Log-rank test. Safety and tolerability also were assessed in this patient subgroup.
Results: The French subgroup of the RECORD-1 study included 72 patients; 42 received everolimus and 30 received placebo. Median PFS was 5.52 months in French patients who received everolimus versus 1.87 months in those who received placebo (hazard ratio: 0.20; 95% confidence interval: 0.12, 0.34; $P < 0.001$). These results are consistent with those observed in the analysis of the total study population. The safety profile observed in the French subgroup of patients was also consistent with previous reports of the safety and tolerability of everolimus therapy.
Conclusions: Everolimus prolonged PFS versus placebo and was well tolerated in the subgroup of French patients with mRCC from the RECORD-1 trial. Everolimus is a novel therapy for patients with limited treatment options.
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7158 POSTER

Impact of Tyrosine Kinase Inhibitors (TKIs) in the treatment of patients with advanced renal cell carcinoma (RCC): A single centre retrospective review at the Hospital Universitario Central de Asturias

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Introduction: For almost the last two decades, cytokines (CKs) have been the only systemic treatment options available for advanced RCC. In recent years, TKIs have demonstrated clinical activity in this tumor. Our purpose has been to describe the experience of a single centre with the use of CKs and TKIs in the treatment of patients with advanced RCC.
Methods: This study was designed as a retrospective chart review in RCC patients being treated with CK and or TKI in our department between July 96 and June 08. Efficacy and toxicity were assessed following OMS criteria. The Kaplan-Meier method was used to estimate progression free survival (PFS) and overall survival (OS).
Results: Ninety-four patients were classified in three groups depending on the modality of treatment administered: forty-six treated only with CKs and/or chemotherapy (27 immunotherapy, one chemotherapy and 18 both), 28 only with TKIs (25 sunitinib and 13 sorafenib) and 20 with TKIs in second-line after failure to CKs (17 sunitinib, eight sorafenib, four bevacizumab and one lapatinib). The median of age was 60 years in the CK group and with TKIs 65 and 62 in first and second line respectively. Eighty-five percent of patients treated with CK were men and 75% in the group of TKIs in first and 80% in second line respectively. Overall 89% of patients had a favourable risk and 11% an intermediate risk. All patients were considered evaluable for toxicity. The main toxicity grade 3−4 (%) was asthenia for both groups of treatment, (10) in TKIs and (15) in CKs. Other grade 1−2 toxicities were mucositis (39), bleeding (8), hypertension (19), skin (33) and hypothyroidism (12.5) related with TKIs and anemia (33), cough (29), asthenia (39) and emesis (14) with CKs. The objective response rate among 80 patients evaluable for activity was 10.6% with CK and 46.5% and 35% with TKIs in first and second line respectively. Disease stabilization with CKs was registered in 59% and with CK in 25% and 50% of patients treated in first and second line respectively. The median PFS with CK was 122 days (IC 95%: 82−162) and with TKIs 201 days (65−337) in first and 346 days (256−436) in second line. The median OS was 229 days (142−316) and 2,074 days (1,152−2,996) for patients treated with CK and TKI respectively.
Conclusions: Our results are in agreement with the activity and survival previously reported in the literature for TKIs in patients with advanced RCC in first and second line treatment with an acceptable toxicity.

7159 POSTER

Loss of work activity and productivity in caregivers attending to patients with advanced renal cell carcinoma treated with temsirolimus or interferon-alfa: evaluations from a phase 3 randomized trial

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Background: In cancer, informal caregiving can influence a caregiver's employment, increasing missed work time as well as reducing productivity while at work. We analyzed the impact of informal caregiving on caregiver's workplace productivity. Workplace productivity of caregivers attending to patients (pts) with advanced renal cell cancer (advRCC) treated with temsirolimus (TEMSR) was compared with that of caregivers attending to pts treated with interferon-alfa (INFa). In addition, we evaluated the reaction of informal caregiving in both treatment groups.
Methods: Data were analyzed from a phase 3 trial of pts with previously untreated, poor-prognosis advRCC (N Engl J Med 2007;356:2271). Pts were randomly assigned to receive 25 mg TEMSR IV weekly, or INFa (titrated to 18 mU) SC 3 times weekly, or TEMSR plus IFNa. The combination arm was not included because efficacy was not better than that of the IFNa arm. Caregiver work productivity and activity impairment questionnaire (WPAI-CG), as well as a caregiver reaction assessment instrument (RAI), was administered at baseline and at 4-wk intervals until wk 32. Participation for the caregiver study was on a voluntary basis. For the current analysis, we evaluated WPAI and RAI at pts' last visits. ANCOVA model was used to compare the two treatment groups. Model covariates included baseline WPAI-CG, RAI, and measures of disease severity.
Results: Of 416 pts entered in the TEMSR (n = 209) and IFNa (n = 207) arms, data were available for 174 caregivers. About 50% of participating caregivers were employed (55% in TEMSR arm & 45% in the INFa arm [p = 0.1724]). Caring for advRCC pts was associated with substantial carer burden; on average, caregivers reported absenteeism of 11 hrs per wk and a 27% reduction in productivity at work. Caregivers caring for TEMSR pts reported significantly lower absenteeism (22% vs. 40%, p = 0.0339), lower overall work productivity loss (34% vs. 49%, p = 0.0178), and lower overall impairment in regular activity (29% vs. 38%, p = 0.0305) than caregivers caring for INFa pts. Based on RAI questionnaire, caregivers of TEMSR pts reported a significantly lower burden on their daily schedule compared with caregivers of INFa pts (14.0 vs. 15.9, p = 0.0043).
Conclusions: Although the study had 42% (174/416) caregiver participation rate, TEMSR therapy in advRCC is associated with reductions in caregiver absenteeism, overall impairment in regular activity, overall work productivity loss, and burden on caregiver schedule compared with IFNa therapy.
Study NCT00065468 was sponsored by Wyeth Pharmaceuticals.

7160 POSTER

Evaluation of adverse event -related hospitalizations in patients with advanced renal cell carcinoma on treatment with temsirolimus or interferon-alfa: results from a phase 3 randomized trial

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Background: First-line immunotherapies for advanced renal cell carcinoma (advRCC) include interleukin-2 and interferon alfa (INFa), administered either alone or in combination. In particular, IFNa has been associated with increased adverse events (AEs) and AE-related hospitalizations. Temsirolimus (TEMSR) is a specific inhibitor of mammalian target of rapamycin kinase and a targeted therapy in advRCC. TEMSR significantly increased overall survival in patients with advRCC compared with INFa in a phase 3 global advRCC (ARCC) trial (N Engl J Med 2007;356:2271). Due to its targeted action, TEMSR could potentially reduce hospitalizations due to AEs. We report evaluation of AE-related hospitalizations for patients on treatment with TEMSR or INFa.
Material and Methods: In the global ARCC trial, patients were randomly assigned to receive 25 mg TEMSR IV weekly, INFa (titrated to 18 mU) 3 times weekly or 15 mg TEMSR IV weekly plus 6 mU INFa 3 times weekly. We evaluated AE-related hospitalizations in TEMSR (n = 209) and INFa (n = 207) groups. AE-related hospitalizations were reported until death or 15 days following the last dose date in case of treatment termination due to disease progression. If last dose date was not available, treatment termination date was used. We analyzed the data using 3 models: Cox model to evaluate the hazard of first hospitalization, Andersen-Gill (AG) proportional rate model, and Prentice-Williams-Peterson (PWP) stratified multiple failure times model. Both AG and PWP models do not discard information past the first hospitalization, unlike the Cox analysis.
Results: A total of 144 AE-related hospitalizations were observed, 80 of these were in INFa group and 64 were in TEMSR group. In time to first hospitalization analysis, the hazard of hospitalization was estimated to be lower by 44% [HR = 0.56; 95% CI (0.402−0.780); p = 0.0006] in TEMSR group vs INFa group. In the AG model, the hazard rate across all hospitalizations was estimated to be lower by 36% [HR = 0.64; 95% CI (0.45−0.92); p = 0.0157] in TEMSR group vs INFa group. Similarly, in the PWP model, the hazard rate across all hospitalizations was estimated to be lower by 28% (HR = 0.72; p = 0.0220) in TEMSR group vs INFa group.
Conclusions: In patients with advRCC, TEMSR-treated patients have significantly longer time to first AE-related hospitalization and significantly fewer AE-related hospitalizations relative to INFa-treated patients.
Study NCT00065468 was sponsored by Wyeth Pharmaceuticals.