

arm. The XP/FP arm showed a 5-point average improvement from baseline between Weeks 22–34.

Role functioning and fatigue scores were similar in both arms until Weeks 34 and 28, respectively, after which H+XP/FP showed sustained improvement over XP/FP.

QLQ-STO22: HRQoL improved over time in both arms. Slight improvements from baseline in the dysphagia score were seen, notably after Week 19 until Weeks 31 (XP/FP) and 61 (H+XP/FP).

**Conclusions:** In ToGA, adding H to XP/FP improved OS without compromising HRQoL; this effect was greater in patients with high HER2 expressing tumours in the H+XP/FP arm, where the time to deterioration in QoL was significantly longer. Consistent with these results, improved HRQoL was observed over time in this patient subgroup, with a sustained effect beyond CT administration when adding H to XP/FP.

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POSTER

### Living Through Pelvic Radiotherapy – Responses of Maintaining Self

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**Background:** Before introducing interventions against distressful symptoms, it is important to describe patients' experiences and the self-care activities that are initiated by patients living through cancer treatment. This study was designed to explore the impact on life living through pelvic radiotherapy with focus on experienced symptoms and self-care activities. **Materials and Methods:** Twenty-nine women undergoing pelvic radiotherapy were prospectively followed were baseline, 3 weeks and 5 weeks of treatment served as time points for data collection. Data were collected within a mixed method design including structured and semi-structured interviews which reflected impact on daily life, symptom experience and self-care activities. Grounded Theory formed data collection and analysis of the semi-structured interviews. Experienced symptoms and aspects of health related quality of life was assessed by EORTC-QLQ-C30 and MFI-20.

**Results:** To be able to maintain oneself was concluded as being central living through pelvic radiotherapy. Being highly distressed by gastrointestinal symptoms respondents set out to do what it takes to survive, to keep the body intact and to be seen and treated as always by others. Diarrhea increased significantly ( $p < 0.001$ ) during treatment as did fatigue ( $p < 0.001$ ). Impact on physical, social and role functions was evident in both the questionnaires and in the semi-structured interviews. Self-care activities in relation to diarrhea and fatigue are described.

**Conclusion:** The result of this study shows that undergoing pelvic radiotherapy has a major impact on the individual with physical, social and role concerns. The gastrointestinal symptoms caused highest distress. Interventions aimed at alleviating distressful symptoms should be complemented with a care based on patients' own experiences and strategies for alleviating symptoms. The caregiver should be supportive in confirming the patients' experiences in the process of maintaining self.

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POSTER

### Health-Related Quality of Life in Small-Cell Lung Cancer: a Systematic Review on Methodological Issues in Randomized Controlled Trials

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**Background:** Lung cancer is a common cancer site and randomized clinical trials (RCTs) often assess lung cancer patients' Health-Related Quality of Life (HRQOL). This study examines the HRQOL methodology reporting in small-cell lung cancer (SCLC) RCTs. The objective was to evaluate the adequacy of HRQOL methodology reporting since 1990 and its benefits for clinical decision making.

**Methods:** A Medline systematic literature review was performed in randomized clinical trials. Eligible RCTs implemented patient-reported HRQOL assessments and oncology treatments (e.g. chemotherapy, radiotherapy, surgery) for adult SCLC patients. Included studies were published over the last two decades, between April 1991 and February 2011. Only studies with sample size  $\geq 100$  and patient age  $\geq 18$  were included. Two independent reviewers evaluated all selected RCTs.

**Results:** Twenty-nine RCTs out of seventy-one studies were classified as eligible for inclusion in our review. HRQOL was the primary endpoint in five RCTs and a secondary endpoint in 24 RCTs. Of the 29 RCTs, 62%

reported that there was no significant difference in overall survival (OS). 50% of the RCTs that did not find any OS differences did find significant differences in HRQOL scores. Tests of statistical significance were applied in 97% of the RCTs and a HRQOL difference between treatment arms was found in 62% of the RCTs. 32% of the RCTs showed clinically significant differences and reported clinical conclusions. The EORTC QLQ-C30 tool was used in 48% of the RCTs.

**Conclusions:** HRQOL assessment in SCLC RCTs provides an added value in the studies where no OS difference is found. However, while the reporting of HRQOL was overall of acceptable standards, improvement in reporting RCT is to be encouraged.

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POSTER

### Effect of Completion-time Windows in the Analysis of Health-Related Quality of Life (HRQOL) Outcomes

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**Aims:** Our aims were to assess if HRQOL scores of the EORTC QLQ-C30 are affected by the specific time point, before or during treatment, at which the questionnaire is completed and whether this could unduly bias the treatment comparisons.

**Patients and Methods:** We analyzed data from one closed EORTC 2-arm RCT of 430 advanced colorectal cancer patients who were treated with CPT-11 in combination with weekly 24-hour infusion 5-FU plus folinic acid versus weekly 24-hour infusion of 5-FU plus folinic acid alone. HRQOL was measured as a secondary endpoint at baseline and over the 9-scheduled chemotherapy cycles using the EORTC QLQ-30 questionnaire. To investigate the effect of questionnaire completion before and during treatment, a 'completion-time window' variable was created to indicate when the EORTC-QLQ-30 was completed relative to cycle dates, defined as 'before' (up to 10 days before the cycle date), 'on' (on cycle date), and 'after' (up to 10 days after the cycle date). Additional sensitivity analysis was performed using extended completion-time windows of 30 to 40 days. HRQOL mean scores were calculated using a linear mixed model including treatment, cycle number, treatment-by-cycle interaction, and the completion-time window variable.

**Results:** The analysis was limited to 6 cycles with the number of patients who completed the EORTC QLQ-C30 ranging from 31–329 over the 6 cycles, yielding a total of 782 completed questionnaires. There were no statistically significant differences in scores in the "before" to "on" comparisons; however statistically significant differences ( $p < 0.05$ ) were observed on 5 subscales for "on" to "after" comparisons. We then formed two groups of patients in which questionnaires were completed "before" or "on", compared to "after". The following statistically significant differences were found in the estimated HRQOL mean values between "before-or-on" compared to "after" completions: decreased social functioning (-5.8) and global health status/QoL (-5.5), and increased nausea/vomiting (4.8), appetite loss (7) and fatigue (7.5). Similar results were observed during the sensitivity analysis. Although all of these differences were in the same direction (i.e., worse mean scores in the after treatment completions), these differences were below the 10 points accepted as clinically meaningful. Treatment effect comparisons between arms were not significantly altered by the inclusion of the completion-time window variable in this trial.

**Conclusion:** Our findings suggest that scores after treatment may be affected by the treatment and thus, the effect of completion-time windows should be tested during the analysis of HRQOL scores. Accounting for this information did not alter the decision regarding treatment comparisons in this case, but might possibly vary in other situations. We recommend, therefore, that outcome bias due to the possible effects of the timing of completion-time windows should be examined in future clinical trials.