



Comparison of quality of life in patients randomized to high-dose once daily (QD) thoracic radiotherapy (TRT) with standard twice daily (BID) TRT in limited stage small cell lung cancer (LS-SCLC) on CALGB 30610 (NCT00632853)

(Alliance for Clinical Trials in Oncology, Sub-study CALGB 70702)

Apar Kishor Ganti, Amylou C. Dueck, Briant Fruth, Andreas Rimner, Saiama Naheed Waqar, Michael D Mix, William J. Petty, Jeffrey A. Bogart





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<u>Dr. Kinjal R. Jani</u>

Director & Head

Dept. of Radiation Oncology



Background

- CALGB 30610 trial 70Gy QD TRT was not associated with a superior overall survival compared to 45Gy BID TRT in limited stage small cell lung cancer
- Since both arms appeared to provide similar clinical benefit, other factors such as quality of life may help oncologists decide on the best treatment approach for their patients.





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Patients and Methods

- Questionnaires FACT-L, FACT Trial Outcome Index-Lung
 Cancer (FACT-L TOI), FACT-Esophageal Cancer Eating and
 Swallowing Indices, ECOG Acute Esophagitis Scale, Hospital
 Anxiety and Depression Scale (HADS), the EQ-5D and a single
 item assessing difficulty swallowing
- Time points Baseline, 3, 5, 7, 12, 26, and 52 weeks after starting radiation therapy





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Patients and Methods

- Assess treatment inconvenience at these time points.
- Primary endpoints FACT-L TOI and FACT eating and swallowing subscales at 12 weeks
- Mean changes from baseline were compared between arms using general linear mixed models





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- 417 patients consented to participate in the patient-reported outcomes substudy
- The completion rate of the questionnaires was 87% at baseline and 71% at week 52



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- CALGB 30610 646 patients
- 417 patients consented to participate in the patient-reported outcomes substudy
- Baseline PROs 364 patients
- 342 patients at least one follow-up PRO
- 340 patients baseline and at least 1 follow-up PRO
- The completion rate of the questionnaires was 87% at baseline and 71% at week 52





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Results - Demographics

	Treatment Arm	
	45 Gy (N=167)	70 Gy (N=171)
Median Age (yrs) (Range)	64 (42.0, 81.0)	62.0 (37.0, 78.0)
Gender, n (%)		
Male	85 (50.9%)	79 (46.2%)
Female	82 (49.1%)	92 (53.8%)
Race, n (%)		
White	148 (88.6%)	146 (85.4%)
Black or African American	13 (7.8%)	17 (9.9%)
Asian	0 (0.0%)	1 (0.6%)
American Indian or Alaska Native	2 (1.2%)	1 (0.6%)
Ethnicity, n (%)		
Hispanic or Latino	6 (3.6%)	5 (2.9%)
Non-Hispanic	156 (93.4%)	156 (91.2%)
ECOG PS, n (%)		
0	78 (46.7%)	84 (49.1%)
1	82 (49.1%)	76 (44.4%)
2	7 (4.2%)	11 (6.4%)



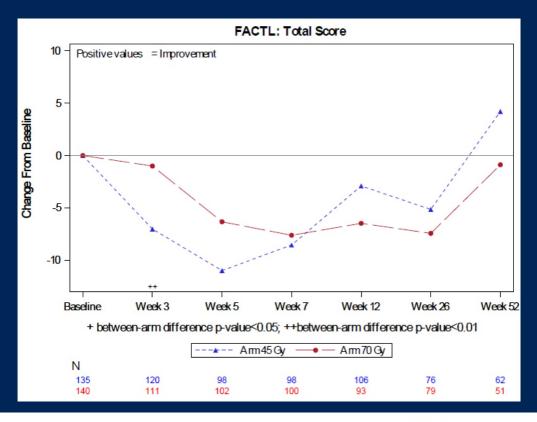


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 The FACT-L total score mean worsening was significantly less in the QD arm at week 3 (-1.0 vs -7.0; P=.003)





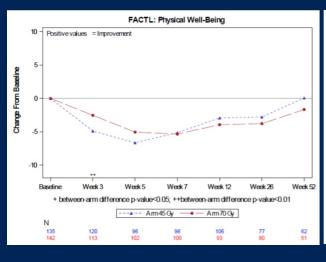


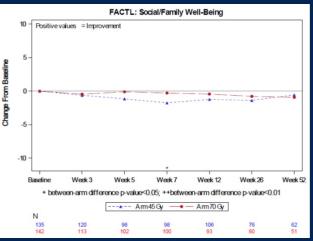
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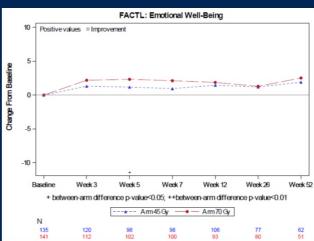




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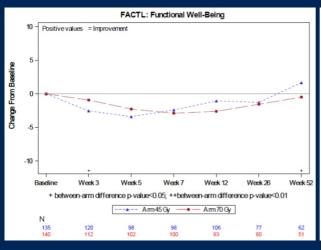


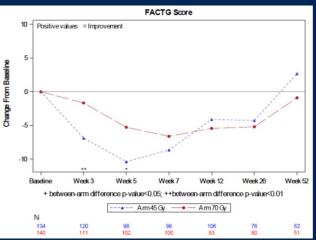
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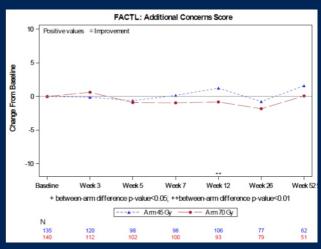




Results









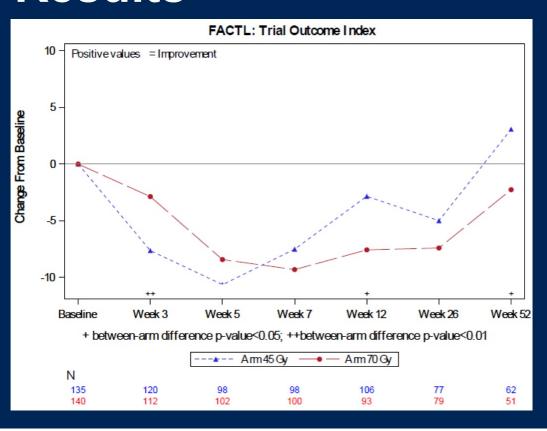


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- FACT-L TOI mean worsening
 - Less in the QD arm at week 3 (-2.9 vs -7.6; P=.003)
 - Greater in the QD
 arm at week 12 (-7.6
 vs -2.8; P=.03).







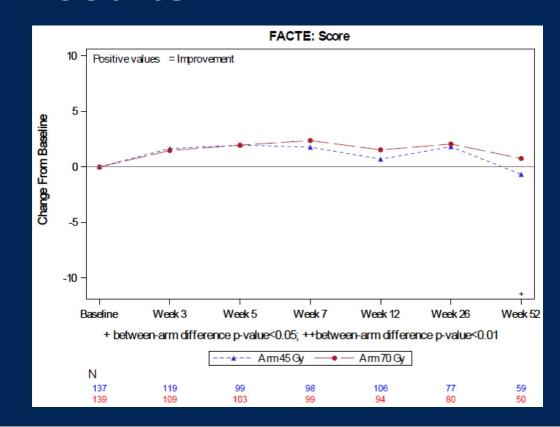
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Results

- FACT-E change in score
 - Better in QD arm at week 52 (0.75 vs. 0.68; p=0.05)







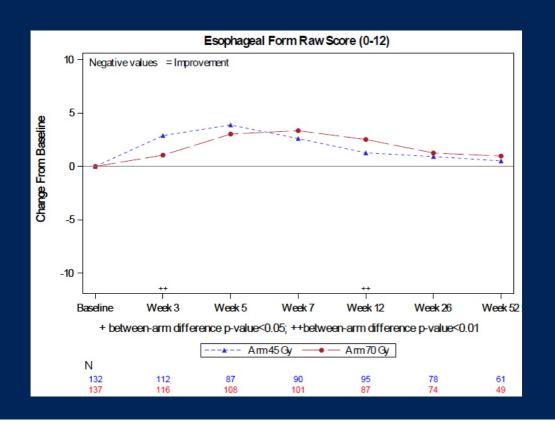
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Results

- Acute esophagitis score
 - Worse in the BID arm at week 3 (2.89 vs. 1.06; p<.001)
 - Worse in the QD arm at week 12 (2.52 vs. 1.27; p=0.002)







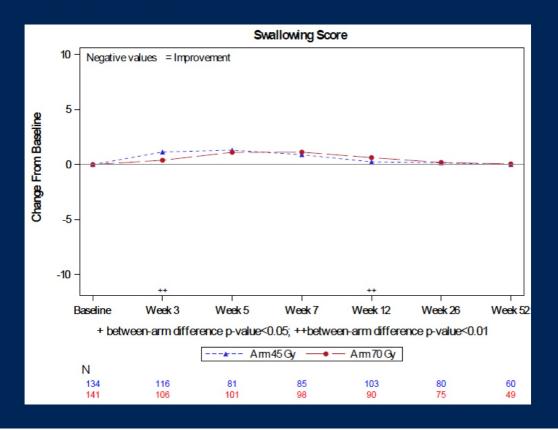
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Results

- Difficulty swallowing
 - Greater in BID arm at week 3 (1.14 vs. 0.39; p<.001)
 - Greater in the QD arm at week 12
 (0.63 vs. 0.24;
 p=.005)





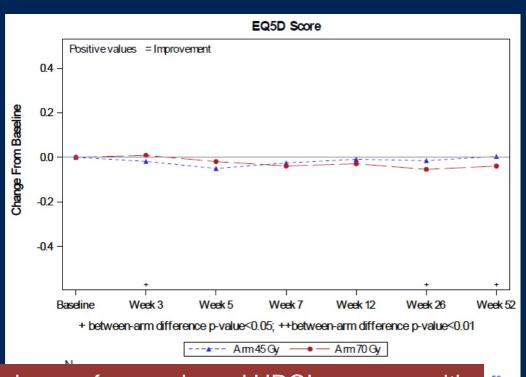


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- EQ-5D
 - Lesser worsening in theQD arm at 3 weeks (-0.04 vs 0.03; P=.002)



The EQ-5D descriptive system is a preference-based HRQL measure with one question for each of the five dimensions that include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression

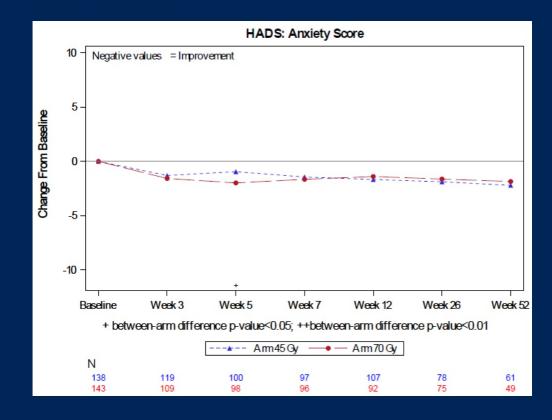
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Results

 Mean worsening in HADS anxiety - less in the QD arm at week 5 (-1.99 vs -0.95; P=.03).







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Results – Treatment Convenience

	Treatment Arm		
	45 Gy (N=352)	70 Gy (N=376)	Total (N=1485)
Tx Convenience Score, n (%)			
Very inconvenient	53 (15.1%)	74 (19.7%)	127 (17.4%)
Somewhat inconvenient	63 (17.9%)	22 (5.9%)	85 (11.7%)
Somewhat convenient	75 (21.3%)	88 (23.4%)	163 (22.4%)
Very convenient	161 (45.7%)	192 (51.1%)	353 (48.5%)
Convenience Category, n (%)*			
Inconvenient	116 (33.0%)	96 (25.5%)	212 (29.1%)
Convenient	236 (67.0%)	280 (74.5%)	516 (70.9%)

* p<.05





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Conclusions

- Both QD and BID radiation regimens were well tolerated.
- The QD arm had better quality of life scores at week 3, but worse scores at week 12
- The QD arm was perceived to be less inconvenient





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