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POSTER

Comparison of Health-related Quality of Life (HRQoL) in Patients Reporting the Same Adverse Event (AE) Fatigue on Different Treatments

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Background: Because AE assessment is done by an outside observer, it is considered by some to be an objective measure of treatment impact. However, as AEs are graded by the treating physician, they alone may not depict the full effect on patients. We examined the relationship between the AE fatigue and HRQoL to assess whether patients with the same grade of severity have the same HRQoL across different treatments.

Methods: In a phase III trial, 750 treatment-naïve patients with metastatic renal cell carcinoma were randomized 1:1 to receive repeated cycles of oral sunitinib (SU) 50 mg/day on a 4-weeks-on-2-weeks-off schedule (n = 375) or interferon- α (IFN) 9 MU subcutaneously thrice weekly (n = 360). We used the following HRQoL scales and subscales as outcomes: FKSI-15, FKSI-DRS, FACT-G, and EQ-5D. AEs were graded using the National Cancer Institute Common Terminology Criteria for AEs (NCI CTCAE), v3.0. We focused on the AE fatigue (grades 1 [lowest] to 4 [highest]), assigning a value of 0 to a patient for whom fatigue was not reported during a cycle. A repeated measures mixed-effects model was used to study the relationship between HRQoL scores and fatigue grade by treatment.

Results: The relationship between HRQoL and the AE fatigue was close to linear. HRQoL was generally better with SU for any grade of AE fatigue. In the absence of AE fatigue, all differences in HRQoL score were not only superior with SU but also statistically significant most of the time (P < 0.05). For AE fatigue of grades 1 and 2, all differences but one (the FKSI item "I have pain") numerically favored SU and the majority were statistically significant. A similar pattern for grade 3 AE fatigue also favored SU but few results were statistically significant, likely because of the smaller sample size. The difference in the FKSI item "I feel fatigued" showed less fatigue with SU for all grades of AE fatigue, a finding that was also statistically significant.

Conclusions: Our results show that patients with the same grade of AE fatigue on different treatments may have different HRQoL. In this study, patients on SU who experienced the same grade of fatigue as patients on IFN generally had more favorable FKSI-15, FKSI-DRS, FACT-G, and EQ-5D scores. Although these scores may have been impacted by other AEs and differences in efficacy, favoring SU, this suggests that assessment of symptomatic AEs by CTCAE grading does not fully capture a patient's experience and should be interpreted alongside HRQoL and other AEs.

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Sense of Coherence (SOC) is Stable up to 3 Years Postoperatively – a Longitudinal Prospective Study in Women Surgically Treated for Breast Cancer

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Background: The majority of women with breast cancer have a long life expectancy, some however with symptoms attributed to treatment which affects quality of life. Sense of coherence (SOC) is a health related quality of life instrument with 13 items that reflect on the individual's ability to manage difficulties according to a salutogenesis theory model by Antonowski. High scoring levels of SOC relate to a better coping strategy to the illness regardless of the severity of the disease. The SOC scoring results may be associated with treatment effects. There is also uncertainty to whether SOC measurements remain stable over time. SOC summated scales vary between 13–91 where 13–45 is considered low. Normdata report scales between 50–70. Overall aim: To elucidate SOC in a prospective longitudinal study where its stability over time, its association with reported symptoms before and after breast cancer treatment is analysed.

Material and Methods: One hundred and twenty five women in a single institution who underwent breast cancer surgery between 1999–2001 were included. Eight declined participation. Descriptive statistics, regression and survival analyses were used.

Results: Mean age of the patients at study entry was 55 (30–76) years. One hundred and seventeen women completed the SOC questionnaire preoperatively, 103 one year postoperatively, 93 after 2 years and 90 after 3 years. Preoperatively 10% scored <55 and 10% >83. Preoperatively 33/111 (26%) reported pain/discomfort in arm/shoulder region. The mean summated SOC scale preoperatively was 70 (SD 10.18), 1 year postoperatively 70 (SD 11.24), 2 years 72 (SD 11.26) and 3 years postoperatively it was 71 (SD 11.39).

Conclusion: This study corroborates those reports stating that SOC is stable over time. As a group our cohort showed that SOC scales were similar to norm data. These data will be further analysed for possible interaction between SOC and treatment modalities.

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Delivering Science Based, Patient Driven Image Guided Prostate Radiotherapy – Striving for Patient-Centred Care in an Era of High Precision Radiation Therapy

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Background: Although transrectal ultrasound-guided fiducial marker implantation for prostate localization during radiotherapy has been traditionally utilized, it is nonetheless an invasive procedure that is not without morbidity. With the advent of cone-beam computed tomography (CBCT)-based setup corrections and evidence showing the non-inferiority of this soft tissue matching technique in experienced hands, the opportunity arises to potentially offer patients a choice of image-guided radiation therapy (IGRT) modalities. However, to date, the authors are unaware of any literature documenting patient involvement in selecting the IGRT modality. The aim of this study is to perform a qualitative study to examine patient self-reported morbidity of fiducial marker insertion and their preference of IGRT modality – CBCT vs. fiducial markers.

Material and Methods: Twenty four patients with a diagnosis of localized prostate cancer who were on dose-escalated radiation therapy were accrued. Prior to radiotherapy, four gold markers were inserted into the prostate using a transrectal approach for target localization during radiation, which is our current standard of care. Detailed self-administered questionnaires and/or structured interviews were used to gather data regarding the patient-perceived morbidity of fiducial marker insertion and their preference of IGRT modality. Content analysis was performed using the questionnaire/interview data and recurring themes were extracted. Simple descriptive statistics were used for the quantitative data.

Results: Overall, fiducial marker insertion represented an unpleasant and uncomfortable experience for patients. A significant proportion (45%) reported experiencing at least moderate pain with the procedure. A psychological sensation of embarrassment was associated with the procedure for some. Nevertheless, patients generally expressed a view of being determined to "do anything that would benefit my chance of curing the prostate cancer" and accepted fiducials because it permitted "accurate treatment". However, if given the option of a non-invasive CBCT technique that could achieve the same outcomes, the majority (90%) either remained neutral or opted for the new non-invasive technique. The mean scores for patient-perceived quality of life/satisfaction ratings using a 7-point scale (1 = Terrible; 7 = Delighted) in each of the global care areas of "radiation therapy", "prostate biopsy", and "marker insertion" were 6.2 (range 5–7), 4.9 (range 1.5–7), and 4.8 (range 1–7), respectively.

Conclusions: Knowledge gained from this study is instrumental for ongoing program development and technology implementation to provide high quality patient-centred care – aiming to deliver not only radiation treatments with high precision, but also with high quality of life factors incorporated.

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Relationship Between Plasma Cytokine Levels and Physical or Psychological Functioning in Patients With Advanced Cancer

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Background: The relationships between cancer-related symptoms and several proinflammatory cytokines have been well documented. However, in previous studies, the number of examined cytokines was limited. Here,