salvage treatment in 7 pts (53.8%) (CHT 2, RPLA 3, CHT+RPLA 2). DSS is achieved in 154 pts (96.25%) at MFU of 10.9 y. There were no CHT related toxic deaths. Statistical analysis failed to demonstrate any difference regarding RR (15% vs 8.1%) and DFS (90.2% vs 96.25%) between 2 analyzed groups of pts. Postoperative complications occurred more frequently in Arm A (21 vs 4 events) ($p < 0.001$). In Arm A ejaculatory potency was preserved in 62.8% vs 37.2% in favor of unilateral RPLA ($p < 0.001$), whereas overall ejaculatory potency was superior in Arm B (60.5% vs 86.5%) ($p < 0.001$).
Conclusions: Our experience with primary CDDP-based CHT and selective RPLA in CS-B1/B2 NSTT is superior to primary RPLA followed by adjunctive CHT since it 's resulted in high survival rate, low RR, acceptable toxicity and post-operative complications necessitating RPLA in only 23% of cases.

4524 POSTER

Renal cell carcinoma: surgical excision and adjuvant radiotherapy for renal bed recurrence

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Background: The use of postoperative radiotherapy (PORT) in the management of renal cell carcinoma (RCC) is controversial and has previously been associated with unacceptable toxicity. We report the toxicity and outcomes of patients undergoing this treatment after excision of locoregional recurrence.
Methods: From a prospective database 35 patients had RCC recurrence excised between 1999–2006. 10 patients received PORT. CT planned 3D PORT was utilised where possible to deliver $\geqslant$50 Gy in 1.8–2.25 Gy daily fractions. Parallel opposed para-aortic PORT was given for isolated lymph node (LN) recurrence to 45 Gy in 25 fractions. Case records were reviewed for acute and late RT toxicity (RTOG CTC grading) and outcomes.
Results: The median (mean, range) interval from primary nephrectomy to recurrence excision was 2.91 years (3.72, 0.51−10.7) and median interval from surgery to PORT was 90.5 days (321, 24–1995). 7 cases received PORT immediately post-surgery: 4 isolated renal bed recurrences, 2 renal bed and LN recurrences, 1 LN recurrence. 3 cases had deferred PORT – 2 further renal bed recurrences, 1 LN disease. The median total dose was 50 Gy (49.9, 45−60). Treatment was well tolerated in all cases with no unplanned gaps or grade 3 or 4 toxicity. Prophylactic antiemetics were given with nausea and vomiting limited to grade 1 in 5 cases, grade 2 in 2 cases. Grade 1 diarrhoea occurred in 1 case. Haematological and hepatic blood indices were unaffected. 1 case had an increase in serum creatinine and nephrotic syndrome due to paraneoplastic phenomenon. After a median follow up of 19.1 months (24.9, 7.4−86), 6 patients remain alive of whom 4 are disease free, 2 have developed distant metastases. Only one patient relapsed with local failure following incomplete resection. The median time to development of distant metastases was 9.7 months (20.1, 2.2−70.1). For patients who received surgery alone ($n = 24$), after a median follow up of 20.7 months, 9 are alive of whom 4 are disease free, 3 have recurrent local disease, and 2 have metastatic disease. The median time to development of local failure from surgery was 2.3 months (5.3, 0−13.1) and metastatic disease 5.1 months (8.9, 2.2−24.8).
Conclusion: PORT following surgical excision of locoregional recurrence is achievable without significant toxicity and may prevent further local relapse. Patients remain at high risk of metastatic disease and systemic treatment should also be considered in this selected group.

4525 POSTER

Self evaluation of side-effects of patients treated sequentially with sunitinib and sorafenib in kidney cancer

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Introduction: Sunitinib (SU) and sorafenib (SO), 2 tyrosine kinase inhibitors (TKIs) are currently standard treatment of metastatic renal cell cancer (MRCC). Toxicity profile of these drugs are different, but fatigue, diarrhea, skin reactions are common side effects. The severity of these side effects is commonly reported through NCTI scale. However, patient's own evaluation might be different from physician's one, and self evaluation might be more accurate to evaluate overall toxicity. The aim of this study was to assess through simple questionnaires, comparative toxicity of SO and SU in patients who received both drugs sequentially.
Methods: A simple autoquestionnaire was given to patients who were treated by either SU or SO after previous SO or SU treatment., after at least 2 cycles. This questionnaire included 7 items: fatigue, diarrhea, stomatitis, anorexia, hand foot syndrom, general feeling and overall QoL. All the items were scored from 0 to 10 through an analogic scale. Analysis was done for each item separately.
Results: from october 2006 to mars 2007, 27 patients with MRCC filled out the questionnaire. 17 patients had received SO first (duration 2−27 months) followed by SU (2−11 months) and 10 had opposite sequence (duration 2−15 mths for SU and 2−11 mths for SO). Fatigue was more important with SU than SO, whatever the order of administration (75% in first line, and 66% in second line). Diarrhea was significantly more common with SO, scaled >5 in 82% of the pts. Stomatitis was more common with SU in both sequence order (75% first line, 80% second line). Hand foot syndrom was more common when given after SU (83%) than before (50%). Anorexia was similar between both drugs. Overall evaluation of QoL was similar with both drugs, but SO was considered as more difficult to handle in 63% of the pts who received SO first and in 57% of the pts who received SU first.
Conclusion: self evaluation in patients who received sequentially SO and SU demonstrated that fatigue, stomatitis were more severe with SU, while diarrhea, hand foot syndrom were more common with SO. Overall, treatment with SU was better accepted by the pts than with SO.

4526 POSTER

Safety profile of single-agent sunitinib malate from the French Temporary Authorization for Use program (Cohort ATU) in metastatic renal cell carcinoma (MRCC) after failure of treatment with cytokines and gastrointestinal stromal tumor (GIST) patients after failure of imatinib mesylate treatment

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Background: Sunitinib malate (Sutent®) is an oral multitargeted tyrosine kinase inhibitor. Its targets include vascular endothelial growth factor receptor (VEGFR), platelet-derived growth factor receptor (PDGFR), KIT, RET and FLT3.
Sutent showed significant clinical activity in MRCC patients, in first line and after failure of cytokine therapy as well as in GIST patients following initial treatment with imatinib.
We report the safety of a French ATU program (Temporary Authorization for Use) initiated on March, 27, 2006. This program included patients with advanced or metastatic RCC who failed treatment with cytokines and patients with unresectable or metastatic GIST refractory or intolerant to imatinib.
Methods: From March 27 to September 22, 2006, 589 patients with advanced and/or MRCC and unresectable and/or metastatic malignant GIST in 147 French centers were treated with a schedule of 50 mg oral dose of Sutent daily for 4 weeks, then 2 weeks rest, until disease progression or intolerance. The data cutoff date for this planned interim analysis was December 31, 2006. This abstract provides the results of this analysis.
Results: The median age of the 544 RCC and 45 GIST patients was 62 years (range 24−84). Performance status (available for 322 patients) was 0−1 in 82%, 2 in 14% and 3−4 in 4% of the patients. At the time of data cut-off, a total of 343 patients received at least 1 cycle of treatment with Sutent with a median of 2 cycles (range 1−6). For the 199 patients evaluable for safety, the most common toxicities (all grades; CTCAE version 3) were asthenia (25%), stomatitis (17%), hand–foot syndrome (16%), thrombocytopenia (13%), diarrhea (11%) and hypertension (9%). The overall incidence of grade 3−4 hematological toxicity was 12% including thrombocytopenia (5%) and neutropenia (4%). Grade 3−4 non-hematological toxicity included asthenia (9%) and gastrointestinal toxicity (6%). Most Sutent-related adverse events improved by interruption of dosing or dose modification. Of the 190 patients who received more than one cycle of Sutent, dose modifications were reported in 63 patients (33%) and cycle delays in 28 patients (15%). Treatment was discontinued in 37 of the 343 patients (11%). Two treatment-related deaths were observed; one MRCC patient experienced diarrhea and septicemia and the other MRCC patient experienced exacerbation of a colonic fistula.
Conclusion: Sutent treatment of patients with advanced or metastatic RCC and GIST was associated with an acceptable safety profile.