytokine-pretreated patients with advanced renal cell carcinoma (RCC) treated with pazopanib: results from a phase III double-blind, placebo-controlled trial

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Background: Anti-cancer agents for the treatment of RCC may have toxicities that can cause considerable decrements for QOL. This study reports on QOL assessments from a double-blind, placebo-controlled Phase III trial of pazopanib 800 mg QD in advanced RCC pts, which showed