3006 POSTER DISCUSSION

Time to Deterioration (TTD) in Patient-reported Outcomes in Phase 3 AXis Trial of Axitinib Vs Sorafenib as Second-line Therapy for Metastatic Renal Cell Carcinoma (mRCC)

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Background: In an international, randomized, phase 3 trial of axitinib vs sorafenib as second-line therapy for mRCC, axitinib demonstrated greater median progression-free survival (PFS) compared to sorafenib (6.7 vs 4.7 mo; HR = 0.665, $P < 0.0001$). For patients who had received a prior cytokine regimen, median PFS was significantly higher in those treated with axitinib vs sorafenib (12.1 vs 6.5 mo; HR = 0.464, $P < 0.0001$); comparable values for those with prior sunitinib therapy were 4.8 vs 3.4 mo (HR = 0.741, $P < 0.0107$). Patient-reported kidney-specific symptom and functional outcome assessments were secondary endpoints.
Patients and Methods: 723 patients were randomized to receive axitinib 5 mg BID or sorafenib 400 mg BID. The Functional Assessment of Cancer Therapy–Kidney Cancer Symptom Index [FKSI-15] and the disease-related symptoms subscale [FKSI-DRS] were administered on Cycle 1 Day 1 before dosing, every 4 weeks while on study, at end of study treatment/withdrawal, and 28 days after final dose. A priori statistical methods included an analysis of TTD using survival analysis methods; reported P values are 1-sided. TTD was defined as a composite endpoint of death/progression/worsening in FKSI, whichever occurred first. Clinically important changes in FKSI-15 and FKSI-DRS were predefined as decreases of $\geqslant$5 and $\geqslant$3 points, respectively. TDD was also examined by prior therapy with either cytokines or sunitinib.
Results: The composite TTD endpoint showed a 16−17% risk reduction for axitinib vs sorafenib (FKSI-15: HR = 0.83, $P = 0.0141$; FKSI-DRS: HR = 0.84, $P = 0.0203$). For patients with prior sunitinib therapy, there were no significant differences between treatments for the composite TTD endpoint ($P > 0.025$), but there was a 23−25% risk reduction in TTD based on FKSI scores alone ($P = 0.023$ for FKSI-15 and $P = 0.038$ for FKSI-DRS). For the prior cytokine therapy subgroup, the composite TTD endpoint demonstrated a 35−39% risk reduction for axitinib vs sorafenib (FKSI-15: HR = 0.61, $P = 0.0004$; FKSI-DRS: HR = 0.65, $P = 0.0024$).
Conclusions: Axitinib had superior PFS compared to sorafenib in second-line advanced RCC patients in a phase 3 trial. This PFS benefit with axitinib corresponded with a delay in worsening of the composite TTD endpoint compared with sorafenib in the overall and prior cytokine-treated subgroup. In the prior sunitinib-treated subgroup, axitinib was associated with delays in worsening of quality of life, but not for the composite TDD endpoint.

3007 POSTER DISCUSSION

The Effect of Guideline Consistent Antiemetic Prophylaxis on Chemotherapy-Induced Nausea and Vomiting (CINV) in the Overall, Acute, and Delayed Phases: the Pan European Emesis Registry (PEER)

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Background: No prospective studies have assessed the effect of guideline consistent antiemetic prophylaxis (GCP) on patient outcomes in the era of modern antiemetic prophylaxis.
Objectives: The primary endpoint was to compare the proportion of patients with Complete Response (CR: No emesis and no use of rescue therapy) in the overall phase (0–120 hours post-chemotherapy) among patients who receive GCP for highly emetogenic chemotherapy (HEC) or moderately emetogenic chemotherapy (MEC) with those receiving guideline inconsistent antiemetic prophylaxis (GIP) during cycle 1. The analysis also compared outcomes during the acute (0−24 hours post chemotherapy administration) and delayed (25–120 hours post chemotherapy administration) periods.
Methods: PEER was a prospective, observational study which enrolled adults initiating single-day HEC or MEC at one of 52 centers located in 8 European countries (Austria, Belgium, France, Germany, Italy, Spain, Sweden, The Netherlands, and UK). Daily diaries were completed by patients for 5 days following chemotherapy for up to 3 cycles. The GCP definition was based on the 2006 MASCC guidelines. The proportion with CR was analyzed using multivariate logistic regression including well known CINV prognostic factors in the model.
Results: 991 patients comprised the evaluable population for cycle 1. The mean age was 56.7 years and 72.9% were female. Patients were classified as receiving HEC (19.1%), females receiving an anthracycline plus cyclophosphamide regimen (Female AC, 46.7%), or MEC (34.2%). The percentage receiving GCP in the overall phase was 29.0% (11.1% HEC, 28.7% Female AC, and 39.2% MEC) and 54.5% (43.4% HEC, 32.2% Female AC, and 91.2% MEC) in the acute phase. For the overall phase, CR was observed in 59.9% and 50.7% for the GCP and GICP groups, respectively ($p = 0.008$). The adjusted odds ratio for CR was 1.43 (95% CI: 1.04, 1.97; $p = 0.027$) for GCP compared to GIP. In the final multivariate model, statistically significant factors associated with CR in the final model included: GCP, MEC, use of primary antiemetics beyond recommended by guideline, no under-dosing of primary antiemetics, no history of nausea or vomiting, less anxiety in the 24 hours prior to chemotherapy, and less nausea in the 24 hours prior to chemotherapy. For the acute phase, CR was observed in 78.9% and 63.4% of the GCP-acute phase and GIP-acute phase patients ($p = 0.02$), respectively, with an adjusted odds ratio of 1.71 (95% CI: 1.19, 2.47; $p = 0.004$). CR in the delayed phase was 67.6% and 59.7% of GCP-overall patients and GICP-overall phase patients ($p < 0.001$), respectively, with an adjusted odds ratio of 1.48 (95% CI: 1.06, 2.05; $p = 0.021$).
Conclusions: Guideline consistent antiemetic prophylaxis reduces the incidence of CINV in the overall, acute, and delayed phases following highly and moderately emetogenic chemotherapy.

3008 POSTER DISCUSSION

CCAT: a UK Initiative to Address the Consequences of Cancer Treatment Through Research, Influence and Practice Development

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Background: People who have been treated for cancer may be left with ongoing long-term physical, social or psychological issues. These problems can have a serious impact on people's lives, but frequently are not recognised or addressed. As the incidence of cancer rises and treatments become more successful, so the number of cancer survivors will increase. The number of people living into old age with the long term impact of cancer treatment is rising rapidly and there is a need to find effective, sustainable ways to better meet these patients' needs.
Methods: The Consequences of Cancer Treatment Collaborative (CCaT) has been set up by the UK charity Macmillan Cancer Support as part of a UK health services initiative to address the growing issue of cancer survivorship (the National Cancer Survivorship Initiative). CCaT is a collaborative of 12 senior nurses and allied health professionals with expertise in clinical practice, service development, research and education. By bridging the gap between research and practice, the group aims to improve care for people living with the effects of treatment, through a range of individual and collective projects.
Results: A wide range of projects have been set up and these include:

- Assessment of a nurse-led bowel management programme for bothersome symptoms after rectal cancer.
- Retrospective evaluation of the prevalence of long term urinary, sexual and bowel dysfunction in colorectal cancer patients.
- Overseeing the adaptation, implementation and evaluation of the Lance Armstrong Foundation "Cancer Transitions" educational programme for cancer survivors.
- Return to work:
  - Occupational Therapist role
  - Occupational health perspectives
- Development of 10 top tips for cancer survivorship