

Introduction

- Definitive concurrent chemoradiotherapy (CCRT) has become the standard of care for patients (pts) with unresectable locally advanced esophageal squamous cell carcinoma (ESCC). However, half of the patients still experience local failure or distant metastasis.
- The PACIFIC study has confirmed that consolidation immunotherapy with durvalumab significantly improves the progression-free survival (PFS) and overall survival (OS) for patients with unresectable, stage III non small cell lung cancer (NSCLC) after CCRT, but the efficacy of consolidation immunotherapy for locally unresectable esophageal cancer is unclear.
- We performed a clinical trial to investigate the clinical efficacy of camrelizumab (an anti-PD-1 monoclonal antibody) on pts with unresectable locally advanced ESCC after definitive CCRT.

Methods

- The study design of this single-arm exploratory study (NCT04286958) is shown in Figure 1.

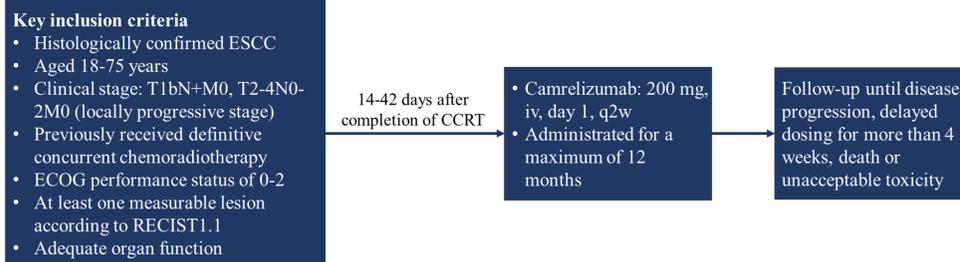


Figure 1 Study design.

- The primary endpoint was PFS, defined as the time from enrollment to disease progression or death from any cause.
- The secondary endpoints included objective response rate (ORR), disease control rate (DCR), duration of response (DoR), OS, and safety. Adverse events (AEs) were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTC AE) version 4.0.

Results

Patient characteristics:

- Fifteen patients with ESCC were recruited between April 2020 and August 2022.
- Baseline characteristics are summarized in Table 1.

Table 1 Baseline characteristics (n = 15)

Baseline characteristics	n (%)
Age, Median (range), years	66 (56-74)
Gender	
Female	8 (53.3%)
Male	7 (46.7%)
Drinking history	
Yes	3 (20.0%)
No	12 (80.0%)
Smoking history	
Yes	4 (26.7%)
No	11 (73.3%)
Clinical Stage	
II	2 (13.3%)
III	13 (86.7%)
Clinical N status	
N0	3 (20.0%)
N1	6 (40.0%)
N2	6 (40.0%)
Tumor location	
Upper esophagus	10 (66.7%)
Middle esophagus	4 (26.7%)
Lower esophagus	1 (6.7%)
ECOG performance status	
0	1 (6.7%)
1	12 (80.0%)
2	2 (13.3%)

Results (continued)

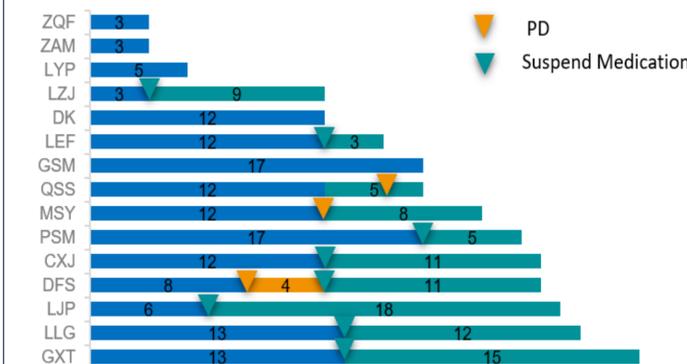


Figure 2 Tumor response to camrelizumab

Safety:

- Adverse events are summarized in Table 2.

Efficacy:

- At the cutoff date of August 31 2022, the interim analysis included 15 patients. 13 pts had stable disease, and 1 patient progressed within one year, 2 patients progressed after 1 year. (Figure 2)
- The median follow-up was 17 months. Median PFS and OS were not reached.
- The mean lung dose (MLD) and V20 of total lung was 1125.42Gy (range:620-1448.4Gy) and 22% (range:8-27%), respectively.

Table 2 Adverse events (n = 15)

Adverse events	Any grade n (%)	Grade 1-2 n (%)	Grade 3 n (%)
Reactive cutaneous capillary endothelial proliferation	10 (66.7%)	10 (66.7%)	0 (0)
Pneumonitis	6 (40.0%)	6 (40.0%)	0 (0)
Hypothyroidism	1 (6.7%)	1 (6.7%)	0 (0)
Hyperthyroidism	2 (13.3%)	2 (13.3%)	0 (0)
Transfusion reaction	1 (6.7%)	1 (6.7%)	0 (0)

Conclusion

- The interim results suggested that consolidative camrelizumab following definitive concurrent chemoradiotherapy might have a promising efficacy and manageable toxicities in patients with unresectable locally advanced ESCC.
- This trial is still ongoing and the final analysis will be conducted after study completion.

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