

Abstract 1369

EFFECT OF TIME WINDOWS IN ANALYSIS OF HEALTH-RELATED QUALITY OF LIFE (HRQOL) OUTCOMES

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AIMS: Our aim was to assess whether HRQOL scores on the EORTC QLQ-C30 scores depend on the timing of questionnaire completion, relative to chemotherapy delivery, and whether including such information in the analysis could influence conclusions regarding treatment effect.

METHODS: In a retrospective analysis of an EORTC 3-arm RCT of 480 advanced NSCLC patients comparing gemcitabine+cisplatin, paclitaxel+gemcitabine, and standard arm paclitaxel+cisplatin, a 'time window' variable was created to indicate when the QLQ-C30 was completed relative to each of the scheduled 6 chemotherapy administration dates: -1 (up to 10 days before), 0 (on cycle date), and 1 (up to 10 days after). HRQOL scores were analyzed in a linear mixed model including treatment, cycle number, treatment-by-cycle interaction, and the time window variable.

RESULTS: The number of patients who completed the QLQ-C30 'before', 'on', and 'after' ranged 72-284, 69-116, and 13-32 respectively over the 6 cycles. No statistically significant differences in scores were noted for before-on comparisons, however 6 subscales showed significant differences ($p < 0.05$) for on-after comparisons. We then formed 2 groups in whom questionnaires were completed before/on versus after. We observed the following statistically significant differences in HRQOL mean values between before/on vs after responses: decreased social functioning (4) and cognitive functioning (5), and increased fatigue (-4), nausea/vomiting (-6), appetite loss (-5), and constipation (-5). The mean score differences of about 4 or 5 points are below the 10 points conventionally accepted as clinically meaningful. Treatment effectiveness comparisons between arms were not significantly changed by the inclusion of the time window variable.

CONCLUSIONS: These results suggest that after-treatment scores may be affected by treatment. The effect of 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 this might possibly vary in other situations.