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Quality of Life (QOL) Analysis of the Randomized Radiation (RT) Dose Escalation NSCLC Trial: “The Rest of the Story”

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Methods and Statistical Considerations

- QOL was collected prospectively via a validated lung cancer instrument: Functional Assessment of Cancer Therapy-Trial Outcome Index (FACT-TOI)
  - FACT-TOI = Physical Well Being (PWB) + Functional Well Being (FWB) + Lung Cancer Subscale (LCS)

- Data are presented here at baseline:
  - 3 months (from start of treatment)
  - 12 months via minimal clinically meaningful changes:
    - >2 points for PWB, FWB or LCS

- Two-sample t-test, Wilcoxon-Mann-Whitney test, and/or chi-square test compared QOL between arms and between technologies

- Effect sizes (ES) are also indicated: a moderate ES ~ 0.3-0.4

- Cox proportional hazards model used for correlating QOL and OS

- 2-sided p-values and 0.05 significance level
QOL Hypothesis

• The primary QOL hypothesis predicted for a clinically meaningful decline (CMD) in the lung cancer subscale (LCS) on the high-dose arm at 3 months
Change in FACT-LCS

- LCS Decline
  - 3 months: 46% (74 Gy), 31% (60 Gy)
  - 12 months: 39% (74 Gy), 36% (60 Gy)

- p-values:
  - p=0.024
  - p=0.7

- Treatment groups: 74 Gy, 60 Gy
Results: Baseline FACTS and OS

• Beyond RT level, baseline QOL (whether PWB, FWB, or FACT-TOI) also predicted for survival, as well as in multivariate analysis (MVA), p=<0.02.

• Every 10 points higher on the FACT-TOI at baseline corresponded to a 14% decreased risk of death
• IMRT was used in 41% and 44% of QOL patients in 60Gy and 74Gy arms (p=0.6), respectively

• While this study was not randomized by technology (ie, IMRT vs 3D), there were no significant differences in patient demographics or treatment factors between IMRT vs 3D

• With important exception that more higher stage patients (43% vs 31% stage IIIB, p=0.037) and larger GTVs (58% vs 39% above median GTV volume, p<0.001) were treated using IMRT (vs 3D)
Conclusions

• Despite few differences in provider-reported toxicity between arms, the PROs tell the “rest of the story” by showing significantly worse QOL on the high dose arm (74Gy) at 3 months, confirming the primary QOL hypothesis.

• In RTOG 0617, baseline QOL significantly predicted for survival on MVA.
  ▪ This analysis raises an intriguing question of whether the decline in QOL on the high dose arm may help account for the survival decrement in this arm over time.
  ▪ Other factors being analyzed include heart volume irradiated, local failure rates, etc.

• While study was not randomized to compare IMRT vs 3D, reduced clinically meaningful decline in QOL appears to be associated with the use of IMRT (vs 3D), suggesting that improved RT treatment techniques may help enhance the therapeutic window for patients with lung cancer.