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11-1-2022

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Patient-Reported Outcomes (PROs) in NRG Oncology RTOG 1010: Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2 Overexpressing (HER2+) Esophageal Adenocarcinoma (EAC)

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Purpose/Objective(s): NRG/RTOG 1010 evaluated the benefit of trastuzumab for patients (pts) with HER2+ localized EAC receiving trimodality therapy. Adding trastuzumab did not improve disease-free (primary endpoint) or overall survival, nor treatment toxicity (Lancet Oncology 2022). The primary PRO objective was improvement (impr) in the FACT-Esophageal Cancer Subscale (ECS) score with trastuzumab at restaging prior to surgery. A secondary objective was to assess if impr in ECS score is associated with pathologic complete response (pCR).

Materials/Methods: Pts with HER2+ EAC (T1N1-2; T2-3N0-2) were stratified by presence of adenopathy & randomized 1:1 to weekly paclitaxel, carboplatin with 50.4 Gy radiation (CRT) followed by surgery ± trastuzumab (CRT+T), 4mg/kg week 1, 2mg/kg/weekly x 5 during CRT, 6 mg/kg x1 prior to surgery, and then 6mg/kg every 3 weeks (wks) x 13. The ECS, v4, was done at baseline, 6-8 wks post-CRT and at 1 & 2 years. Impr in ECS and its Swallowing Index (SI) & Eating Index (EI) were defined as increases of 5, 2 & 2 points, respectively, from baseline. PRO sample size provided ≥ 80% power with 1-sided 0.05 alpha & a chi-squared test to determine if the proportion of pts categorized as improved at 6-8 wks is ≥ 25% higher for the CRT+T arm. Correlation between pCR & impr in ECS score was evaluated via chi-squared test.

Results: From 2010-2015, 203 HER2+ pts were randomized; 194 eligible. Of 171 PRO consenting pts, the ECS was completed by 162 (95%) at baseline, 108 (64%) 6-8 wks, 82 (49%) 1 year & 55 (33%) at 2 years. The main reason for FACT-E noncompliance was pt death. Patient & tumor characteristics were similar between arms. Median age was 63 years; 86% male; 96% white; 65% Zubrod 0, 80% cT3 & 71% cN1-2 (AJCC 7th ed). For ECS scores at 6-8 wks, the mean change (Δ) was higher (better) from baseline at 4.6 (95% CI: 1.3, 7.8) for the CRT+T arm vs 0.9 (95% CI: -2.7, 4.6) for the CRT arm; the proportion of pts with an impr in 6-8 wks ECS was higher on the CRT+T arm (46% vs 38% on the CRT arm) although not significantly different (p=0.39). Table 1 shows ECS, SI & EI scores for all time-points. At 6-8 wks, 30% with a pCR had an impr in ECS vs 45% of nonpCR pts (p=0.18). There were no significant correlations between pCR and ECS, SI & EI impr at any time points.

Conclusion: The addition of trastuzumab to trimodality therapy for localized HER2+ EAC did not significantly improve survival or PROs. ECS

score improvement following therapy was not associated with a pCR. The higher proportion of pts with improved ECS at 6-8 weeks and 2 years in the CRT+T arm is interesting and suggests that HER2 may still be an important target to explore.

Abstract 117 – Table 1

Table 1	CRT+T		CRT		p
	Mean Δ	% Impr	Mean Δ	% Impr	
6-8 wks ECS	4.6	46	0.9	38	0.39
6-8 wks SI, EI	2.6, 1.1	56, 46	0.9, 0.4	45, 38	0.24, 0.39
1 yr ECS	1.4	39	2.8	42	0.78
1 yr SI, EI	1.9, -0.4	52, 36	2.2, 0.6	58, 31	0.59, 0.59
2 yr ECS	1.3	41	-0.3	27	0.28
2 yr SI, EI	1.2, -0.2	64, 32	1.0, -0.03	43, 27	0.15, 0.69

Author Disclosure: L.A. Kachnic: None. J. Moughan: None. T.S. Hong: None. M.G. Haddock: ISORT. N. Tahir: None. H.H. Yoon: Research Grant; CARsgen. Consultant; Bristol Myer Squibb, AstraZeneca, Astellas, BeiGene, Novartis. Advisory Board; Bristol Myer Squibb, AstraZeneca, Astellas, BeiGene, Novartis. D.A. Diaz Pardo: None. C.M. Anderson: Travel Expenses; Elekta. Enrolling patients on industry-sponsored clinical trial, discussing research related to trial drug with the company; Galera Therapeutics, Inc. S.A. Seaward: None. C. Lominska: None. P. O'Brien: None. A. W. Katz: None. J. Salo: None. A.D. Christie: Stock; Amaris, Nokia, Ericson, GE. J.A. Dorth: Travel Expenses; Varian. R. Aljumaily: None. E.M. Gore: Partner; Stuart Wong. Review publications, authorship, and policy; NRG Oncology. H.P. Safyan: None. B. Movsas: None.

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Effectiveness of S-1–Based Chemoradiotherapy and S-1 Consolidation in Elderly Patients with Esophageal Squamous Cell Carcinoma: A Multicenter Randomized Phase III Clinical Trial

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Purpose/Objective(s): There has been a steady increase in the incidence of esophageal squamous cell carcinoma (ESCC) among elderly patients. The optimal treatment approach of elderly ESCC patients was still vague.

Materials/Methods: Between March 2017 and April 2020, 339 patients were screened in 10 centers in China; 184 and 146 patients were randomized into the S-1 based chemoradiotherapy followed by S-1 monotherapy