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.