3002 POSTER DISCUSSION

Final quality of life (QOL) results with geographical analysis for sunitinib versus interferon-alfa as first-line therapy in patients with metastatic renal cell carcinoma (mRCC)

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Background: In a randomized, phase 3 trial (ClinicalTrials.gov: NCT00083889; sponsor: Pfizer), sunitinib showed superior progression-free survival (primary endpoint) and objective response rate over interferon-alfa (IFN-α) (11 vs. 5 mo and 47% vs. 12%, respectively; P < 0.000001) as first-line mRCC therapy, with a median overall survival of more than 2 years (Figlin et al. ASCO '08). Here, we report the final QOL results from this trial with geographical analysis of patients in the United States (US) vs. the European Union (EU).
Material and Methods: 750 treatment-naïve mRCC patients were randomized 1:1 to receive sunitinib 50 mg orally once-daily in recurring 6-week cycles of 4 weeks on drug, 2 weeks off, or IFN-α 9 MU subcutaneously thrice-weekly. QOL was measured by 9 endpoints: the Functional Assessment of Cancer Therapy − General (FACT-G), which has 4 subscales, the FACT-Kidney Symptom Index − 15 item (FKSI-15), which includes a Disease-Related Symptoms (FKSI-DRS) subscale, and the EQ-5D questionnaire's utility index (EQ-5D Index) and visual analog scale (EQ-VAS). The primary QOL endpoint was FKSI-DRS. Higher scores indicated better outcomes. Patients completed questionnaires on days 1 and 28 of each cycle. Data were analyzed for the intent-to-treat population using mixed-effects models (MM), supplemented with pattern-mixture models (PMM). We also compared QOL of patients in the US with patients in the EU (France, Germany, Italy, Poland, Spain and United Kingdom).
Results: Patients on sunitinib reported better FKSI-15 and FKSI-DRS scores than those on IFN-α, with a significant difference in the overall means across cycles (4.06 and 2.36, respectively; P < 0.0001; MM). Similarly, differences in means for FACT-G (and all subscales), EQ-5D Index, and EQ-VAS all significantly favored sunitinib (P < 0.05). Per pre-established thresholds, between-treatment differences in mean scores were clinically meaningful for FKSI-15, FKSI-DRS, FACT-G, and the FACT-G functional well-being subscale. In the US subpopulation, all endpoints, with the exception of the EQ-5D index score, significantly favored sunitinib over IFN-α (P < 0.05). In the EU subpopulation, 5 of the 9 QOL endpoints significantly favored sunitinib over IFN-α (P < 0.05). Between-treatment differences were similar for both subpopulations. Results from PMM were similar.
Conclusions: Sunitinib provides superior QOL over IFN-α, in addition to superior efficacy, as first-line mRCC therapy, with similar findings in the US and EU.

3003 POSTER DISCUSSION

Intercessory prayer improves spiritual wellbeing in a randomised controlled trial in patients with cancer

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Background: Anecdotal evidence and a growing number of clinical trials suggest a positive impact of intercessory prayer on health outcomes. However little trial evidence is available in patients with cancer on how prayer affects outcomes such as wellbeing. This study ("Spiritual well-being" ANZCTR 00083833) aimed to assess the affect of remote Christian intercessory prayer on the spiritual wellbeing and quality of life (QoL) of patients with initial diagnoses of cancer.
Materials and Methods: A total of 999 eligible patients with new appointments at an Australian cancer centre were randomised to receive remote intercessory prayer (n = 509) or no prayer (n = 490). With institutional ethics committee approval, in line with previous studies of this kind, patients remained blind to the intervention but gave consent to having QoL and spirituality studied by completing the Mental Adjustment to Cancer (MAC) scale and the Functional Assessment of Chronic Illness Therapy – Spiritual Well-being (FACIT-Sp). Demographic and disease information was also collected and verified against medical records. Patients were then asked to repeat the FACIT-Sp six-months later with 66.7% complying. An established Christian prayer chain was provided with sufficient but unidentifiable information about each intervention patient and added them to their usual prayer lists and practices.
Results: Randomisation was successful in making groups comparable across demographic and disease characteristics. For the primary endpoint of Spiritual Wellbeing, the intervention group showed significantly greater improvements over time compared to the control group (p = 0.02, partial $\eta^2 = 0.01$). When Spiritual Wellbeing was deconstructed, improvements over time were found for the factors of Peace and Faith while scores on the Meaning factor appeared to worsen. Of the remaining QoL subscales, the intervention group showed significantly greater improvements in Emotional Wellbeing than the control group (p = 0.04, partial $\eta^2 = 0.01$). There were no significant differences between groups on other wellbeing subscales.
Conclusion: Patients with cancer who were randomly allocated to receive remote intercessory prayer showed small, significant improvements in their Spiritual Wellbeing which we have previously shown to be an important, unique domain in the assessment of QoL.

3004 POSTER DISCUSSION

Disease awareness affects reversely health-related quality of life (HRQL) of cancer patients and their family members

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Background: It was observed that disease awareness affects mainly the relatives of cancer patients undergoing chemotherapy, while patients were not influenced as much. Aim of this study was to explore how disease knowledge affects HRQL of both cancer patients and their family members.
Material and methods: 212 family members (133 women) of mean age 48.9±14.3 and 212 cancer patients undergoing chemotherapy (119 females) of mean age 57.3±14.6 completed the SF-36 health survey by personal interview. The SF-36 survey contains eight scales measuring physical functioning (PF), role physical (RP), bodily pain (BP), general health perception (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH), with higher scores (0–100 range) reflecting better-perceived health. Physical Component Summary (PCS) and Mental Component Summary (MCS) describe the overall physical and mental health. Data analysis was performed with SPSS version 13.0 while statistical analysis was performed with Mann Whitney's U test. Significance was set at 0.05.
Results: Table 1 summarizes the results of our study.
Conclusion: Disease awareness highly affects the HRQL of cancer patients and their family members in a reverse fashion. Knowledge of the disease seems to exert a positive influence on patients' physical and mental parameters while it provokes mainly a mental distress on relatives' quality of life. Tailored and balanced interventions are necessary for the support of both population groups.

Table 1

	PF	RP	BP	GH	VT	SF	RE	MH	PCS	MCS
Patients										
Aware	71.4* (28.5)	26.4 (37.2)	65.7 (36.2)	50.2 (24.5)	59.2 (24.8)	65.0 (36.6)	56.5 (42.1)	64.9 (20.3)	40.5 (11.6)	45.9 (11.8)
Not aware	67.3 (32.4)	40.2 (42.7)	67.0 (34.6)	64.5 (18.9)	68.2 (22.1)	74.3 (34.4)	70.5 (39.4)	71.8 (18.7)	42.2 (11.2)	50.9 (11.7)
p	0.572	**0.021**	0.876	**<0.001**	**0.009**	0.071	**0.023**	**0.032**	0.425	**0.004**
Family Members										
Aware	94.9 * (14.5)	86.3 (30.1)	90.5 (20.1)	73.3 (18.6)	71.6 (26.2)	71.0 (29.9)	65.9 (38.1)	65.1 (21.8)	56.7 (7.6)	43.6 (12.2)
Not aware	91.7 (17.1)	77.9 (38.0)	85.8 (27.7)	71.0 (18.7)	59.5 (23.5)	56.6 (36.8)	37.2 (39.8)	51.5 (23.6)	58.1 (9.1)	33.6 (13.8)
p	**0.024**	0.129	0.482	0.355	**0.002**	0.010	**<0.001**	**<0.001**	0.078	**<0.001**

* Mean score and (1SD) is described.

3005 POSTER DISCUSSION

Risk of mortality in patients with cancer experiencing febrile neutropenia

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Background: Febrile neutropenia (FN) is a potentially life-threatening condition that may develop in patients with cancer treated with chemotherapy. The risk of mortality from FN is not well characterized in current clinical practice. This observational study evaluates mortality in patients with FN compared to those not experiencing FN.

Materials and Methods: Cancer patients receiving chemotherapy in clinical practice were identified from the HealthCore Integrated Research Database®, a geographically diverse, fully adjudicated longitudinal claims database covering 13 health plans and more than 20 million US lives. Enrollment data, medical (hospital and outpatient) and prescription claims, and mortality (confirmed using the National Death Index) were examined for eligible patients from January 2001 – December 2006. FN patients were propensity score-matched (1:1) within each tumor type of interest (Non-Hodgkins Lymphoma, breast, lung, colorectal, and ovarian cancer) to those not experiencing FN. Study endpoints included overall mortality (anytime during follow-up) and early mortality (during a chemotherapy course). Proportional hazards regression was used to calculate hazard ratios (HR) with 95% confidence intervals for the propensity score-matched cohort adjusted for demographics, comorbidities, and other covariates.
Results: Matched FN and control groups each included 5,176 patients; average follow-up times were 14.4 and 15.3 months, respectively. Crude incidence rates of overall and early mortality were significantly higher for patients in the FN group than in controls for combined tumor types (7.9/1000 person-months [PM] vs. 5.6/1000 PM, $P < 0.0001$; and 3.4/1000 PM vs. 2.4/1000 PM, $P = 0.0001$, respectively). Proportional hazards regression demonstrated a significant increase in risk of overall and early mortality in patients with FN compared to controls (HR = 1.53 [1.35–1.72] and HR = 1.54 [1.29–1.85]), respectively.
Conclusions: The adjusted risk of mortality in patients experiencing FN is at least 50% higher than in comparably-matched patients without FN. This supports the inference that infectious complications due to neutropenia resulting from myelosuppressive chemotherapy are still significant and should be avoided.

3006 POSTER DISCUSSION

Predictive factors for toxicity of non platinum chemotherapy

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Background: Excepted for platinum based chemotherapy (CT), the doses of anticancer drugs are usually calculated according to the body surface area. The aim of this prospective study was to identify, in a routine practice, predictive risk factors of toxicity and to evaluate their evolution over time.
Methods: Patients (pts) with solid tumours treated with a non platinum based CT were included. Several criteria were evaluated at baseline, after 3 or 6 courses (according to the protocol) and at the end of the CT: age, sex, performance status (PS), weight, type of tumour, number of previous CT, cancer treatment, renal function (Cockcroft-Gault formula) and albumin.
Results: 200 pts were included between October 2007 and June 2008 at François Baclesse Center. The most frequent types of cancer were breast (60%) and digestive (29%); 43% of pts had metastases. The main CT were Taxanes, Fec, Folfox and Folfiri. Initial characteristics were: F/M sex ratio 75%/25%, mean age 58 years (22 to 85), PS 0 79%, baseline weight loss 30%, normal renal function (creatinine clearance over than 90 mL/min) 66% and an albumin level upper than 34 g/L in 53% of cases.
During CT 30% of pts contracted an infection, 78% presented at least a grade 2 toxocity (45% after 1 cycle and 75% after 3 cycles). Toxicities were mainly dermatological (grade >1; 51%), neurological (grade >1; 38%), digestive (grade >2; 18%) and haematological (12% fever aplasia, 43% grade 3−4 neutropenia and 10% thrombopenia). As a result, 38.5% of pts had a dose reduction or a delay of CT. Moreover, 10% of pts stopped CT before the end due to toxicity. Interestingly, 67% of them had at baseline hypoalbuminemia (>grade 1) or impaired renal function (less than 90 mL/min).
During treatment, 22% of pts had a decrease of renal function. Among 38% of pts who lost weight during CT, 30% presented a decline of creatinine clearance.
In multivariate analysis, predictive factors of digestive toxicity ($p < 0.05$) were older than 65, abdominal surgery, weight loss and digestive cancers. Low level of albumin, bone radiotherapy and breast cancer predicted haematological toxicity ($p < 0.05$).
Conclusion: A majority of pts with non plainum CT develop early significant toxicity with a modification of the standard treatment protocol in about 30% of cases. Identification of baseline predictive factors should help to adjust the initial dosage of CT to anticipate toxicity. Before starting CT, renal function and albumin level should be assessed in a routine practice.

3007 POSTER DISCUSSION

Herpes zoster in solid tumor and hematologic malignancy patients – a cohort study in a managed care organization

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Background: Given the limited available data, the aim of this study was to estimate the incidence of Herpes Zoster (HZ) among patients with invasive cancer.
Material and Methods: In this retrospective cohort study, we used the Kaiser Permanente Northern California cancer registry to identify adult health plan members diagnosed with an invasive hematologic malignancy (HM) or solid tumor malignancy (STM) during 2001–2005. Potential episodes of HZ were ascertained from time of cancer diagnosis through 2006 from electronic databases using inpatient, emergency department, and outpatient diagnoses, laboratory tests, and prescriptions for antivirals. HZ diagnoses were confirmed by abstraction and clinical review of information from patients' medical records. Incidence rates were calculated as the number of new occurrences of HZ per person years (py) of follow-up. Age- and sex-standardized incidence ratios (SIRs) were computed to compare HZ rates in cancer patients to reported rates in the general population (Yawn *et al*, 2007).
Results: Among the 11,044 STM patients (mean age 66 years at cancer diagnosis, range 18–103), the overall rate of HZ was 12/1000 py (total 21,522 py); it was 15/1000 py for breast cancer patients (n = 2026), 10/1000 py for prostate cancer patients (n = 2276), 20/1000 py for lung cancer patients (n = 1498), and 7/1000 py for colon cancer patients (n = 973). In STM patients, rates of HZ increased with increasing age at cancer diagnosis. Among all 2715 HM patients (mean age 66 years at cancer diagnosis, range 18–100), the overall rate of HZ was 31/1000 py (total 4465 py); it was 51/1000 py for Hodgkin lymphoma patients (n = 154), 25/1000 py for non-Hodgkin lymphoma patients (n = 1442), 56/1000 py for multiple myeloma patients (n = 416); and 23/1000 py for patients with myeloid leukemia (n = 319). Among both STM and HM patients, rates were similar among Caucasians and African Americans and were higher in persons with higher levels of immunosuppression. The SIRs and 95% confidence intervals for STM and HM were 1.8 (1.6−2.1) and 4.7 (4.0−5.6), respectively.
Conclusions: The incidence of HZ was higher among HM patients than among STM patients and varied in both groups by cancer subtype. Compared to reported incidence rates in the general population, the rate of HZ was nearly 2 times higher in patients with STM and 5 times higher in patients with HM.

3008 POSTER DISCUSSION

Renal function evolution in cancer patients results of the IRMA-2 study

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Background: In 2007, the IRMA-1 study reported the high prevalence of renal insufficiency (RI) in cancer patients. Because of this high frequency, the IRMA-2 study started to investigate the evolution of renal function in cancer patients.
Methods: Data were collected for cancer patients presenting at one of the 19 IRMA-2 centers in March 2005. Data included: sex, age, weight, serum creatinine (SCR), haemoglobinemia, type of tumour, metastasis (bone and/or visceral) anticancer drugs. Dialysis, myeloma and lymphoma patients were not included. Glomerular filtration rate (GFR) was estimated with the abbreviated MDRD (aMDRD) formula. Patients were retrospectively followed during 2 years after the inclusion, every 6 months, from March 2005 (T0) to March 2007 (T24).
Results: 4945 cancer patients (breast 1816, colorectal 747, lung 463, ovarian 294, prostate 251 . . .) were included in 19 cancer centre in France. Median age 60.0, mean weight 66.2, 62.8% were women. In the all population, mean GFR decreased from 90.8 to 83.7 ml/min/1.73m^2 over the