

Impact of Tislelizumab on Health-Related Quality of Life in Asian Patients with Esophageal Squamous Cell Carcinoma

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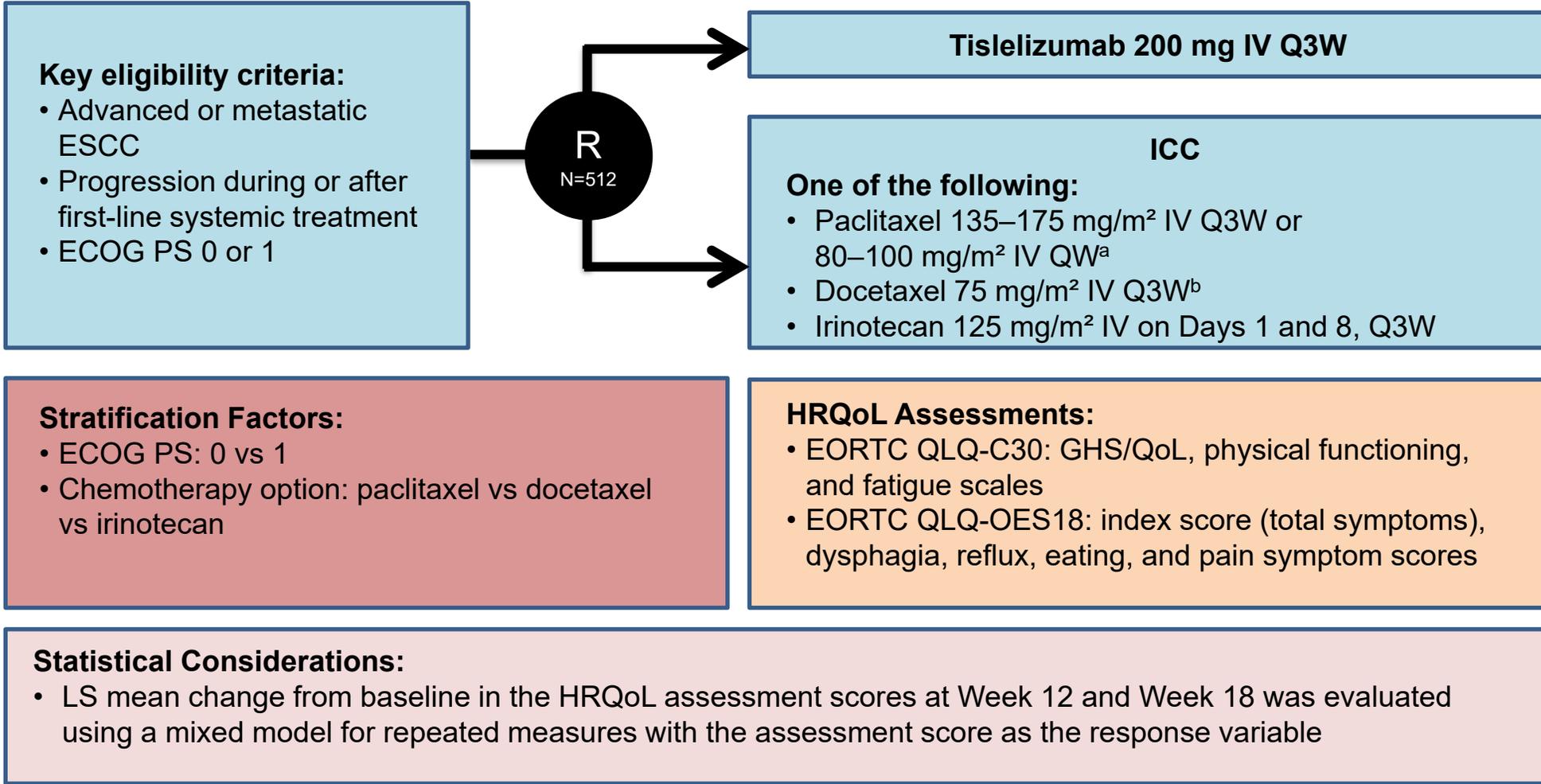
Conflicts of Interest

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Name of lead presenter	Ken Kato	Institution or company/position	National Cancer Center Hospital, Tokyo/Medical Oncologist
	No	If yes, please specify the name of company, organization, your status.	
Employee or adviser of company and/or profit-making organization	X		
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Lecturer fee	<input type="checkbox"/>	Ono Pharmaceutical, Bristol Myers Squibb, Eli Lilly, Taiho Pharmaceutical	
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Representative of organization for clinical study receiving research expenses from company	<input type="checkbox"/>	Ono Pharmaceutical, Bristol Myers Squibb, MDS Pharma Services, Shionogi, BeiGene, Chugai Pharmaceutical Co, AstraZeneca, Bayer, Oncolys BioPharma	

Introduction

- Incidence of ESCC is highest in Asian adults¹
 - Patients with ESCC experience severe symptom burden and associated reductions in HRQoL²⁻⁵
- RATIONALE-302 (NCT03430843), a global, open-label, randomized, phase 3 study compared tislelizumab with ICC as second-line treatment for patients with advanced or metastatic ESCC⁶
 - Tislelizumab was associated with improved overall survival, a higher objective response rate, and a more durable anti-tumor response compared with ICC
 - Analysis of the ITT population in RATIONALE-302 found overall HRQoL, fatigue, and physical functioning were maintained in patients who received tislelizumab, but worsened in patients who received ICC⁷
- Given the heavy disease burden of ESCC among Asian people, this post-hoc analysis assessed HRQoL and symptom burden of tislelizumab compared with chemotherapy in the Asian subgroup of patients in RATIONALE-302

Methods



^aFor Japan: 100 mg/m² IV in cycles consisting of weekly dosing for 6 weeks, followed by one week of rest; ^bFor Japan: 70 mg/m² IV Q3W.
ECOG PS, Eastern Cooperative Oncology Group performance status; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer quality of life core questionnaire; EORTC QLQ-OES18, European Organization for Research and Treatment of Cancer quality of life oesophageal questionnaire; ESCC, esophageal squamous cell carcinoma; GHS, global health status; ICC, investigator-chosen chemotherapy; IV, intravenous; LS, least squares; Q3W, every 3 weeks; QoL, quality of life; QW, once a week; R, randomization.

Patient Demographics and Characteristics

- Of 512 patients in the ITT population, the Asian subgroup consisted of 404 patients

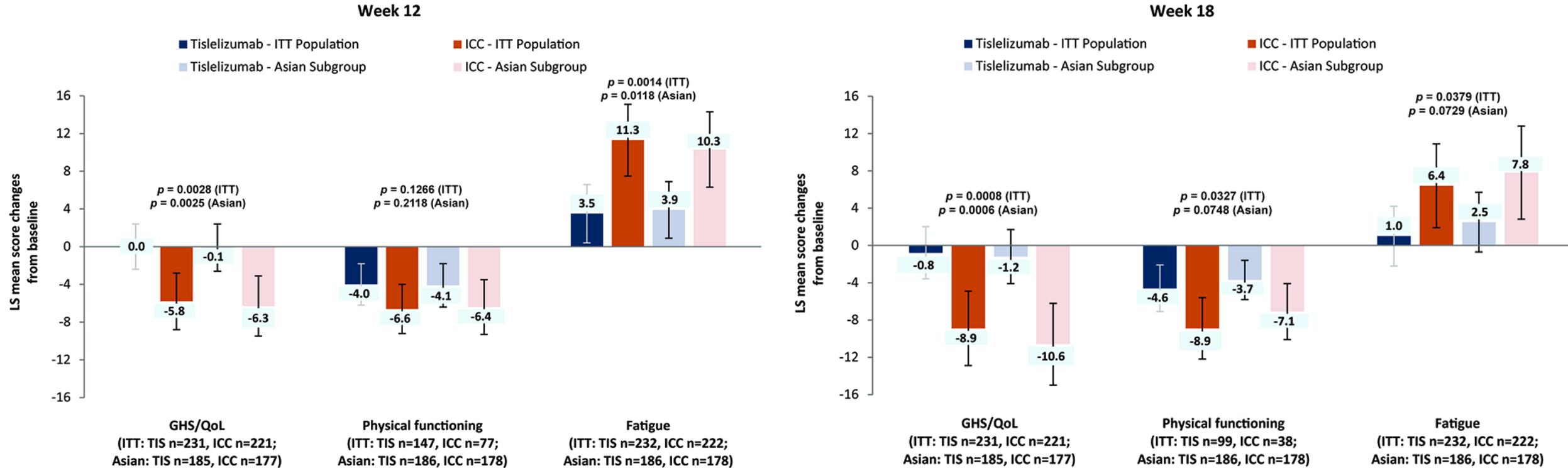
	Asian Subgroup		ITT Population	
	Tislelizumab (n = 201)	ICC (n = 203)	Tislelizumab (n = 256)	ICC (n = 256)
Age				
Median, years (range)	61.0 (40-83)	62.0 (41-81)	62.0 (40-86)	63.0 (35-81)
<65 years, n (%)	132 (65.7)	137 (67.5)	157 (61.3)	161 (62.9)
≥65 years, n (%)	69 (34.3)	66 (32.5)	99 (38.7)	95 (37.1)
Sex, n (%)				
Male	180 (89.6)	179 (88.2)	217 (84.8)	215 (84.0)
Female	21 (10.4)	24 (11.8)	39 (15.2)	41 (16.0)
Race, n (%)				
Asian Indian	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)
Chinese	161 (80.1)	162 (79.8)	161 (62.9)	163 (63.7)
Japanese	25 (12.4)	25 (12.3)	25 (9.8)	25 (9.8)
Korean	15 (7.5)	16 (7.9)	15 (5.9)	16 (6.3)
White/Caucasian	0 (0.0)	0 (0.0)	53 (20.7)	44 (17.2)
Black/African American	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
Not Reported	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Unknown	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)

Patient Demographics and Characteristics (2)

- Within the Asian subgroup, the proportion of patients with metastatic disease was slightly higher among those who received tislelizumab vs ICC

	Asian Subgroup		ITT Population	
	Tislelizumab (n = 201)	ICC (n = 203)	Tislelizumab (n = 256)	ICC (n = 256)
ECOG performance status, n (%)				
0	43 (21.4)	42 (20.7)	66 (25.8)	60 (23.4)
1	158 (78.6)	161 (79.3)	190 (74.2)	196 (76.6)
Smoking status, n (%)				
Never	55 (27.4)	48 (23.6)	68 (26.6)	63 (24.6)
Former	135 (67.2)	136 (67.0)	162 (63.3)	159 (62.1)
Current	11 (5.5)	18 (8.9)	26 (10.2)	33 (12.9)
Missing	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
Previous therapies, n (%)				
Chemotherapy	71 (35.3)	80 (39.4)	94 (36.7)	101 (39.5)
Chemo-Radiotherapy	129 (64.2)	123 (60.6)	161 (62.9)	155 (60.5)
Other	1 (0.5)	0 (0.0)	1 (0.4)	0 (0.0)
Disease stage at study entry, n (%)				
Locally advanced	3 (1.5)	14 (6.9)	5 (2.0)	20 (7.8)
Metastatic	198 (98.5)	189 (93.1)	251 (98.0)	236 (92.2)

EORTC QLQ-C30 Results

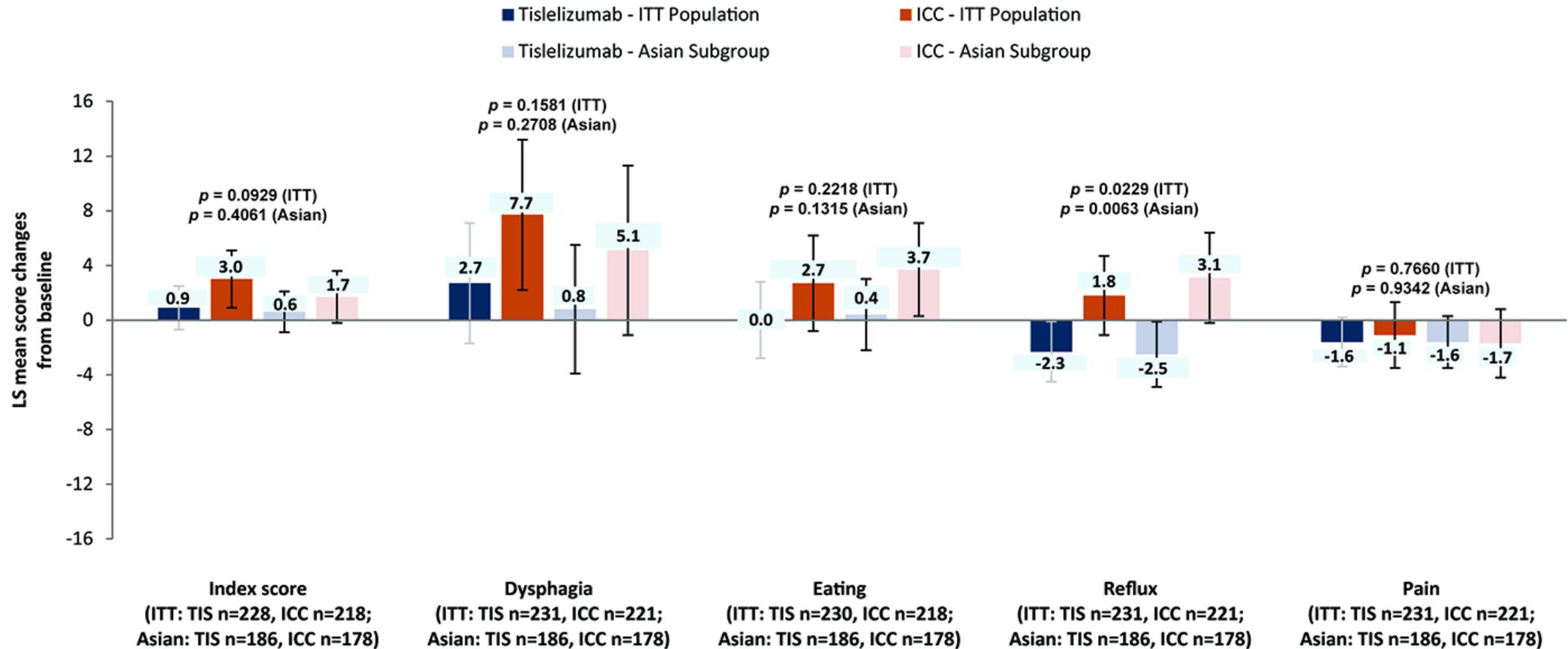


- Baseline completion rates for the HRQoL assessments in the Asian subgroup were $\geq 95.5\%$, as were the adjusted completion rates. At Week 12 and Week 18, the completion rates and the adjusted completion rates remained high ($\geq 96.4\%$)
- Compared with baseline, worsening of GHS/QoL, physical functioning, and fatigue were lower in the tislelizumab arm versus the ICC arm at Weeks 12 and 18 in the Asian subgroup

n: patients with baseline and at least one post-baseline measurement.

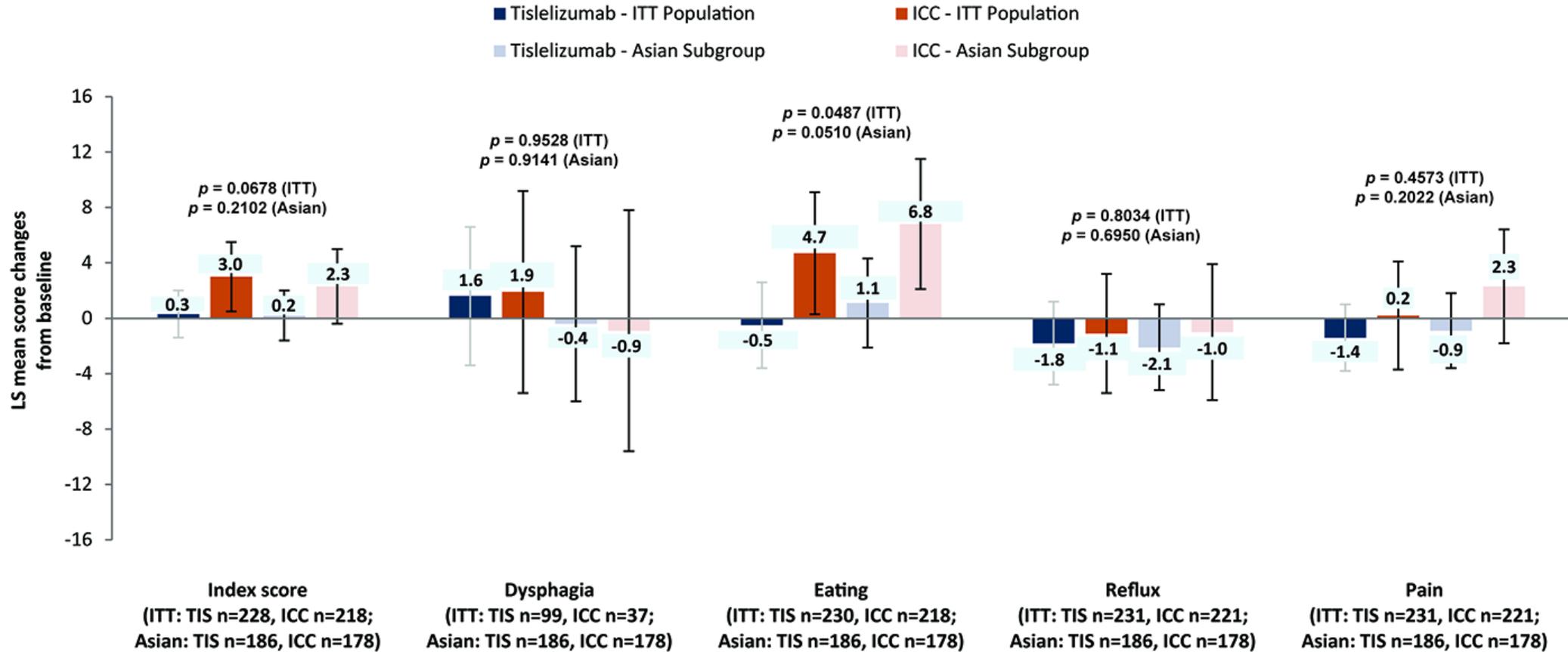
EORTC QLQ-C30, European Organization for Research and Treatment of Cancer quality of life core questionnaire; GHS, global health status; ICC, investigator-chosen chemotherapy; ITT, intent-to-treat; LS, least squares; QoL, quality of life; TIS, tislelizumab.

EORTC QLQ-OES18 Results: Week 12



- At Week 12, the tislelizumab arm experienced maintenance across symptoms except in reflux, which improved in the tislelizumab arm and worsened in the ICC arm for the Asian subgroup

EORTC QLQ-OES18 Results: Week 18



- At Week 18, the Asian subgroup experienced maintenance across symptoms except in eating, which maintained in the tislelizumab arm and worsened in the ICC arm

n: patients with baseline and at least one post-baseline measurement.

EORTC QLQ-OES18, European Organization for Research and Treatment of Cancer quality of life oesophageal questionnaire; ICC, investigator-chosen chemotherapy; ITT, intent-to-treat; LS, least squares; TIS, tislelizumab.

Discussion

- Tislelizumab monotherapy as a second-line treatment for Asian patients with advanced or metastatic ESCC was associated with more favorable HRQoL outcomes than ICC
- The results from the Asian subgroup largely mirrored those previously reported for the ITT population of RATIONALE-302
 - In the Asian subgroup, like in the ITT population, patients who received tislelizumab demonstrated maintenance in GHS/QoL at Weeks 12 and 18 while ICC-treated patients experienced a decline
 - Patients who received tislelizumab also experienced less fatigue than patients who received ICC at Weeks 12 and 18, similar to the ITT population
 - Finally, problem eating was maintained and reflux symptoms improved in patients who received tislelizumab vs ICC in the Asian subgroup, which was also observed in the ITT population
- These HRQoL results from the Asian subgroup of RATIONALE-302 indicate that tislelizumab is a potential new second-line treatment option for Asian patients with advanced or metastatic ESCC

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